Anhang 4-G:
Ergänzende Unterlagen

Axicabtagen-Ciloleucel (Yescarta®)

Gilead Sciences GmbH

Behandlung von Patienten mit rezidiviertem oder refraktärem DLBCL und HGBL nach Erstlinien-Chemotherapie

Stand: 30.06.2023

Anhang 4-G: Ergänzende Unterlagen

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Anhang 4-G1.1: Begleitmedikation - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-1 (Anhang): Liste der Begleitmedikationen - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
Subjects with any concomitant medication	170 (100)	168 (100)	338 (100)
ACARBOSE	1 (1)	0	1 (0)
ACETAZOLAMIDE	2 (1)	0	2 (1)
ACETYLCYSTEINE	2 (1)	0	2 (1)
ACETYLSALICYLIC ACID	19 (11)	22 (13)	41 (12)
ACETYLSALICYLIC ACID;BUTALBITAL;CAFFEINE	1 (1)	0	1 (0)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	2 (1)	2 (1)	4 (1)
ACICLOVIR	122 (72)	84 (50)	206 (61)
ADENOSINE	1 (1)	0	1 (0)
ADENOSINE TRIPHOSPHATE	0	1 (1)	1 (0)
ADRENERGIC AND DOPAMINERGIC AGENTS	1 (1)	0	1 (0)
ALBUMIN HUMAN	11 (6)	9 (5)	20 (6)
ALENDRONIC ACID	2 (1)	2 (1)	4 (1)
ALFUZOSIN	0	1 (1)	1 (0)
ALGELDRATE;MAGNESIUM HYDROXIDE	1 (1)	0	1 (0)
ALIZAPRIDE	3 (2)	3 (2)	6 (2)
ALLANTOIN;DL- LACTIC ACID;GLYCEROL;HYETELLOSE;MACROGOL;OCTENIDINE HYDROCHLORIDE	0	2 (1)	2 (1)
ALLOPURINOL	124 (73)	75 (45)	199 (59)
ALOE VERA	0	1 (1)	1 (0)
ALPRAZOLAM	6 (4)	8 (5)	14 (4)
ALTEPLASE	24 (14)	12 (7)	36 (11)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
ALUMINIUM HYDROXIDE	1 (1)	1 (1)	2 (1)
ALUMINIUM HYDROXIDE-MAGNESIUM CARBONATE;LIDOCAINE HYDROCHLORIDE;MAGNESIUM HYDROXIDE;MAGNESIUM TRISILICATE	0	1 (1)	1 (0)
ALUMINIUM HYDROXIDE;DIPHENHYDRAMINE;LIDOCAINE;MAGNESIUM HYDROXIDE;SIMETICONE	1 (1)	2 (1)	3 (1)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;OXETACAINE	0	1 (1)	1 (0)
ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE	0	1 (1)	1 (0)
ALUMINIUM;MAGNESIUM HYDROXIDE;SIMETICONE	9 (5)	8 (5)	17 (5)
ALUMINUM MAGNESIUM HYDROXIDE	1 (1)	5 (3)	6 (2)
AMIDOTRIZOIC ACID	2 (1)	1 (1)	3 (1)
AMIKACIN	5 (3)	3 (2)	8 (2)
AMILORIDE	1 (1)	3 (2)	4 (1)
AMINO ACIDS NOS	1 (1)	0	1 (0)
AMINOCAPROIC ACID	1 (1)	0	1 (0)
AMIODARONE	6 (4)	4 (2)	10 (3)
AMITRIPTYLINE	4 (2)	4 (2)	8 (2)
AMITRIPTYLINE;GABAPENTIN	1 (1)	0	1 (0)
AMLODIPINE	14 (8)	20 (12)	34 (10)
AMLODIPINE BESILATE;BENAZEPRIL HYDROCHLORIDE	1 (1)	0	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
AMOXICILLIN	3 (2)	4 (2)	7 (2)
AMOXICILLIN;CLAVULANIC ACID	17 (10)	20 (12)	37 (11)
AMOXICILLIN;SULBACTAM	1 (1)	0	1 (0)
AMPHOTERICIN B	5 (3)	9 (5)	14 (4)
AMPHOTERICIN B, LIPOSOME	2 (1)	0	2 (1)
AMPICILLIN;SULBACTAM	1 (1)	1 (1)	2 (1)
ANAKINRA	2 (1)	0	2 (1)
ANASTROZOLE	1 (1)	0	1 (0)
ANESTHETICS	0	1 (1)	1 (0)
ANTICOAGULANT CITRATE DEXTROSE	1 (1)	15 (9)	16 (5)
ANTIINFECTIVES AND ANTISEPTICS FOR LOCAL ORAL TREATMENT	1 (1)	0	1 (0)
APIXABAN	8 (5)	4 (2)	12 (4)
APREPITANT	1 (1)	43 (26)	44 (13)
ARIPIPRAZOLE	0	1 (1)	1 (0)
ASCORBIC ACID	4 (2)	2 (1)	6 (2)
ASCORBIC ACID;VITAMIN B COMPLEX	1 (1)	0	1 (0)
ATENOLOL	4 (2)	4 (2)	8 (2)
ATORVASTATIN	14 (8)	17 (10)	31 (9)
ATOVAQUONE	11 (6)	0	11 (3)
ATROPINE	1 (1)	0	1 (0)
ATROPINE;DIPHENOXYLATE	4 (2)	4 (2)	8 (2)
AZITHROMYCIN	15 (9)	8 (5)	23 (7)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
AZTREONAM	5 (3)	2 (1)	7 (2)
BACITRACIN	6 (4)	4 (2)	10 (3)
BACITRACIN;NEOMYCIN;POLYMYXIN B	4 (2)	4 (2)	8 (2)
BACITRACIN;POLYMYXIN B	1 (1)	0	1 (0)
BACLOFEN	12 (7)	16 (10)	28 (8)
BARIUM	5 (3)	7 (4)	12 (4)
BECLOMETASONE	0	1 (1)	1 (0)
BEMIPARIN SODIUM	1 (1)	2 (1)	3 (1)
BENAZEPRIL	2 (1)	1 (1)	3 (1)
BENZOCAINE	1 (1)	1 (1)	2 (1)
BENZOCAINE;MENTHOL	3 (2)	4 (2)	7 (2)
BENZONATATE	24 (14)	5 (3)	29 (9)
BENZYDAMINE	1 (1)	5 (3)	6 (2)
BENZYL ALCOHOL;BENZYL BENZOATE;BENZYL CINNAMATE;WOOL FAT;ZINC	0	1 (1)	1 (0)
BENZYL ALCOHOL;CETYLPYRIDINIUM	1 (1)	2 (1)	3 (1)
BENZYLPENICILLIN	1 (1)	1 (1)	2 (1)
BETAMETHASONE	0	2 (1)	2 (1)
BETAMETHASONE;CALCIPOTRIOL	1 (1)	0	1 (0)
BETAMETHASONE;CLOTRIMAZOLE	1 (1)	0	1 (0)
BETHANECHOL	1 (1)	0	1 (0)
BIFIDOBACTERIUM INFANTIS;LACTOBACILLUS ACIDOPHILUS	1 (1)	0	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
BIOTIN	1 (1)	0	1 (0)
BISACODYL	10 (6)	7 (4)	17 (5)
BISOPROLOL	5 (3)	3 (2)	8 (2)
BISOPROLOL;HYDROCHLOROTHIAZIDE	0	1 (1)	1 (0)
BLOOD CELLS, PACKED HUMAN	47 (28)	77 (46)	124 (37)
BRIMONIDINE;TIMOLOL	2 (1)	0	2 (1)
BRINZOLAMIDE	1 (1)	0	1 (0)
BROTIZOLAM	1 (1)	0	1 (0)
BUDESONIDE	0	1 (1)	1 (0)
BUDESONIDE;FORMOTEROL	0	1 (1)	1 (0)
BUMETANIDE	1 (1)	2 (1)	3 (1)
BUPIVACAINE	1 (1)	1 (1)	2 (1)
BUPIVACAINE;EPINEPHRINE	0	1 (1)	1 (0)
BUPRENORPHINE	0	2 (1)	2 (1)
BUPROPION	3 (2)	5 (3)	8 (2)
BUSPIRONE	1 (1)	0	1 (0)
BUTALBITAL;CAFFEINE;PARACETAMOL	7 (4)	4 (2)	11 (3)
CAFFEINE	5 (3)	0	5 (1)
CAFFEINE;PARACETAMOL	0	1 (1)	1 (0)
CAFFEINE;SODIUM BENZOATE	1 (1)	0	1 (0)
CALAMINE;MENTHOL;ZINC OXIDE	0	1 (1)	1 (0)
CALAMINE;PRAMOCAINE	1 (1)	0	1 (0)
CALCITONIN	1 (1)	0	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
CALCIUM	3 (2)	4 (2)	7 (2)
CALCIUM ACETATE	1 (1)	0	1 (0)
CALCIUM ASCORBATE	0	1 (1)	1 (0)
CALCIUM CARBONATE	21 (12)	23 (14)	44 (13)
CALCIUM CARBONATE;COLECALCIFEROL	11 (6)	9 (5)	20 (6)
CALCIUM CHLORIDE	5 (3)	11 (7)	16 (5)
CALCIUM CHLORIDE DIHYDRATE;MAGNESIUM CHLORIDE HEXAHYDRATE;MALIC ACID;POTASSIUM CHLORIDE;SODIUM ACETATE TRIHYDRATE;SODIUM CHLORIDE	0	2 (1)	2 (1)
CALCIUM CHLORIDE;GLUCOSE MONOHYDRATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	0	1 (1)	1 (0)
CALCIUM CHLORIDE;GLUCOSE;POTASSIUM CHLORIDE;SODIUM LACTATE	0	1 (1)	1 (0)
CALCIUM CHLORIDE;MAGNESIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM ACETATE;SODIUM CHLORIDE	0	1 (1)	1 (0)
CALCIUM CHLORIDE;POTASSIUM;SODIUM CHLORIDE;SODIUM LACTATE	15 (9)	11 (7)	26 (8)
CALCIUM CHLORIDE;SODIUM CHLORIDE;SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC	0	1 (1)	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
CALCIUM CHLORIDE;SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)	0	1 (1)	1 (0)
CALCIUM CITRATE	1 (1)	0	1 (0)
CALCIUM FOLINATE	3 (2)	3 (2)	6 (2)
CALCIUM GLUCONATE	20 (12)	32 (19)	52 (15)
CALCIUM GLUCONATE;SODIUM CHLORIDE	0	1 (1)	1 (0)
CALCIUM LEVOMEFOLATE;CYANOCOBALAMIN;MAGNESIUM;MAGNESIUM GLYCEROPHOSPHATE;PYRIDOXINE HYDROCHLORIDE;TAURINE	1 (1)	0	1 (0)
CALCIUM;COLECALCIFEROL	1 (1)	3 (2)	4 (1)
CALCIUM;MAGNESIUM	1 (1)	0	1 (0)
CALCIUM;MAGNESIUM;POTASSIUM	0	1 (1)	1 (0)
CALCIUM;VITAMIN D NOS	1 (1)	0	1 (0)
CAMPHOR;MENTHOL	1 (1)	2 (1)	3 (1)
CANAGLIFLOZIN	2 (1)	1 (1)	3 (1)
CANDESARTAN	2 (1)	0	2 (1)
CANNABIS SATIVA	1 (1)	2 (1)	3 (1)
CAPECITABINE	0	1 (1)	1 (0)
CARBIDOPA;LEVODOPA	1 (1)	0	1 (0)
CARBOMER	1 (1)	1 (1)	2 (1)
CARBOMER;GLYCEROL;PARAFFIN, LIQUID;POLYCARBOPHIL	0	1 (1)	1 (0)
CARBOPLATIN	1 (1)	0	1 (0)
CARMELLOSE	1 (1)	2 (1)	3 (1)

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Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
CARMELLOSE;GLYCEROL	0	1 (1)	1 (0)
CARMELLOSE;SORBINICATE	11 (6)	8 (5)	19 (6)
CARMUSTINE	0	1 (1)	1 (0)
CARVEDILOL	2 (1)	5 (3)	7 (2)
CASPOFUNGIN	4 (2)	1 (1)	5 (1)
CEFALEXIN	0	4 (2)	4 (1)
CEFAZOLIN	8 (5)	15 (9)	23 (7)
CEFDINIR	2 (1)	1 (1)	3 (1)
CEFEPIME	90 (53)	44 (26)	134 (40)
CEFOTAXIME	1 (1)	1 (1)	2 (1)
CEFPODOXIME	4 (2)	2 (1)	6 (2)
CEFTAZIDIME	15 (9)	3 (2)	18 (5)
CEFTRIAXONE	11 (6)	5 (3)	16 (5)
CEFUROXIME	3 (2)	1 (1)	4 (1)
CELECOXIB	5 (3)	1 (1)	6 (2)
CETIRIZINE	21 (12)	25 (15)	46 (14)
CETIRIZINE;PSEUDOEPHEDRINE	1 (1)	0	1 (0)
CETYLPYRIDINIUM;CHLORHEXIDINE	0	2 (1)	2 (1)
CHLORHEXIDINE	19 (11)	19 (11)	38 (11)
CHLORHEXIDINE GLUCONATE;MACROGOL;SACCHARIN SODIUM;SODIUM BICARBONATE;SODIUM EDETATE	0	1 (1)	1 (0)
CHLORHEXIDINE;LIDOCAINE	1 (1)	1 (1)	2 (1)
CHLORPHENAMINE	4 (2)	6 (4)	10 (3)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
CHLORPHENAMINE;HYDROCODONE	2 (1)	0	2 (1)
CHLORPROMAZINE	1 (1)	3 (2)	4 (1)
CHONDROITIN;GLUCOSAMINE	1 (1)	2 (1)	3 (1)
CHONDROITIN;GLUCOSAMINE HYDROCHLORIDE;METHYLSULFONYLMETHANE	0	1 (1)	1 (0)
CIDOFOVIR	1 (1)	0	1 (0)
CILASTATIN;IMIPENEM	1 (1)	1 (1)	2 (1)
CINCHOCAINE	0	1 (1)	1 (0)
CINNAMOMUM VERUM	0	1 (1)	1 (0)
CINNARIZINE	0	1 (1)	1 (0)
CIPROFLOXACIN	47 (28)	47 (28)	94 (28)
CITALOPRAM	3 (2)	2 (1)	5 (1)
CITRIC ACID;POTASSIUM BICARBONATE	0	1 (1)	1 (0)
CITRIC ACID;POTASSIUM BICARBONATE;POTASSIUM CITRATE	1 (1)	0	1 (0)
CLARITHROMYCIN	2 (1)	0	2 (1)
CLAVULANIC ACID	1 (1)	0	1 (0)
CLEMASTINE	12 (7)	15 (9)	27 (8)
CLINDAMYCIN	3 (2)	5 (3)	8 (2)
CLOBETASOL	2 (1)	1 (1)	3 (1)
CLONAZEPAM	4 (2)	2 (1)	6 (2)
CLONIDINE	4 (2)	2 (1)	6 (2)
CLOPIDOGREL	1 (1)	2 (1)	3 (1)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
CLOTRIMAZOLE	6 (4)	7 (4)	13 (4)
COCAINE HYDROCHLORIDE	1 (1)	1 (1)	2 (1)
CODEINE	4 (2)	4 (2)	8 (2)
CODEINE PHOSPHATE	2 (1)	0	2 (1)
CODEINE;GUAIFENESIN	2 (1)	1 (1)	3 (1)
CODEINE;PARACETAMOL	3 (2)	6 (4)	9 (3)
COLCHICINE	1 (1)	0	1 (0)
COLECALCIFEROL	27 (16)	24 (14)	51 (15)
COLISTIN	3 (2)	2 (1)	5 (1)
COLLAGENASE	1 (1)	0	1 (0)
CORTISONE	0	1 (1)	1 (0)
CURCUMIN	3 (2)	4 (2)	7 (2)
CYANOCOBALAMIN	12 (7)	10 (6)	22 (7)
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE	1 (1)	2 (1)	3 (1)
CYCLIZINE	1 (1)	4 (2)	5 (1)
CYCLOBENZAPRINE	4 (2)	6 (4)	10 (3)
CYCLOPHOSPHAMIDE	0	2 (1)	2 (1)
CYTARABINE	0	2 (1)	2 (1)
DALTEPARIN	9 (5)	9 (5)	18 (5)
DAPSONE	11 (6)	1 (1)	12 (4)
DAPTOMYCIN	6 (4)	2 (1)	8 (2)
DESONIDE	1 (1)	0	1 (0)

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
DESVENLAFAXINE	2 (1)	0	2 (1)
DEXAMETHASONE	81 (48)	125 (74)	206 (61)
DEXAMETHASONE;GENTAMICIN	0	1 (1)	1 (0)
DEXAMETHASONE;TOBRAMYCIN	1 (1)	0	1 (0)
DEXAMFETAMINE	1 (1)	0	1 (0)
DEXCHLORPHENIRAMINE	4 (2)	5 (3)	9 (3)
DEXCHLORPHENIRAMINE MALEATE	3 (2)	3 (2)	6 (2)
DEXMEDETOMIDINE	6 (4)	0	6 (2)
DEXPANTHENOL	2 (1)	4 (2)	6 (2)
DEXTRAN;HYPROMELLOSE	2 (1)	1 (1)	3 (1)
DEXTRIN	0	1 (1)	1 (0)
DEXTROMETHORPHAN	3 (2)	2 (1)	5 (1)
DEXTROMETHORPHAN;DOXYLAMINE;PARACETAMOL;PSEUDOEPHEDRINE	1 (1)	0	1 (0)
DEXTROMETHORPHAN;GUAIFENESIN	6 (4)	4 (2)	10 (3)
DIAZEPAM	2 (1)	4 (2)	6 (2)
DICLOFENAC	4 (2)	3 (2)	7 (2)
DICYCLOVERINE	3 (2)	2 (1)	5 (1)
DIETARY SUPPLEMENT	0	1 (1)	1 (0)
DIGOXIN	2 (1)	2 (1)	4 (1)
DILTIAZEM	4 (2)	3 (2)	7 (2)
DIMENHYDRINATE	3 (2)	2 (1)	5 (1)
DIMETICONE;GLYCEROL;PETROLATUM	1 (1)	2 (1)	3 (1)

Data cutoff date = 18MAR2021
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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
DIMETINDENE MALEATE	0	1 (1)	1 (0)
DIOSMECTITE	1 (1)	1 (1)	2 (1)
DIPHENHYDRAMINE	123 (72)	101 (60)	224 (66)
DIPHENHYDRAMINE;LIDOCAINE	1 (1)	0	1 (0)
DIPHENHYDRAMINE;PARACETAMOL	1 (1)	0	1 (0)
DIPHENHYDRAMINE;ZINC ACETATE	1 (1)	1 (1)	2 (1)
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID	1 (1)	1 (1)	2 (1)
DIPHTHERIA VACCINE;PERTUSSIS VACCINE;TETANUS VACCINE	6 (4)	3 (2)	9 (3)
DOCUSATE	40 (24)	42 (25)	82 (24)
DOCUSATE;SENNA ALEXANDRINA	37 (22)	26 (15)	63 (19)
DOMPERIDONE	2 (1)	6 (4)	8 (2)
DOPAMINE	2 (1)	0	2 (1)
DORZOLAMIDE	1 (1)	0	1 (0)
DOXEPIN	2 (1)	0	2 (1)
DOXYCYCLINE	9 (5)	6 (4)	15 (4)
DOXYLAMINE SUCCINATE;FOLIC ACID;PYRIDOXINE	0	2 (1)	2 (1)
DRONABINOL	1 (1)	1 (1)	2 (1)
DULAGLUTIDE	1 (1)	0	1 (0)
DULOXETINE	5 (3)	2 (1)	7 (2)
DUTASTERIDE	0	1 (1)	1 (0)
DUTASTERIDE;TAMSULOSIN HYDROCHLORIDE	0	1 (1)	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
EDOXABAN	2 (1)	0	2 (1)
ELECTROLYTE SOLUTIONS [UMBRELLA TERM]	1 (1)	2 (1)	3 (1)
ELECTROLYTES NOS	9 (5)	8 (5)	17 (5)
ELECTROLYTES NOS;GLUCOSE	0	2 (1)	2 (1)
ELECTROLYTES NOS;MACROGOL	1 (1)	0	1 (0)
ELTROMBOPAG	1 (1)	0	1 (0)
EMOLLIENTS AND PROTECTIVES	2 (1)	1 (1)	3 (1)
EMPAGLIFLOZIN	1 (1)	0	1 (0)
EMU OIL	1 (1)	0	1 (0)
ENALAPRIL	4 (2)	2 (1)	6 (2)
ENOXAPARIN	74 (44)	67 (40)	141 (42)
ENOXOLONE;HYALURONATE SODIUM;POVIDONE	0	4 (2)	4 (1)
ENTECAVIR	5 (3)	5 (3)	10 (3)
EPHEDRINE	2 (1)	2 (1)	4 (1)
EPINEPHRINE	1 (1)	0	1 (0)
EPINEPHRINE;LIDOCAINE	0	7 (4)	7 (2)
EPIRUBICIN	0	1 (1)	1 (0)
EPOETIN ALFA	0	1 (1)	1 (0)
EPTIFIBATIDE	0	1 (1)	1 (0)
ERGOCALCIFEROL	4 (2)	8 (5)	12 (4)
ERGOCALCIFEROL;RETINOL	1 (1)	0	1 (0)
ERTAPENEM	1 (1)	2 (1)	3 (1)
ERYTHROMYCIN	1 (1)	0	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
ESCITALOPRAM	6 (4)	3 (2)	9 (3)
ESKETAMINE	0	1 (1)	1 (0)
ESOMEPRAZOLE	6 (4)	10 (6)	16 (5)
ESTRADIOL	0	3 (2)	3 (1)
ETHINYLESTRADIOL;LEVONORGESTREL	0	1 (1)	1 (0)
ETOMIDATE	6 (4)	0	6 (2)
ETOPOSIDE	0	4 (2)	4 (1)
EXENATIDE	0	1 (1)	1 (0)
EZETIMIBE	0	1 (1)	1 (0)
FACTOR I (FIBRINOGEN)	2 (1)	0	2 (1)
FACTOR I (FIBRINOGEN);FACTOR VIII (ANTIHAEMOPHILIC FACTOR);FACTOR XIII (FIBRIN STABILISING FACTOR);VON WILLEBRAND FACTOR	5 (3)	0	5 (1)
FAMCICLOVIR	1 (1)	2 (1)	3 (1)
FAMOTIDINE	38 (22)	41 (24)	79 (23)
FENOFIBRATE	3 (2)	0	3 (1)
FENOTEROL;IPRATROPIUM	1 (1)	0	1 (0)
FENTANYL	30 (18)	45 (27)	75 (22)
FERROUS FUMARATE	2 (1)	0	2 (1)
FERROUS GLUCONATE	1 (1)	1 (1)	2 (1)
FERROUS SULFATE	4 (2)	6 (4)	10 (3)
FERROUS SULFATE;FOLIC ACID	1 (1)	0	1 (0)
FEXOFENADINE	4 (2)	2 (1)	6 (2)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
FIDAXOMICIN	1 (1)	0	1 (0)
FILGRASTIM	72 (42)	93 (55)	165 (49)
FINASTERIDE	3 (2)	3 (2)	6 (2)
FISH OIL	2 (1)	3 (2)	5 (1)
FLECAINIDE	1 (1)	0	1 (0)
FLUCLOXACILLIN	0	2 (1)	2 (1)
FLUCONAZOLE	107 (63)	71 (42)	178 (53)
FLUDEOXYGLUCOSE (18F)	12 (7)	16 (10)	28 (8)
FLUDROCORTISONE	2 (1)	0	2 (1)
FLUNITRAZEPAM	0	1 (1)	1 (0)
FLUOCINONIDE	1 (1)	1 (1)	2 (1)
FLUOROURACIL	1 (1)	0	1 (0)
FLUOXETINE	1 (1)	5 (3)	6 (2)
FLUTICASONE	11 (6)	9 (5)	20 (6)
FLUTICASONE;SALMETEROL	4 (2)	1 (1)	5 (1)
FLUVOXAMINE	1 (1)	0	1 (0)
FOLIC ACID	9 (5)	6 (4)	15 (4)
FOLIC ACID;MINERALS NOS;VITAMINS NOS	0	1 (1)	1 (0)
FOLINIC ACID	1 (1)	0	1 (0)
FONDAPARINUX	0	2 (1)	2 (1)
FORMOTEROL;MOMETASONE	2 (1)	0	2 (1)
FOSAPREPITANT	0	49 (29)	49 (14)
FOSCARNET	1 (1)	0	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
FOSFOMYCIN	0	1 (1)	1 (0)
FOSPHENYTOIN	1 (1)	0	1 (0)
FUROSEMIDE	49 (29)	72 (43)	121 (36)
GABAPENTIN	20 (12)	15 (9)	35 (10)
GADOBENIC ACID MEGLUMINE	4 (2)	0	4 (1)
GADOBUTROL	6 (4)	4 (2)	10 (3)
GANCICLOVIR	2 (1)	0	2 (1)
GENTAMICIN	1 (1)	2 (1)	3 (1)
GLIBENCLAMIDE	2 (1)	0	2 (1)
GLICLAZIDE	1 (1)	0	1 (0)
GLIMEPIRIDE	2 (1)	0	2 (1)
GLIPIZIDE	1 (1)	2 (1)	3 (1)
GLUCAGON	0	1 (1)	1 (0)
GLUCOSAMINE	0	1 (1)	1 (0)
GLUCOSE	6 (4)	10 (6)	16 (5)
GLUCOSE OXIDASE;LACTOFERRIN;LACTOPEROXIDASE;LYSOZYME	1 (1)	2 (1)	3 (1)
GLUCOSE;MAGNESIUM SULFATE	1 (1)	1 (1)	2 (1)
GLUCOSE;MAGNESIUM;POTASSIUM;SODIUM CHLORIDE	0	1 (1)	1 (0)
GLUCOSE;POTASSIUM CHLORIDE	0	2 (1)	2 (1)
GLUCOSE;POTASSIUM;SODIUM CHLORIDE	1 (1)	2 (1)	3 (1)
GLUCOSE;SODIUM ACETATE;SODIUM CHLORIDE	0	1 (1)	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
GLUCOSE;SODIUM BICARBONATE	2 (1)	1 (1)	3 (1)
GLUCOSE;SODIUM CHLORIDE	7 (4)	17 (10)	24 (7)
GLYCEROL	3 (2)	0	3 (1)
GLYCEROL;PARAFFIN, LIQUID;WHITE SOFT PARAFFIN	1 (1)	0	1 (0)
GLYCERYL TRINITRATE	1 (1)	3 (2)	4 (1)
GLYCINE MAX EXTRACT;WHEY PROTEIN	2 (1)	0	2 (1)
GLYCINE MAX SEED OIL;LECITHIN	2 (1)	0	2 (1)
GLYCOPYRRONIUM	1 (1)	0	1 (0)
GRANISETRON	2 (1)	13 (8)	15 (4)
GRANULOCYTE COLONY STIMULATING FACTOR	0	3 (2)	3 (1)
GUAIFENESIN	13 (8)	4 (2)	17 (5)
HALOPERIDOL	12 (7)	6 (4)	18 (5)
HEME IRON POLYPEPTIDE	1 (1)	0	1 (0)
HEPARIN	19 (11)	27 (16)	46 (14)
HEPATITIS A VACCINE	0	2 (1)	2 (1)
HEPATITIS B VACCINE	6 (4)	3 (2)	9 (3)
HERICIUM ERINACEUS MYCELIUM	1 (1)	0	1 (0)
HIB VACCINE CONJ	6 (4)	3 (2)	9 (3)
HOMATROPINE METHYLBROMIDE;HYDROCODONE BITARTRATE	1 (1)	0	1 (0)
HOMATROPINE;HYDROCODONE	1 (1)	0	1 (0)
HYALURONIC ACID	1 (1)	1 (1)	2 (1)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
HYDRALAZINE	7 (4)	5 (3)	12 (4)
HYDROCHLOROTHIAZIDE	3 (2)	8 (5)	11 (3)
HYDROCHLOROTHIAZIDE;LISINOPRIL	0	1 (1)	1 (0)
HYDROCHLOROTHIAZIDE;LOSARTAN	0	4 (2)	4 (1)
HYDROCHLOROTHIAZIDE;TELMISARTAN	1 (1)	0	1 (0)
HYDROCHLOROTHIAZIDE;TRIAMTERENE	0	1 (1)	1 (0)
HYDROCHLOROTHIAZIDE;VALSARTAN	0	2 (1)	2 (1)
HYDROCODONE	3 (2)	2 (1)	5 (1)
HYDROCODONE;PARACETAMOL	5 (3)	17 (10)	22 (7)
HYDROCORTISONE	12 (7)	42 (25)	54 (16)
HYDROCORTISONE;LIDOCAINE	0	1 (1)	1 (0)
HYDROCORTISONE;PRAMOCAINE	1 (1)	0	1 (0)
HYDROMORPHONE	37 (22)	23 (14)	60 (18)
HYDROXYCHLOROQUINE	1 (1)	0	1 (0)
HYDROXYZINE	3 (2)	3 (2)	6 (2)
HYETELLOSE;OCTENIDINE HYDROCHLORIDE;PROPYLENE GLYCOL	0	1 (1)	1 (0)
HYOSCINE	1 (1)	5 (3)	6 (2)
HYPROMELLOSE	5 (3)	8 (5)	13 (4)
IBANDRONATE SODIUM	0	1 (1)	1 (0)
IBUPROFEN	27 (16)	7 (4)	34 (10)
ICHTHAMMOL;TITANIUM DIOXIDE;ZINC OXIDE	0	1 (1)	1 (0)
IFOSFAMIDE	0	3 (2)	3 (1)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
IMMUNOGLOBULIN HUMAN NORMAL	28 (16)	2 (1)	30 (9)
INDOMETACIN	3 (2)	0	3 (1)
INFLUENZA VACCINE	5 (3)	6 (4)	11 (3)
INFLUENZA VACCINE INACT	6 (4)	2 (1)	8 (2)
INFLUENZA VACCINE INACT SPLIT 4V	1 (1)	1 (1)	2 (1)
INSULIN	18 (11)	8 (5)	26 (8)
INSULIN ASPART	11 (6)	7 (4)	18 (5)
INSULIN DETEMIR	2 (1)	1 (1)	3 (1)
INSULIN GLARGINE	16 (9)	4 (2)	20 (6)
INSULIN GLULISINE	0	1 (1)	1 (0)
INSULIN LISPRO	20 (12)	12 (7)	32 (9)
INVESTIGATIONAL DRUG	1 (1)	0	1 (0)
IODIXANOL	1 (1)	0	1 (0)
IOHEXOL	16 (9)	14 (8)	30 (9)
IOMEPROL	0	3 (2)	3 (1)
IOPAMIDOL	3 (2)	5 (3)	8 (2)
IOXITALAMATE MEGLUMINE	0	1 (1)	1 (0)
IOXITALAMIC ACID	0	2 (1)	2 (1)
IPRATROPIUM	8 (5)	3 (2)	11 (3)
IPRATROPIUM;SALBUTAMOL	11 (6)	5 (3)	16 (5)
IRBESARTAN	2 (1)	1 (1)	3 (1)
IRON	1 (1)	0	1 (0)
ISAVUCONAZONIUM	3 (2)	1 (1)	4 (1)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
ISOPHANE INSULIN	2 (1)	4 (2)	6 (2)
IVERMECTIN	0	1 (1)	1 (0)
KETAMINE	4 (2)	1 (1)	5 (1)
KETOROLAC	5 (3)	3 (2)	8 (2)
LABETALOL	2 (1)	0	2 (1)
LACOSAMIDE	4 (2)	0	4 (1)
LACTOBACILLUS ACIDOPHILUS	1 (1)	1 (1)	2 (1)
LACTOBACILLUS RHAMNOSUS	1 (1)	0	1 (0)
LACTULOSE	20 (12)	16 (10)	36 (11)
LAMIVUDINE	3 (2)	1 (1)	4 (1)
LAMOTRIGINE	0	1 (1)	1 (0)
LANSOPRAZOLE	6 (4)	9 (5)	15 (4)
LATANOPROST	2 (1)	0	2 (1)
LATANOPROST;TIMOLOL	0	1 (1)	1 (0)
LENOGRASTIM	1 (1)	5 (3)	6 (2)
LERCANIDIPINE	1 (1)	0	1 (0)
LETERMOVIR	1 (1)	0	1 (0)
LEUPRORELIN	1 (1)	0	1 (0)
LEVETIRACETAM	125 (74)	1 (1)	126 (37)
LEVOCETIRIZINE	1 (1)	0	1 (0)
LEVOFLOXACIN	64 (38)	45 (27)	109 (32)
LEVOMEPROMAZINE	0	5 (3)	5 (1)
LEVONORGESTREL	1 (1)	0	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
LEVOSALBUTAMOL	6 (4)	2 (1)	8 (2)
LEVOSALBUTAMOL HYDROCHLORIDE	0	1 (1)	1 (0)
LEVOTHYROXINE	11 (6)	14 (8)	25 (7)
LIDOCAINE	42 (25)	45 (27)	87 (26)
LIDOCAINE;NIFEDIPINE	1 (1)	0	1 (0)
LIDOCAINE;PRILOCAINE	7 (4)	7 (4)	14 (4)
LINAGLIPTIN	0	1 (1)	1 (0)
LINAGLIPTIN;METFORMIN	1 (1)	0	1 (0)
LINEZOLID	3 (2)	0	3 (1)
LINUM USITATISSIMUM SEED OIL	0	1 (1)	1 (0)
LIPEGFILGRASTIM	0	2 (1)	2 (1)
LIRAGLUTIDE	1 (1)	0	1 (0)
LISDEXAMFETAMINE MESILATE	0	2 (1)	2 (1)
LISINOPRIL	11 (6)	9 (5)	20 (6)
LITHIUM	0	2 (1)	2 (1)
LOPERAMIDE	35 (21)	45 (27)	80 (24)
LOPINAVIR;RITONAVIR	1 (1)	0	1 (0)
LORATADINE	32 (19)	31 (18)	63 (19)
LORATADINE;PSEUDOEPHEDRINE	14 (8)	1 (1)	15 (4)
LORAZEPAM	60 (35)	65 (39)	125 (37)
LORMETAZEPAM	0	1 (1)	1 (0)
LOSARTAN	6 (4)	8 (5)	14 (4)
LOVASTATIN	1 (1)	0	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
LUBIPROSTONE	0	1 (1)	1 (0)
LYNESTRENOL	1 (1)	0	1 (0)
LYSINE	0	1 (1)	1 (0)
MACROGOL	59 (35)	74 (44)	133 (39)
MAGIC MOUTHWASH	5 (3)	19 (11)	24 (7)
MAGNESIUM	3 (2)	3 (2)	6 (2)
MAGNESIUM AMINO ACID CHELATE	11 (6)	11 (7)	22 (7)
MAGNESIUM ASPARTATE DIHYDRATE	3 (2)	3 (2)	6 (2)
MAGNESIUM BROMIDE;MAGNESIUM FLUORIDE;MAGNESIUM HYDROXIDE	0	2 (1)	2 (1)
MAGNESIUM CHELATE	0	2 (1)	2 (1)
MAGNESIUM CHLORIDE	0	2 (1)	2 (1)
MAGNESIUM CITRATE	7 (4)	8 (5)	15 (4)
MAGNESIUM GLUCONATE	0	1 (1)	1 (0)
MAGNESIUM HYDROXIDE	7 (4)	2 (1)	9 (3)
MAGNESIUM OXIDE	26 (15)	27 (16)	53 (16)
MAGNESIUM SULFATE	79 (46)	81 (48)	160 (47)
MAGNESIUM SULFATE;MANNITOL;POTASSIUM	0	3 (2)	3 (1)
MAGNESIUM SULFATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE	2 (1)	6 (4)	8 (2)
MAGNESIUM;POTASSIUM;SODIUM	1 (1)	0	1 (0)
MAGNESIUM;SODIUM CHLORIDE	1 (1)	2 (1)	3 (1)
MANNITOL	2 (1)	16 (10)	18 (5)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
MARAVIROC	1 (1)	0	1 (0)
MEASLES VACCINE LIVE (ENDERS-EDMONSTON);MUMPS VACCINE LIVE (JERYL LYNN);RUBELLA VACCINE LIVE (WISTAR RA 27/3)	1 (1)	0	1 (0)
MEBEVERINE	0	1 (1)	1 (0)
MECLOZINE	1 (1)	1 (1)	2 (1)
MEFENAMIC ACID	0	1 (1)	1 (0)
MEGESTROL	2 (1)	1 (1)	3 (1)
MELATONIN	25 (15)	14 (8)	39 (12)
MELPERONE	1 (1)	0	1 (0)
MEMANTINE	0	1 (1)	1 (0)
MENTHA X PIPERITA OIL;METHYL SALICYLATE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 (1)	2 (1)	3 (1)
MENTHOL	1 (1)	3 (2)	4 (1)
MEROPENEM	33 (19)	12 (7)	45 (13)
MESNA	0	19 (11)	19 (6)
METAMIZOLE	9 (5)	6 (4)	15 (4)
METFORMIN	16 (9)	14 (8)	30 (9)
METFORMIN;SITAGLIPTIN	1 (1)	0	1 (0)
METHADONE	2 (1)	1 (1)	3 (1)
METHOCARBAMOL	2 (1)	2 (1)	4 (1)
METHOTREXATE	0	3 (2)	3 (1)
METHYLNALTREXONE	0	1 (1)	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
METHYLPHENIDATE	1 (1)	0	1 (0)
METHYLPREDNISOLONE	21 (12)	14 (8)	35 (10)
METHYLTHIONINIUM CHLORIDE	0	1 (1)	1 (0)
METOCLOPRAMIDE	34 (20)	43 (26)	77 (23)
METOPROLOL	25 (15)	22 (13)	47 (14)
METOPROLOL SUCCINATE	1 (1)	1 (1)	2 (1)
METRONIDAZOLE	17 (10)	13 (8)	30 (9)
MICAFUNGIN	7 (4)	2 (1)	9 (3)
MICONAZOLE	2 (1)	0	2 (1)
MIDAZOLAM	24 (14)	34 (20)	58 (17)
MIDODRINE	4 (2)	1 (1)	5 (1)
MINERALS NOS;VITAMINS NOS	0	1 (1)	1 (0)
MINOCYCLINE	4 (2)	0	4 (1)
MIRTAZAPINE	8 (5)	3 (2)	11 (3)
MOMETASONE	0	2 (1)	2 (1)
MONASCUS PURPUREUS	0	1 (1)	1 (0)
MONTELUKAST	5 (3)	2 (1)	7 (2)
MORPHINE	24 (14)	28 (17)	52 (15)
MOXIFLOXACIN	3 (2)	0	3 (1)
MULTIVITAMINS WITH MINERALS [UMBRELLA TERM]	1 (1)	1 (1)	2 (1)
MULTIVITAMINS, OTHER COMBINATIONS	0	1 (1)	1 (0)
MULTIVITAMINS, PLAIN	28 (16)	15 (9)	43 (13)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
MUPIROCIN	10 (6)	2 (1)	12 (4)
NADROPARIN	4 (2)	3 (2)	7 (2)
NALOXEGOL	1 (1)	1 (1)	2 (1)
NALOXONE	0	3 (2)	3 (1)
NALOXONE;OXYCODONE	1 (1)	1 (1)	2 (1)
NAPHAZOLINE;PHENIRAMINE	0	1 (1)	1 (0)
NAPROXEN	5 (3)	5 (3)	10 (3)
NEBIVOLOL	1 (1)	0	1 (0)
NEOSTIGMINE	1 (1)	0	1 (0)
NETUPITANT;PALONOSETRON	0	7 (4)	7 (2)
NICARDIPINE	1 (1)	0	1 (0)
NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;THIAMINE MONONITRATE	0	1 (1)	1 (0)
NICOTINE	7 (4)	5 (3)	12 (4)
NICOTINIC ACID	0	1 (1)	1 (0)
NIFEDIPINE	3 (2)	1 (1)	4 (1)
NITROFURANTOIN	0	3 (2)	3 (1)
NIVOLUMAB	0	1 (1)	1 (0)
NOREPINEPHRINE	11 (6)	4 (2)	15 (4)
NUTRIENTS NOS	2 (1)	3 (2)	5 (1)
NYSTATIN	22 (13)	21 (13)	43 (13)
OCTREOTIDE	1 (1)	3 (2)	4 (1)
OLANZAPINE	9 (5)	20 (12)	29 (9)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
OLMESARTAN	2 (1)	1 (1)	3 (1)
OMEGA-3 FATTY ACIDS	6 (4)	2 (1)	8 (2)
OMEPRAZOLE	28 (16)	41 (24)	69 (20)
ONDANSETRON	103 (61)	146 (87)	249 (74)
OSELTAMIVIR	5 (3)	2 (1)	7 (2)
OTHER VIRAL VACCINES	8 (5)	1 (1)	9 (3)
OXALIPLATIN	0	1 (1)	1 (0)
OXAZEPAM	4 (2)	2 (1)	6 (2)
OXYBUTYNIN	2 (1)	1 (1)	3 (1)
OXYCODONE	67 (39)	57 (34)	124 (37)
OXYCODONE HYDROCHLORIDE;PARACETAMOL	1 (1)	0	1 (0)
OXYCODONE;PARACETAMOL	7 (4)	1 (1)	8 (2)
OXYGEN	46 (27)	13 (8)	59 (17)
OXYMETAZOLINE	4 (2)	1 (1)	5 (1)
PALONOSETRON	1 (1)	22 (13)	23 (7)
PANCRELIPASE	0	1 (1)	1 (0)
PANTOPRAZOLE	62 (36)	68 (40)	130 (38)
PANTOTHENIC ACID	0	1 (1)	1 (0)
PARACETAMOL	167 (98)	153 (91)	320 (95)
PARAFFIN	1 (1)	0	1 (0)
PARAFFIN, LIQUID	1 (1)	0	1 (0)
PARAFFIN, LIQUID;SODIUM PICOSULFATE	0	1 (1)	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
PARAFFIN, LIQUID;WHITE SOFT PARAFFIN;WOOL FAT	1 (1)	0	1 (0)
PAROXETINE	1 (1)	0	1 (0)
PASSIFLORA INCARNATA	1 (1)	0	1 (0)
PEGFILGRASTIM	10 (6)	101 (60)	111 (33)
PEGVISOMANT	1 (1)	0	1 (0)
PEMBROLIZUMAB	1 (1)	0	1 (0)
PEMETREXED	1 (1)	0	1 (0)
PENICILLIN NOS	0	2 (1)	2 (1)
PENTAMIDINE	20 (12)	5 (3)	25 (7)
PERFLUBUTANE POLYMER MICROSPHERES	0	1 (1)	1 (0)
PERINDOPRIL ARGININE	0	1 (1)	1 (0)
PETHIDINE	13 (8)	5 (3)	18 (5)
PETROLATUM	4 (2)	2 (1)	6 (2)
PHENAZOPYRIDINE	3 (2)	2 (1)	5 (1)
PHENETICILLIN	0	3 (2)	3 (1)
PHENOL	1 (1)	2 (1)	3 (1)
PHENOXYMETHYLPENICILLIN POTASSIUM	0	1 (1)	1 (0)
PHENYLEPHRINE	5 (3)	3 (2)	8 (2)
PHENYTOIN	0	1 (1)	1 (0)
PHOSPHORIC ACID SODIUM;SODIUM PHOSPHATE DIBASIC	1 (1)	0	1 (0)
PHOSPHORUS	5 (3)	3 (2)	8 (2)
PHYTOMENADIONE	10 (6)	7 (4)	17 (5)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
PIMECROLIMUS	1 (1)	1 (1)	2 (1)
PIOGLITAZONE	0	1 (1)	1 (0)
PIPERACILLIN	1 (1)	0	1 (0)
PIPERACILLIN;TAZOBACTAM	66 (39)	26 (15)	92 (27)
PIRITRAMIDE	0	1 (1)	1 (0)
PITAVASTATIN	1 (1)	0	1 (0)
PLANTAGO AFRA	2 (1)	0	2 (1)
PLANTAGO OVATA	3 (2)	1 (1)	4 (1)
PLANTAGO OVATA HUSK	1 (1)	1 (1)	2 (1)
PLASMA	2 (1)	2 (1)	4 (1)
PLATELETS	10 (6)	84 (50)	94 (28)
PLERIXAFOR	0	36 (21)	36 (11)
PNEUMOCOCCAL VACCINE 13V	8 (5)	4 (2)	12 (4)
PNEUMOCOCCAL VACCINE CONJ	0	1 (1)	1 (0)
PNEUMOCOCCAL VACCINE POLYSACCH 23V	1 (1)	2 (1)	3 (1)
POLIO VACCINE INACT	6 (4)	2 (1)	8 (2)
POLYETHYLENE	0	1 (1)	1 (0)
POLYVINYL ALCOHOL;POVIDONE	2 (1)	1 (1)	3 (1)
POSACONAZOLE	6 (4)	1 (1)	7 (2)
POTASSIUM	0	8 (5)	8 (2)
POTASSIUM ACETATE	0	1 (1)	1 (0)
POTASSIUM BICARBONATE	1 (1)	1 (1)	2 (1)
POTASSIUM CHLORIDE	105 (62)	97 (58)	202 (60)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
POTASSIUM CHLORIDE;SODIUM CHLORIDE	6 (4)	16 (10)	22 (7)
POTASSIUM CHLORIDE;SODIUM PHOSPHATE	1 (1)	0	1 (0)
POTASSIUM CITRATE	1 (1)	1 (1)	2 (1)
POTASSIUM GLUCONATE	0	2 (1)	2 (1)
POTASSIUM PHOSPHATE DIBASIC	3 (2)	2 (1)	5 (1)
POTASSIUM PHOSPHATE DIBASIC;SODIUM	0	1 (1)	1 (0)
POTASSIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE	2 (1)	0	2 (1)
POTASSIUM PHOSPHATE MONOBASIC	35 (21)	26 (15)	61 (18)
POTASSIUM PHOSPHATE MONOBASIC;SODIUM PHOSPHATE	13 (8)	19 (11)	32 (9)
POTASSIUM;SODIUM	2 (1)	0	2 (1)
POTASSIUM;SODIUM BICARBONATE;SODIUM CHLORIDE	0	1 (1)	1 (0)
POTASSIUM;SODIUM CHLORIDE	1 (1)	2 (1)	3 (1)
POVIDONE-IODINE	0	1 (1)	1 (0)
PRAMOCAINE	2 (1)	0	2 (1)
PRAVASTATIN	1 (1)	5 (3)	6 (2)
PREDNISOLONE	0	27 (16)	27 (8)
PREDNISONE	5 (3)	8 (5)	13 (4)
PREGABALIN	8 (5)	7 (4)	15 (4)
PROBENECID	1 (1)	0	1 (0)
PROBIOTICS NOS	3 (2)	1 (1)	4 (1)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
PROCHLORPERAZINE	76 (45)	83 (49)	159 (47)
PROMETHAZINE	15 (9)	7 (4)	22 (7)
PROPOFOL	15 (9)	11 (7)	26 (8)
PROPRANOLOL	1 (1)	0	1 (0)
PROTAMINE	1 (1)	0	1 (0)
PROTEIN	1 (1)	1 (1)	2 (1)
PRUNUS DOMESTICA FRUIT;SENNA ALEXANDRINA LEAF	1 (1)	0	1 (0)
PSEUDOEPHEDRINE	3 (2)	0	3 (1)
PTEROSTILBENE	0	1 (1)	1 (0)
PYRIDOXINE	3 (2)	6 (4)	9 (3)
PYRIDOXINE;THIAMINE	0	1 (1)	1 (0)
QUETIAPINE	5 (3)	2 (1)	7 (2)
QUINAPRIL	1 (1)	0	1 (0)
RABEPRAZOLE	2 (1)	1 (1)	3 (1)
RACECADOTRIL	0	1 (1)	1 (0)
RACEPINEFRINE	1 (1)	0	1 (0)
RAMELTEON	5 (3)	1 (1)	6 (2)
RAMIPRIL	0	3 (2)	3 (1)
RANITIDINE	13 (8)	19 (11)	32 (9)
RASBURICASE	4 (2)	2 (1)	6 (2)
REMDESIVIR	2 (1)	0	2 (1)
REMIFENTANIL	1 (1)	0	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
RESVERATROL	0	1 (1)	1 (0)
RIBAVIRIN	0	2 (1)	2 (1)
RISEDRONATE SODIUM	1 (1)	0	1 (0)
RITUXIMAB	0	6 (4)	6 (2)
RIVAROXABAN	10 (6)	7 (4)	17 (5)
RIZATRIPTAN	2 (1)	2 (1)	4 (1)
ROCURONIUM	11 (6)	2 (1)	13 (4)
ROFLUMILAST	0	1 (1)	1 (0)
ROLAPITANT	1 (1)	3 (2)	4 (1)
ROMIPLOSTIM	0	1 (1)	1 (0)
ROPINIROLE	1 (1)	1 (1)	2 (1)
ROSUVASTATIN	5 (3)	6 (4)	11 (3)
SACCHAROMYCES BOULARDII	0	1 (1)	1 (0)
SALBUTAMOL	19 (11)	12 (7)	31 (9)
SAXAGLIPTIN	1 (1)	0	1 (0)
SENNA ALEXANDRINA	39 (23)	42 (25)	81 (24)
SERENOA REPENS	0	2 (1)	2 (1)
SERTRALINE	2 (1)	3 (2)	5 (1)
SEVELAMER	1 (1)	2 (1)	3 (1)
SILDENAFIL	3 (2)	0	3 (1)
SILTUXIMAB	1 (1)	0	1 (0)
SILYBUM MARIANUM	3 (2)	0	3 (1)
SIMETICONE	15 (9)	10 (6)	25 (7)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
SIMVASTATIN	8 (5)	6 (4)	14 (4)
SITAGLIPTIN	1 (1)	2 (1)	3 (1)
SITOSTEROL	0	1 (1)	1 (0)
SODIUM	1 (1)	0	1 (0)
SODIUM ACETATE	0	1 (1)	1 (0)
SODIUM ACETATE;SODIUM CHLORIDE	1 (1)	0	1 (0)
SODIUM BICARBONATE	10 (6)	18 (11)	28 (8)
SODIUM BICARBONATE;SODIUM CHLORIDE	9 (5)	20 (12)	29 (9)
SODIUM BICARBONATE;WATER FOR INJECTION	1 (1)	0	1 (0)
SODIUM CHLORIDE	122 (72)	99 (59)	221 (65)
SODIUM CITRATE	1 (1)	1 (1)	2 (1)
SODIUM CITRATE;SODIUM LAURYL SULFATE	0	1 (1)	1 (0)
SODIUM FLUORIDE	0	2 (1)	2 (1)
SODIUM GLYCEROPHOSPHATE	0	2 (1)	2 (1)
SODIUM HYPOCHLORITE	1 (1)	0	1 (0)
SODIUM PERCHLORATE	1 (1)	0	1 (0)
SODIUM PHOSPHATE	33 (19)	12 (7)	45 (13)
SODIUM PICOSULFATE	2 (1)	2 (1)	4 (1)
SODIUM POLYSTYRENE SULFONATE	0	1 (1)	1 (0)
SOLIFENACIN SUCCINATE	0	1 (1)	1 (0)
SOLUTIONS FOR PARENTERAL NUTRITION	6 (4)	8 (5)	14 (4)
SOTALOL	1 (1)	0	1 (0)
SPIRONOLACTONE	2 (1)	2 (1)	4 (1)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
STEM CELLS NOS	0	1 (1)	1 (0)
STOMATOLOGICAL PREPARATIONS	0	2 (1)	2 (1)
SUCRALFATE	3 (2)	6 (4)	9 (3)
SUGAMMADEX	3 (2)	1 (1)	4 (1)
SULFAMETHOXAZOLE	1 (1)	1 (1)	2 (1)
SULFAMETHOXAZOLE;TRIMETHOPRIM	98 (58)	75 (45)	173 (51)
SUMATRIPTAN	5 (3)	0	5 (1)
SUXAMETHONIUM	4 (2)	0	4 (1)
TACROLIMUS	2 (1)	0	2 (1)
TADALAFIL	1 (1)	2 (1)	3 (1)
TAMSULOSIN	9 (5)	3 (2)	12 (4)
TAZOBACTAM	1 (1)	0	1 (0)
TECHNETIUM (99M TC) ETIFENIN	0	1 (1)	1 (0)
TECHNETIUM TC 99M	0	2 (1)	2 (1)
TEICOPLANIN	4 (2)	1 (1)	5 (1)
TEMAZEPAM	9 (5)	5 (3)	14 (4)
TENOFOVIR	2 (1)	3 (2)	5 (1)
TESTOSTERONE	3 (2)	0	3 (1)
TESTOSTERONE UNDECANOATE	1 (1)	0	1 (0)
TETRACOSACTIDE	5 (3)	0	5 (1)
THIAMINE	8 (5)	10 (6)	18 (5)
THIOCTIC ACID	0	1 (1)	1 (0)
TICAGRELOR	0	1 (1)	1 (0)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
TINZAPARIN	2 (1)	2 (1)	4 (1)
TIOTROPIUM	1 (1)	0	1 (0)
TIZANIDINE	1 (1)	1 (1)	2 (1)
TOBRAMYCIN	2 (1)	0	2 (1)
TOCILIZUMAB	114 (67)	0	114 (34)
TOPIRAMATE	1 (1)	1 (1)	2 (1)
TORASEMIDE	0	2 (1)	2 (1)
TRAMADOL	40 (24)	28 (17)	68 (20)
TRANEXAMIC ACID	0	1 (1)	1 (0)
TRAVOPROST	1 (1)	0	1 (0)
TRAZODONE	13 (8)	8 (5)	21 (6)
TRIAMCINOLONE	6 (4)	5 (3)	11 (3)
TRIAMTERENE	1 (1)	0	1 (0)
TRIMETHOPRIM	1 (1)	1 (1)	2 (1)
TROPICAMIDE	1 (1)	0	1 (0)
UBIDECARENONE	4 (2)	1 (1)	5 (1)
UBIQUINOL	0	1 (1)	1 (0)
UMECLIDINIUM;VILANTEROL	0	1 (1)	1 (0)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	0	1 (1)	1 (0)
UREA	1 (1)	0	1 (0)
UROKINASE	0	1 (1)	1 (0)
URSODEOXYCHOLIC ACID	8 (5)	6 (4)	14 (4)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

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Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
VACCINIUM MACROCARPON	2 (1)	1 (1)	3 (1)
VALACICLOVIR	57 (34)	43 (26)	100 (30)
VALERIANA OFFICINALIS ROOT	1 (1)	0	1 (0)
VALGANCICLOVIR	2 (1)	1 (1)	3 (1)
VALPROATE SODIUM	1 (1)	0	1 (0)
VALPROIC ACID	1 (1)	1 (1)	2 (1)
VALSARTAN	1 (1)	0	1 (0)
VANCOMYCIN	76 (45)	28 (17)	104 (31)
VARICELLA ZOSTER VACCINE	0	1 (1)	1 (0)
VECURONIUM	2 (1)	0	2 (1)
VENLAFAXINE	3 (2)	6 (4)	9 (3)
VERAPAMIL	1 (1)	1 (1)	2 (1)
VITAMIN B COMPLEX	3 (2)	3 (2)	6 (2)
VITAMIN B12 AND FOLIC ACID	1 (1)	0	1 (0)
VITAMIN D NOS	3 (2)	5 (3)	8 (2)
VITAMIN K NOS	4 (2)	4 (2)	8 (2)
VITAMINS, OTHER COMBINATIONS	4 (2)	0	4 (1)
VORICONAZOLE	4 (2)	2 (1)	6 (2)
WARFARIN	1 (1)	2 (1)	3 (1)
XYLOMETAZOLINE	1 (1)	1 (1)	2 (1)
ZAFIRLUKAST	1 (1)	1 (1)	2 (1)
ZALEPLON	3 (2)	2 (1)	5 (1)
ZANAMIVIR	1 (1)	1 (1)	2 (1)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Table 14.3.3.1.3. Concomitant Medications (Safety Analysis Set)

Preferred Name	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	Overall (N = 338)
ZINC	0	1 (1)	1 (0)
ZINC GLUCONATE	0	1 (1)	1 (0)
ZINC OXIDE	0	1 (1)	1 (0)
ZINC SULFATE	0	1 (1)	1 (0)
ZINGIBER OFFICINALE RHIZOME	1 (1)	0	1 (0)
ZOLEDRONIC ACID	0	1 (1)	1 (0)
ZOLPIDEM	14 (8)	5 (3)	19 (6)
ZOPICLONE	1 (1)	7 (4)	8 (2)

Data cutoff date = 18MAR2021
Note: Concomitant medications are medications administered on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm. Medications with an onset during the retreatment period are excluded.
Note: Medications are coded using WHO Drug Dictionary March 2020 version.

Data Source: ADSL, ADCM Program Name: t_cm.sas Output Generated: 20210820T09:45

Anhang 4-G1.2: Exposition gegenüber patientenindividueller Therapie - RCT mit dem zu bewertenden Arzneimittel - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-2 (Anhang): Exposition gegenüber der verschiedenen Behandlungen der patientenindividuellen Therapie - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Table 14.3.3.3.3. Exposure to Study Treatment (Standard of Care) (Safety Analysis Set)

	Standard of Care (N = 168)
Subjects received any standard of care second-line salvage chemotherapy	168 (100)
Number of cycles received	
1 cycle	16 (10)
2 cycles	91 (54)
3 cycles	61 (36)
Number of subjects responded with CR/PR but did not receive HDT-ASCT[a]	3 (2)
Number of subjects responded with CR/PR and received HDT-ASCT	62 (37)
After 2 cycles	20 (12)
After 3 cycles	42 (25)
Rituximab + Ifosfamide, Carboplatin, and Etoposide (R-ICE)	84 (50)
Number of cycles received	
1 cycle	8 (5)
2 cycles	47 (28)
3 cycles	29 (17)
Number of subjects responded with CR/PR but did not receive HDT-ASCT[a]	2 (1)
Number of subjects responded with CR/PR and received HDT-ASCT	35 (21)
After 2 cycles	13 (8)
After 3 cycles	22 (13)
Rituximab + Etoposide, Methylprednisolone, Cytarabine, and Cisplatin (R-ESHAP)	5 (3)
Number of cycles received	
1 cycle	1 (1)
2 cycles	1 (1)
3 cycles	3 (2)
Number of subjects responded with CR/PR but did not receive HDT-ASCT[a]	0 (0)
Number of subjects responded with CR/PR and received HDT-ASCT	2 (1)
After 3 cycles	2 (1)

Data cutoff date = 18MAR2021
Abbreviations: ASCT, autologous stem cell transplant; CR, complete response; HDT, high-dose therapy; PR, partial response.
Note: Subjects who responded with PR or CR after 2 or 3 cycles of second-line salvage chemotherapy may have proceeded to HDT and ASCT.
a. Subjects who responded with CR/PR at Day 50 visit but didn't proceed with HDT-ASCT due to disease progression, or those who initiated HDT but did not complete ASCT, are excluded.

Data Source: ADSL, ADEX Program Name: t_ex_soc.sas Output Generated: 20210820T09:46

Table 14.3.3.3.3. Exposure to Study Treatment (Standard of Care) (Safety Analysis Set)

	Standard of Care (N = 168)
Rituximab + Gemcitabine, Dexamethasone, and Cisplatin/Carboplatin (R-GDP)	42 (25)
Number of cycles received	
1 cycle	4 (2)
2 cycles	20 (12)
3 cycles	18 (11)
Number of subjects responded with CR/PR but did not receive HDT-ASCT[a]	1 (1)
Number of subjects responded with CR/PR and received HDT-ASCT	15 (9)
After 2 cycles	5 (3)
After 3 cycles	10 (6)
Rituximab + Dexamethasone, High-dose Cytarabine and Cisplatin/Oxaliplatin (R-DHAP/R-DHAX)	37 (22)
Number of cycles received	
1 cycle	3 (2)
2 cycles	23 (14)
3 cycles	11 (7)
Number of subjects responded with CR/PR but did not receive HDT-ASCT[a]	0 (0)
Number of subjects responded with CR/PR and received HDT-ASCT	10 (6)
After 2 cycles	2 (1)
After 3 cycles	8 (5)

Data cutoff date = 18MAR2021
Abbreviations: ASCT, autologous stem cell transplant; CR, complete response; HDT, high-dose therapy; PR, partial response.
Note: Subjects who responded with PR or CR after 2 or 3 cycles of second-line salvage chemotherapy may have proceeded to HDT and ASCT.
a. Subjects who responded with CR/PR at Day 50 visit but didn't proceed with HDT-ASCT due to disease progression, or those who initiated HDT but did not complete ASCT, are excluded.

Data Source: ADSL, ADEX Program Name: t_ex_soc.sas Output Generated: 20210820T09:46

Anhang 4-G1.3: Folgetherapien - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-3 (Anhang): Liste der Folgetherapien - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Table 14.3.3.2.2. Subsequent Therapy (Safety Analysis Set)

	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Subjects with any subsequent therapy	70 (41)	120 (71)	190 (56)
ATEZOLIZUMAB	0 (0)	3 (2)	3 (1)
AXICABTAGENE CILOLEUCEL	0 (0)	75 (45)	75 (22)
BENDAMUSTINE	3 (2)	5 (3)	8 (2)
BRENTUXIMAB VEDOTIN	1 (1)	2 (1)	3 (1)
BRENTUXIMAB-CHP	0 (0)	1 (1)	1 (0)
BU/CY	0 (0)	1 (1)	1 (0)
CAR T	0 (0)	5 (3)	5 (1)
CODOX-M/IVAC	1 (1)	0 (0)	1 (0)
COPANLISIB	1 (1)	1 (1)	2 (1)
CY	0 (0)	22 (13)	22 (7)
CYTARABINE	1 (1)	1 (1)	2 (1)
DEXAMETHASONE	6 (4)	9 (5)	15 (4)
ESHAP	1 (1)	0 (0)	1 (0)
ETOPOSIDE	1 (1)	2 (1)	3 (1)
FLUDARABINE	0 (0)	17 (10)	17 (5)
GDP	3 (2)	0 (0)	3 (1)
GEM/OX	2 (1)	4 (2)	6 (2)
GEMCITABINE	1 (1)	1 (1)	2 (1)
GEMVINOR	0 (0)	1 (1)	1 (0)
HIGH DOSE METHYLPREDNISOLONE	0 (0)	2 (1)	2 (1)
HYDROCORTISONE	0 (0)	1 (1)	1 (0)
HYPER CVAD	0 (0)	1 (1)	1 (0)
IBRUTINIB	8 (5)	5 (3)	13 (4)
ICE	2 (1)	1 (1)	3 (1)
IFOSFAMIDE	1 (1)	1 (1)	2 (1)
IGEV	0 (0)	1 (1)	1 (0)
IP ON CLINICAL STUDY	2 (1)	0 (0)	2 (1)
IPILIMUMAB	2 (1)	0 (0)	2 (1)
LEAM	0 (0)	1 (1)	1 (0)
LENALIDOMIDE	8 (5)	11 (7)	19 (6)

Data cutoff date = 18MAR2021
Note: Therapies taken during retreatment period in the axicabtagene ciloleucel arm are excluded.

Data Source: ADSL, ADCM Program Name: t_anticancer.sas Output Generated: 20210820T09:45

Table 14.3.3.2.2. Subsequent Therapy (Safety Analysis Set)

	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
METHOTREXATE, HD	2 (1)	5 (3)	7 (2)
METHOTREXATE, IT	0 (0)	4 (2)	4 (1)
MINI-BEAM	0 (0)	3 (2)	3 (1)
MONSUNETUZUMAB	4 (2)	1 (1)	5 (1)
NIVOLUMAB	11 (6)	4 (2)	15 (4)
OBINUTUZIMAB	5 (3)	1 (1)	6 (2)
PEMBROLIZUMAB	5 (3)	5 (3)	10 (3)
PEP-C	0 (0)	1 (1)	1 (0)
POLATUZUMAB VEDOTIN	8 (5)	9 (5)	17 (5)
POLATUZUMAB VEDOTIN, BENDAMUSTINE, RITUXIMAB (POLA-BR)	12 (7)	18 (11)	30 (9)
PREDNISOLONE	0 (0)	1 (1)	1 (0)
PREDNISONE	3 (2)	3 (2)	6 (2)
R-BENDAMUSTINE	1 (1)	1 (1)	2 (1)
R-CHOP	1 (1)	0 (0)	1 (0)
R-CVP	1 (1)	0 (0)	1 (0)
R-DHAP	14 (8)	3 (2)	17 (5)
R-DHAX	5 (3)	0 (0)	5 (1)
R-ESHAP	0 (0)	2 (1)	2 (1)
R-GDP	11 (6)	5 (3)	16 (5)
R-GEM/OX	6 (4)	7 (4)	13 (4)
R-HYPER-CVAD	0 (0)	1 (1)	1 (0)
R-ICE	24 (14)	5 (3)	29 (9)
R-IGEV	0 (0)	1 (1)	1 (0)
R-IVE	1 (1)	0 (0)	1 (0)
R-LENALIDOMIDE	6 (4)	7 (4)	13 (4)
R-VIM	3 (2)	1 (1)	4 (1)
RITUXIMAB	11 (6)	20 (12)	31 (9)
SELINEXOR	2 (1)	0 (0)	2 (1)
TAFASITAMAB	1 (1)	2 (1)	3 (1)
TBI	1 (1)	0 (0)	1 (0)
TISAGENLECLEUCEL	0 (0)	16 (10)	16 (5)

Data cutoff date = 18MAR2021
Note: Therapies taken during retreatment period in the axicabtagene ciloleucel arm are excluded.

Data Source: ADSL, ADCM Program Name: t_anticancer.sas Output Generated: 20210820T09:45

Table 14.3.3.2.2. Subsequent Therapy (Safety Analysis Set)

	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
VARLILUMAB	4 (2)	2 (1)	6 (2)
VENETOCLAX	6 (4)	1 (1)	7 (2)
VINCRISTINE	1 (1)	2 (1)	3 (1)
XRT	20 (12)	34 (20)	54 (16)
Other			
ACALABRUTINIB (BTK INHIBITOR) + STAT INHIBITOR	1 (1)	0 (0)	1 (0)
ANTI-CD20 BISPECIFIC AB RGN-1979	0 (0)	1 (1)	1 (0)
AT13387 IN ALK+ ALCL, MANTLE CELL LYMPHOMA, AND BCL6+ DLBCL	0 (0)	1 (1)	1 (0)
BIS-CHLORETHYL-NITROSO-UREA	0 (0)	1 (1)	1 (0)
BTCT4465A	0 (0)	1 (1)	1 (0)
CA-4948	0 (0)	1 (1)	1 (0)
CD19/CD22 CAR T	0 (0)	1 (1)	1 (0)
CLINICAL TRIAL	1 (1)	0 (0)	1 (0)
CLINICAL TRIAL (RO-POLA: RO7082859, OBINUTUZUMAB, POLATUZUMAB)	1 (1)	0 (0)	1 (0)
CLINICAL TRIAL - ORAL DIHIDROOROTATE	1 (1)	0 (0)	1 (0)
CLINICAL TRIAL DRUG (IMMUNOTHERAPY, BITE, ANTICD3/CD20)	0 (0)	1 (1)	1 (0)
CPI-613	1 (1)	0 (0)	1 (0)
CRSP-ONC-001	0 (0)	1 (1)	1 (0)
DEANGELIS PROTOCOL CONT.: LEUCOVORIN, DEXAMETHAZONE, CYTARIBINE, WBRT	0 (0)	1 (1)	1 (0)
DEANGELIS PROTOCOL: METHOTREXATE, VINCRISTINE, CAP PROCARBAZINE	0 (0)	1 (1)	1 (0)
EED INHIBITOR	1 (1)	0 (0)	1 (0)
FIMEPINOSTAT	1 (1)	0 (0)	1 (0)
FT516-101	1 (1)	0 (0)	1 (0)
IMMUNOTHERAPY	0 (0)	1 (1)	1 (0)
INHIBITOR OF THE BET FAMILY OF BROMODOMAINS	0 (0)	1 (1)	1 (0)
IP (BI-SPECIFIC ANTIBODY)	1 (1)	0 (0)	1 (0)
LONCASTUXIMAB (ADCT-402)	1 (1)	0 (0)	1 (0)
LONCASTUXIMAB TESIRINE	1 (1)	1 (1)	2 (1)
MALT-1 INHIBITOR	0 (0)	1 (1)	1 (0)
MASS DEBULKING SURGERY	1 (1)	0 (0)	1 (0)
MELPHALAN	0 (0)	1 (1)	1 (0)

Data cutoff date = 18MAR2021
Note: Therapies taken during retreatment period in the axicabtagene ciloleucel arm are excluded.

Data Source: ADSL, ADCM Program Name: t_anticancer.sas Output Generated: 20210820T09:45

Table 14.3.3.2.2. Subsequent Therapy (Safety Analysis Set)

	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
MGD013 MACROGENICS CLINICAL TRIAL	1 (1)	0 (0)	1 (0)
MRNA-2752 + DURVALUMAB	1 (1)	0 (0)	1 (0)
MT-3724	1 (1)	0 (0)	1 (0)
NK CELLS INFUSION	0 (0)	1 (1)	1 (0)
ORALLY AVAILABLE SMALL MOLECULE CC-99282	1 (1)	0 (0)	1 (0)
PCE2BO	0 (0)	1 (1)	1 (0)
PEG-ASPARGASE, TEMSIROLIMUS, METFORMIN	0 (0)	1 (1)	1 (0)
PEGFILGASTRIM	0 (0)	1 (1)	1 (0)
PROCARBAZINE	1 (1)	0 (0)	1 (0)
R-HEMICOLECTOMY	0 (0)	1 (1)	1 (0)
R-HYPERCYTOXAN	1 (1)	0 (0)	1 (0)
SPLENECTOMIA	1 (1)	0 (0)	1 (0)
THIOPTEPA	1 (1)	0 (0)	1 (0)
TRPH-222 CLINICAL TRIAL	1 (1)	0 (0)	1 (0)
TTI-621	0 (0)	1 (1)	1 (0)
UTOMILUMAB	0 (0)	1 (1)	1 (0)
XMAB13676-01	0 (0)	1 (1)	1 (0)

Data cutoff date = 18MAR2021
Note: Therapies taken during retreatment period in the axicabtagene ciloleucel arm are excluded.

Data Source: ADSL, ADCM Program Name: t_anticancer.sas Output Generated: 20210820T09:45

Anhang 4-G2: Ergänzende Darstellung der Studienergebnisse in der RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Anhang 4-G2.1: Ergänzende Darstellung zu EFS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-4 (Anhang): Ergebnisse zu EFS nach Prüfarztbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Table 14.2.1.1.2. Event-free Survival Per Investigator Assessment (Full Analysis Set)

	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Number of subjects	180	179
Events, n (%)	103 (57)	140 (78)
Censored, n (%)	77 (43)	39 (22)
Hazard ratio (95% CI), stratified	0.404 (0.311, 0.525)	NA
Hazard ratio (95% CI), stratified (derived)	0.408 (0.313, 0.530)	NA
Hazard ratio (95% CI), unstratified	0.431 (0.333, 0.557)	NA
KM median (95% CI) EFS time (months)	10.8 (5.0, 28.6)	2.3 (1.7, 3.1)
Min, Max EFS time (months)	0, 31	0, 33
Event		
Disease progression, n (%)	85 (47)	98 (55)
Best response of SD up to and including Day 150 assessment post randomization, n (%)	2 (1)	0 (0)
New lymphoma therapy, n (%)	5 (3)	37 (21)
Death from any cause, n (%)	11 (6)	5 (3)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EFS, event-free survival; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; NA, not applicable; NE, not estimable; SCT, stem cell transplant; SD, stable disease.
Note: EFS is defined as the time from randomization to the earliest date of disease progression per Lugano Classification (Cheson et al, 2014), commencement of new lymphoma therapy (including SCT in the axicabtagene ciloleucel arm without axicabtagene ciloleucel-induced response or retreatment of axicabtagene ciloleucel), or death from any cause.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system. The derived stratification factors are based on data collected on case report forms.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care therapy. The Breslow method is used to handle the ties for the Cox regression models.

Data Source: ADSL, ADTTE Program Name: t_efs.sas Output Generated: 20210820T09:01

Table 14.2.1.1.2. Event-free Survival Per Investigator Assessment (Full Analysis Set)

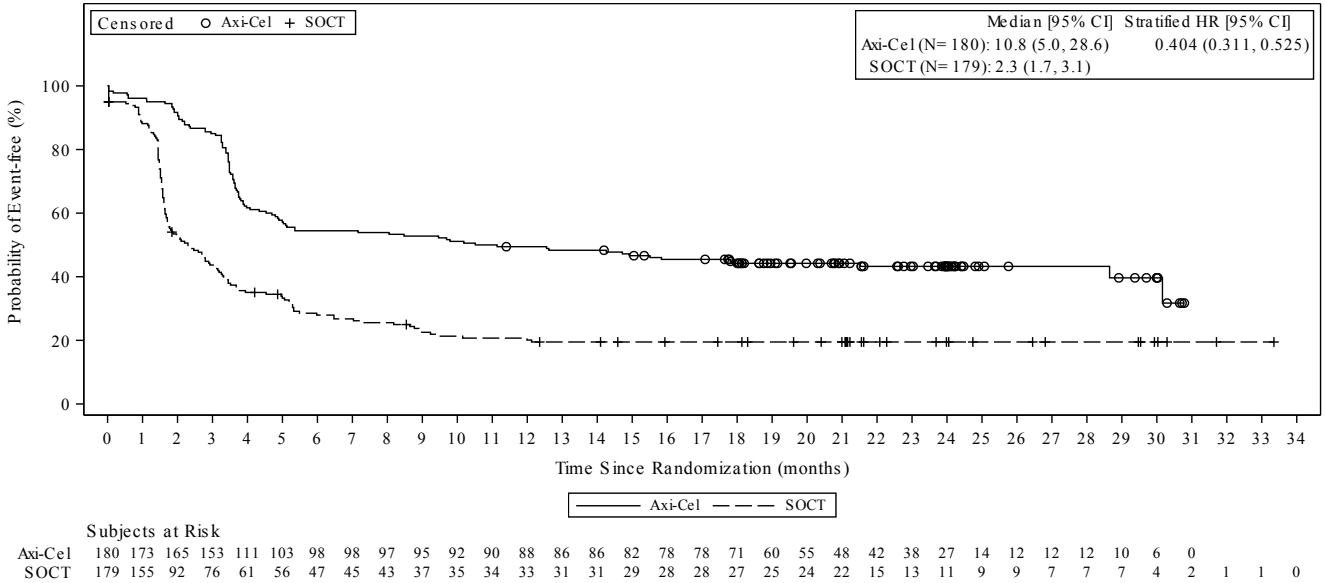
	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Censoring reason		
Response ongoing, n (%)	77 (43)	34 (19)
No post-baseline disease assessment, n (%)	0 (0)	1 (1)
Full withdrawal of consent, n (%)	0 (0)	2 (1)
Lost to follow up, n (%)	0 (0)	2 (1)
Event-free rate, % (95% CI) by KME		
3 month	85.0 (78.9, 89.5)	43.7 (36.3, 50.9)
6 month	54.4 (46.9, 61.4)	27.9 (21.5, 34.7)
9 month	52.8 (45.2, 59.8)	22.5 (16.6, 29.0)
12 month	49.4 (42.0, 56.5)	20.1 (14.5, 26.4)
15 month	46.6 (39.2, 53.7)	19.5 (13.9, 25.7)
18 month	44.2 (36.8, 51.3)	19.5 (13.9, 25.7)
21 month	44.2 (36.8, 51.3)	19.5 (13.9, 25.7)
24 month	43.3 (35.8, 50.5)	19.5 (13.9, 25.7)
27 month	43.3 (35.8, 50.5)	19.5 (13.9, 25.7)
30 month	39.6 (30.1, 49.0)	19.5 (13.9, 25.7)
33 month	NE (NE, NE)	19.5 (13.9, 25.7)
Median (95% CI) follow-up time (months) (reverse KM approach)	23.0 (20.9, 24.0)	21.2 (20.4, 23.7)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EFS, event-free survival; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; NA, not applicable; NE, not estimable; SCT, stem cell transplant; SD, stable disease.
Note: EFS is defined as the time from randomization to the earliest date of disease progression per Lugano Classification (Cheson et al, 2014), commencement of new lymphoma therapy (including SCT in the axicabtagene ciloleucel arm without axicabtagene ciloleucel-induced response or retreatment of axicabtagene ciloleucel), or death from any cause.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system. The derived stratification factors are based on data collected on case report forms.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care therapy. The Breslow method is used to handle the ties for the Cox regression models.

Data Source: ADSL, ADTTE Program Name: t_efs.sas Output Generated: 20210820T09:01

Abbildung 1 (Anhang): Kaplan-Meier Plot zu EFS nach Prüfarztbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Figure 14.2.1.1.2. Kaplan-Meier Plot of Event-free Survival Per Investigator Assessment (Full Analysis Set)



Data Cutoff Date = 18MAR2021
Abbreviations: Axi-cel, axicabtagene ciloleucel; CI, confidence interval; EFS, event-free survival; HR, hazard ratio; SOCT, standard of care therapy.
Note: EFS is defined as the time from randomization to the earliest date of disease progression per Lugano Classification (Cheson et al, 2014), commencement of new lymphoma therapy (including stem cell transplant in the axicabtagene ciloleucel arm without axicabtagene ciloleucel-induced response or retreatment of axicabtagene ciloleucel), or death from any cause.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.
Note: Stratified Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care. The Breslow method is used to handle the ties for the Cox regression models.

Data Source: ADSL, ADTTE Program Name: f_km.sas Output Generated: 20210820T09:05

Tabelle 4-5 (Anhang): Ergebnisse zu EFS nach Zentralbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Table 14.2.1.1.1. Event-free Survival Per Central Assessment (Full Analysis Set)

	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Number of subjects	180	179
Events, n (%)	108 (60)	144 (80)
Censored, n (%)	72 (40)	35 (20)
Stratified log-rank p-value	<.0001	NA
Hazard ratio (95% CI), stratified	0.398 (0.308, 0.514)	NA
Stratified (derived) log-rank p-value	<.0001	NA
Hazard ratio (95% CI), stratified (derived)	0.406 (0.313, 0.525)	NA
Unstratified log-rank p-value	<.0001	NA
Hazard ratio (95% CI), unstratified	0.423 (0.328, 0.544)	NA
KM median (95% CI) EFS time (months)	8.3 (4.5, 15.8)	2.0 (1.6, 2.8)
Min, Max EFS time (months)	0, 31	0, 33
Event		
Disease progression, n (%)	82 (46)	75 (42)
Best response of SD up to and including Day 150 assessment post randomization, n (%)	4 (2)	0 (0)
New lymphoma therapy, n (%)	9 (5)	63 (35)
Axicabtagene ciloleucel retreatment, n (%)	2 (1)	0 (0)
Death from any cause, n (%)	11 (6)	6 (3)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EFS, event-free survival; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; NA, not applicable; NE, not estimable; SCT, stem cell transplant; SD, stable disease.
Note: EFS is defined as the time from randomization to the earliest date of disease progression per Lugano Classification (Cheson et al, 2014), commencement of new lymphoma therapy (including SCT in the axicabtagene ciloleucel arm without axicabtagene ciloleucel-induced response or retreatment of axicabtagene ciloleucel), or death from any cause.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system. The derived stratification factors are based on data collected on case report forms.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care therapy. The Breslow method is used to handle the ties for the Cox regression models.
Note: One-sided p-value from log rank test is presented.

Data Source: ADSL, ADTTE Program Name: t_efs.sas Output Generated: 20210820T09:01

Table 14.2.1.1.1. Event-free Survival Per Central Assessment (Full Analysis Set)

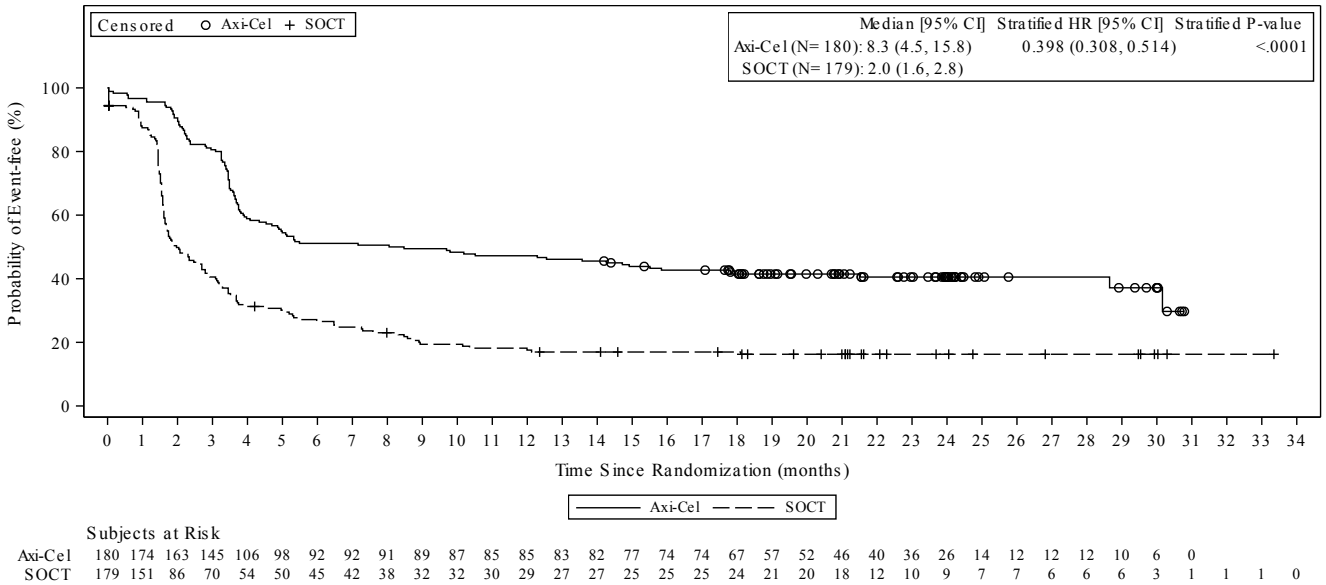
	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Censoring reason		
Response ongoing, n (%)	72 (40)	28 (16)
Response assessed but no disease at baseline and post-baseline, n (%)	0 (0)	3 (2)
No post-baseline disease assessment, n (%)	0 (0)	1 (1)
Full withdrawal of consent, n (%)	0 (0)	1 (1)
Lost to follow up, n (%)	0 (0)	2 (1)
Event-free rate, % (95% CI) by KME		
3 month	80.6 (74.0, 85.6)	40.5 (33.2, 47.8)
6 month	51.1 (43.6, 58.1)	26.6 (20.2, 33.3)
9 month	49.4 (42.0, 56.5)	19.4 (13.8, 25.6)
12 month	47.2 (39.8, 54.3)	17.6 (12.3, 23.6)
15 month	43.9 (36.5, 50.9)	17.0 (11.8, 23.0)
18 month	41.5 (34.2, 48.6)	17.0 (11.8, 23.0)
21 month	41.5 (34.2, 48.6)	16.3 (11.1, 22.2)
24 month	40.5 (33.2, 47.7)	16.3 (11.1, 22.2)
27 month	40.5 (33.2, 47.7)	16.3 (11.1, 22.2)
30 month	37.2 (28.0, 46.3)	16.3 (11.1, 22.2)
33 month	NE (NE, NE)	16.3 (11.1, 22.2)
Median (95% CI) follow-up time (months) (reverse KM approach)	23.0 (20.9, 24.0)	21.2 (20.4, 23.7)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EFS, event-free survival; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; NA, not applicable; NE, not estimable; SCT, stem cell transplant; SD, stable disease.
Note: EFS is defined as the time from randomization to the earliest date of disease progression per Lugano Classification (Cheson et al, 2014), commencement of new lymphoma therapy (including SCT in the axicabtagene ciloleucel arm without axicabtagene ciloleucel-induced response or retreatment of axicabtagene ciloleucel), or death from any cause.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system. The derived stratification factors are based on data collected on case report forms.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care therapy. The Breslow method is used to handle the ties for the Cox regression models.
Note: One-sided p-value from log rank test is presented.

Data Source: ADSL, ADTTE Program Name: t_efs.sas Output Generated: 20210820T09:01

Abbildung 2 (Anhang): Kaplan-Meier Plot zu EFS nach Zentralbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Figure 14.2.1.1.1. Kaplan-Meier Plot of Event-free Survival Per Central Assessment (Full Analysis Set)



Data Cutoff Date = 18MAR2021
Abbreviations: Axi-cel, axicabtagene ciloleucel; CI, confidence interval; EFS, event-free survival; HR, hazard ratio; SOCT, standard of care therapy.
Note: EFS is defined as the time from randomization to the earliest date of disease progression per Lugano Classification (Cheson et al, 2014), commencement of new lymphoma therapy (including stem cell transplant in the axicabtagene ciloleucel arm without axicabtagene ciloleucel-induced response or retreatment of axicabtagene ciloleucel), or death from any cause.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.
Note: Stratified Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care. The Breslow method is used to handle the ties for the Cox regression models.
Note: One-sided p-value from log rank test is presented.

Data Source: ADSL, ADTTE Program Name: f_km.sas Output Generated: 20210820T09:04

Anhang 4-G2.2: Ergänzende Darstellung zu PFS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-6 (Anhang): Ergebnisse zu PFS nach Prüfarztbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Table 14.2.4.1.2. Progression-free Survival Per Investigator Assessment (Full Analysis Set)

	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Number of subjects	180	179
Events, n (%)	96 (53)	103 (58)
Censored, n (%)	84 (47)	76 (42)
Stratified log-rank p-value	<.0001	NA
Hazard ratio (95% CI), stratified	0.490 (0.368, 0.652)	NA
Unstratified log-rank p-value	<.0001	NA
Hazard ratio (95% CI), unstratified	0.524 (0.396, 0.694)	NA
KM median (95% CI) PFS time (months)	14.7 (5.4, NE)	3.7 (2.9, 5.3)
Min, Max PFS time (months)	0, 31	0, 33
Event		
Disease progression, n (%)	85 (47)	98 (55)
Death from any cause, n (%)	11 (6)	5 (3)
Censoring reason		
Response ongoing, n (%)	79 (44)	34 (19)
New lymphoma therapy, n (%)	5 (3)	37 (21)
No post-baseline disease assessment, n (%)	0 (0)	1 (1)
Full withdrawal of consent, n (%)	0 (0)	2 (1)
Lost to follow up, n (%)	0 (0)	2 (1)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; NA, not applicable; PFS, progression-free survival; SCT, stem cell transplant.
Note: PFS is defined as the time from the randomization date to the date of disease progression or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including SCT in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care therapy. The Breslow method is used to handle the ties for the Cox regression models.
Note: One-sided p-value from log rank test is presented.

Data Source: ADSL, ADTTE Program Name: t_pfs.sas Output Generated: 20210820T09:04

Table 14.2.4.1.2. Progression-free Survival Per Investigator Assessment (Full Analysis Set)

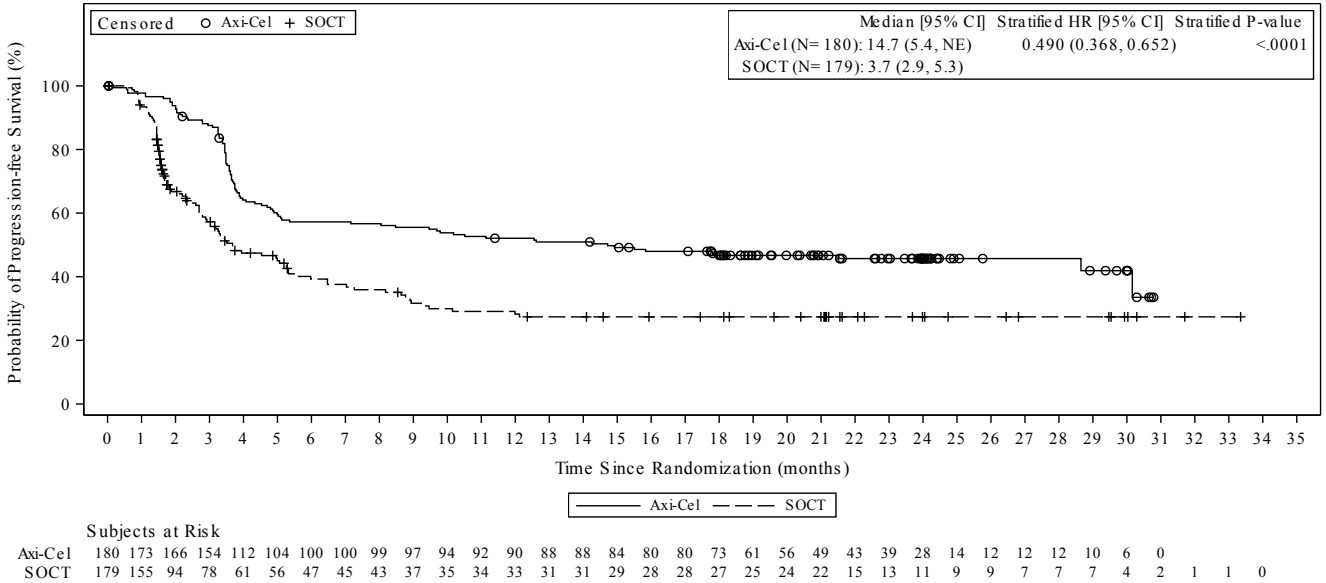
	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Progression-free rate, % (95% CI) by KME		
3 month	87.6 (81.7, 91.6)	57.3 (49.0, 64.8)
6 month	57.2 (49.6, 64.2)	39.3 (31.1, 47.3)
9 month	55.5 (47.9, 62.5)	31.7 (23.9, 39.7)
12 month	52.1 (44.4, 59.2)	28.2 (20.8, 36.2)
15 month	49.2 (41.6, 56.3)	27.4 (20.0, 35.3)
18 month	46.7 (39.1, 53.9)	27.4 (20.0, 35.3)
21 month	46.7 (39.1, 53.9)	27.4 (20.0, 35.3)
24 month	45.7 (38.1, 53.0)	27.4 (20.0, 35.3)
27 month	45.7 (38.1, 53.0)	27.4 (20.0, 35.3)
30 month	41.9 (31.9, 51.6)	27.4 (20.0, 35.3)
33 month	NE (NE, NE)	27.4 (20.0, 35.3)
Median (95% CI) follow-up time (months) (reverse KM approach)	22.6 (20.8, 24.0)	19.6 (14.6, 21.2)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; NA, not applicable; PFS, progression-free survival; SCT, stem cell transplant.
Note: PFS is defined as the time from the randomization date to the date of disease progression or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including SCT in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care therapy. The Breslow method is used to handle the ties for the Cox regression models.
Note: One-sided p-value from log rank test is presented.

Data Source: ADSL, ADTTE Program Name: t_pfs.sas Output Generated: 20210820T09:04

Abbildung 3 (Anhang): Kaplan-Meier Plot zu PFS nach Prüfarztbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Figure 14.2.4.1.2. Kaplan-Meier Plot of Progression-free Survival Per Investigator Assessment (Full Analysis Set)



Data Cutoff Date = 18MAR2021
Abbreviations: Axi-cel, axicabtagene ciloleucel; CI, confidence interval; HR, hazard ratio; SCT, stem cell transplant; SOCT, standard of care therapy.
Note: Progression-free survival is defined as the time from the randomization date to the date of disease progression or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including SCT in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.
Note: Stratified Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care. The Breslow method is used to handle the ties for the Cox regression models.
Note: One-sided p-value from log rank test is presented.

Data Source: ADSL, ADTTE Program Name: f_km.sas Output Generated: 20210820T09:05

Tabelle 4-7 (Anhang): Ergebnisse zu PFS nach Zentralbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Table 14.2.4.1.1. Progression-free Survival Per Central Assessment (Full Analysis Set)

	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Number of subjects	180	179
Events, n (%)	93 (52)	81 (45)
Censored, n (%)	87 (48)	98 (55)
Hazard ratio (95% CI), stratified	0.562 (0.414, 0.762)	NA
Hazard ratio (95% CI), unstratified	0.594 (0.440, 0.802)	NA
KM median (95% CI) PFS time (months)	14.9 (7.2, NE)	5.0 (3.4, 8.5)
Min, Max PFS time (months)	0, 31	0, 33
Event		
Disease progression, n (%)	82 (46)	75 (42)
Death from any cause, n (%)	11 (6)	6 (3)
Censoring reason		
Response ongoing, n (%)	76 (42)	28 (16)
New lymphoma therapy, n (%)	9 (5)	61 (34)
Subsequent stem cell transplant, n (%)	0 (0)	2 (1)
Axicabtagene ciloleucel retreatment, n (%)	2 (1)	0 (0)
Response assessed but no disease at baseline and post-baseline, n (%)	0 (0)	3 (2)
No post-baseline disease assessment, n (%)	0 (0)	1 (1)
Full withdrawal of consent, n (%)	0 (0)	1 (1)
Lost to follow up, n (%)	0 (0)	2 (1)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; NA, not applicable; NE, not estimable; PFS, progression-free survival; SCT, stem cell transplant.
Note: PFS is defined as the time from the randomization date to the date of disease progression or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including SCT in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care therapy. The Breslow method is used to handle the ties for the Cox regression models.

Data Source: ADSL, ADTTE Program Name: t_pfs.sas Output Generated: 20210820T09:04

Table 14.2.4.1.1. Progression-free Survival Per Central Assessment (Full Analysis Set)

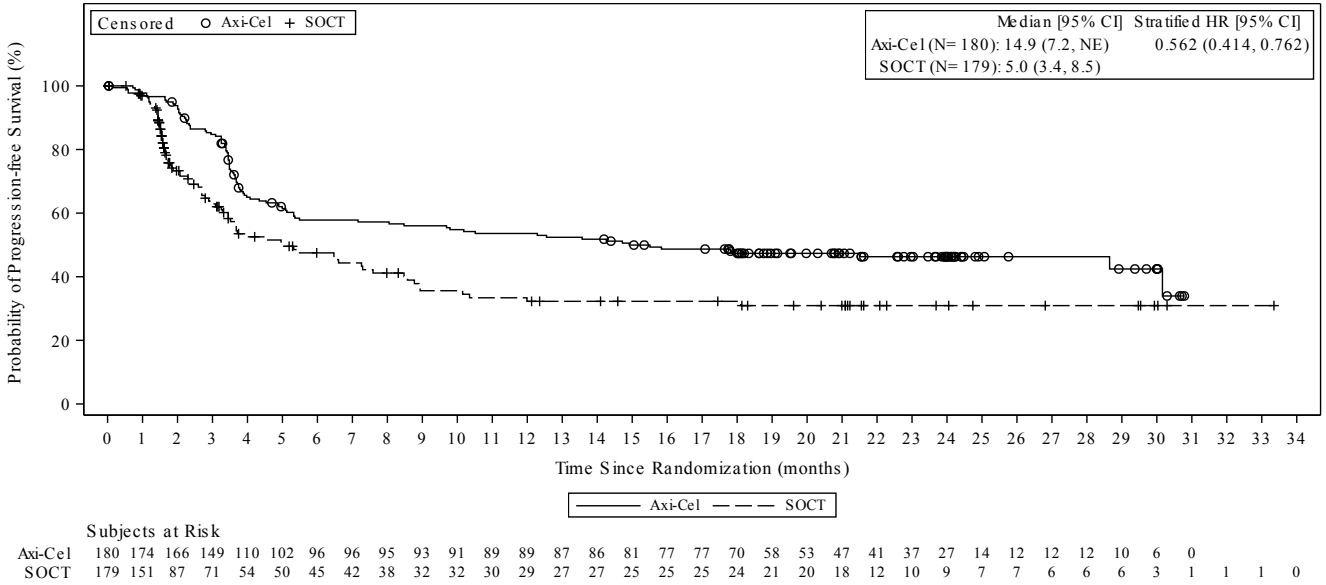
	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Progression-free rate, % (95% CI) by KME		
3 month	84.7 (78.5, 89.3)	62.9 (53.9, 70.6)
6 month	57.8 (50.1, 64.8)	47.5 (38.2, 56.3)
9 month	56.0 (48.3, 63.1)	35.6 (26.6, 44.7)
12 month	53.6 (45.8, 60.7)	32.3 (23.5, 41.4)
15 month	50.0 (42.2, 57.2)	32.3 (23.5, 41.4)
18 month	47.3 (39.6, 54.7)	32.3 (23.5, 41.4)
21 month	47.3 (39.6, 54.7)	30.9 (22.2, 40.1)
24 month	46.3 (38.5, 53.7)	30.9 (22.2, 40.1)
27 month	46.3 (38.5, 53.7)	30.9 (22.2, 40.1)
30 month	42.4 (32.3, 52.2)	30.9 (22.2, 40.1)
33 month	NE (NE, NE)	30.9 (22.2, 40.1)
Median (95% CI) follow-up time (months) (reverse KM approach)	21.6 (20.7, 23.7)	12.1 (3.7, 18.3)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; NA, not applicable; NE, not estimable; PFS, progression-free survival; SCT, stem cell transplant.
Note: PFS is defined as the time from the randomization date to the date of disease progression or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including SCT in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care therapy. The Breslow method is used to handle the ties for the Cox regression models.

Data Source: ADSL, ADTTE Program Name: t_pfs.sas Output Generated: 20210820T09:04

Abbildung 4 (Anhang): Kaplan-Meier Plot zu PFS nach Zentralbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Figure 14.2.4.1.1. Kaplan-Meier Plot of Progression-free Survival Per Central Assessment (Full Analysis Set)



Data Cutoff Date = 18MAR2021
Abbreviations: Axi-cel, axicabtagene ciloleucel; CI, confidence interval; HR, hazard ratio; NE, not estimable; SCT, stem cell transplant; SOCT, standard of care therapy.
Note: Progression-free survival is defined as the time from the randomization date to the date of disease progression or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including SCT in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.
Note: Stratified Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care. The Breslow method is used to handle the ties for the Cox regression models.

Data Source: ADSL, ADTTE **Program Name: f_km.sas** **Output Generated: 20210820T09:05**

Anhang 4-G2.3: Ergänzende Darstellung zu ORR - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-8 (Anhang): Ergebnisse zu ORR nach Prüfarztbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Table 14.2.2.1.2. Summary of Objective Response Rate and Best Overall Response Per Investigator Assessment (Full Analysis Set)

Response Category	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Number of objective responders (CR + PR), n (%)	149 (83)	80 (45)
95% CI for ORR	(76.5, 88.0)	(37.3, 52.3)
Difference in ORR (95% CI)	38.1 (28.1, 47.0)	-
Complete response, n (%)	110 (61)	61 (34)
95% CI for response rate	(53.6, 68.3)	(27.2, 41.5)
Partial response, n (%)	39 (22)	19 (11)
95% CI for response rate	(15.9, 28.4)	(6.5, 16.1)
Stable disease, n (%)	9 (5)	30 (17)
95% CI for response rate	(2.3, 9.3)	(11.6, 23.1)
Progressive disease, n (%)	17 (9)	55 (31)
95% CI for response rate	(5.6, 14.7)	(24.1, 38.0)
Not evaluable, n (%)	1 (1)	0 (0)
95% CI for response rate	(0.0, 3.1)	(0.0, 2.0)
Not done, n (%)	4 (2)	14 (8)
95% CI for response rate	(0.6, 5.6)	(4.3, 12.8)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CR, complete response; ORR, objective response rate; PR, partial response.
Note: 95% CI for rate is from the Clopper-Pearson method, and the 95% CI for the difference in ORR (standard of care arm as reference group) is from Wilson's score method with continuity correction.
Note: Response assessments per Lugano Classification (Cheson et al, 2014).
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.

Data Source: ADSL, ADEFF Program Name: t_orr.sas Output Generated: 20210820T09:03

Tabelle 4-9 (Anhang): Ergebnisse zu ORR nach Zentralbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Table 14.2.2.1.1. Summary of Objective Response Rate and Best Overall Response Per Central Assessment (Full Analysis Set)

Response Category	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Number of objective responders (CR + PR), n (%)	150 (83)	90 (50)
95% CI for ORR	(77.1, 88.5)	(42.7, 57.8)
Difference in ORR (95% CI)	33.1 (23.2, 42.1)	-
Stratified CMH test p-value	<.0001	-
Complete response, n (%)	117 (65)	58 (32)
95% CI for response rate	(57.6, 71.9)	(25.6, 39.8)
Partial response, n (%)	33 (18)	32 (18)
95% CI for response rate	(13.0, 24.8)	(12.6, 24.3)
Stable disease, n (%)	5 (3)	33 (18)
95% CI for response rate	(0.9, 6.4)	(13.0, 24.9)
Progressive disease, n (%)	21 (12)	38 (21)
95% CI for response rate	(7.4, 17.3)	(15.5, 28.0)
Undefined/ no disease, n (%)	0 (0)	4 (2)
95% CI for response rate	(0.0, 2.0)	(0.6, 5.6)
Not evaluable, n (%)	0 (0)	0 (0)
95% CI for response rate	(0.0, 2.0)	(0.0, 2.0)
Not done, n (%)	4 (2)	14 (8)
95% CI for response rate	(0.6, 5.6)	(4.3, 12.8)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CMH, Cochran-Mantel-Haenszel; CR, complete response; ORR, objective response rate; PR, partial response.
Note: 95% CI for rate is from the Clopper-Pearson method, and the 95% CI for the difference in ORR (standard of care arm as reference group) is from Wilson's score method with continuity correction.
Note: Response assessments per Lugano Classification (Cheson et al, 2014).
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.
Note: One-sided p-value from CMH test is presented.

Data Source: ADSL, ADEFF Program Name: t_orr.sas Output Generated: 20210820T09:03

Anhang 4-G2.4: Ergänzende Darstellung zu DOR - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-10 (Anhang): Ergebnisse zu DOR nach Prüfarztbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Table 14.2.3.1.2. Duration of Response Per Investigator Assessment (Full Analysis Set)

	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Number of objective responders (CR + PR)	149	80
Events, n (%)	68 (46)	40 (50)
Censored, n (%)	81 (54)	40 (50)
Hazard ratio (95% CI), stratified	0.769 (0.516, 1.147)	NA
Hazard ratio (95% CI), unstratified	0.839 (0.567, 1.241)	NA
KM median (95% CI) DOR (months)	26.5 (13.1, NE)	7.8 (5.0, NE)
Min, Max DOR (months)	0, 29	0, 32
Events		
Disease progression, n (%)	60 (40)	38 (48)
Death from any cause, n (%)	8 (5)	2 (3)
Censoring reasons		
Response ongoing, n (%)	79 (53)	34 (43)
New lymphoma therapy, n (%)	2 (1)	5 (6)
Lost to follow up, n (%)	0 (0)	1 (1)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CR, complete response; DOR, duration of response; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; PR, partial response.
Note: Percentages are based on number of subjects in the analysis set with objective response.
Note: DOR is defined as the time from the first objective response to disease progression per Lugano Classification (Cheson et al, 2014) or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including stem cell transplant in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: Response assessments per Lugano Classification (Cheson et al, 2014).
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via IXRS.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care therapy. The Breslow method is used to handle the ties for the Cox regression models.

Data Source: ADSL, ADTTE Program Name: t_dor.sas Output Generated: 20210820T09:03

Table 14.2.3.1.2. Duration of Response Per Investigator Assessment (Full Analysis Set)

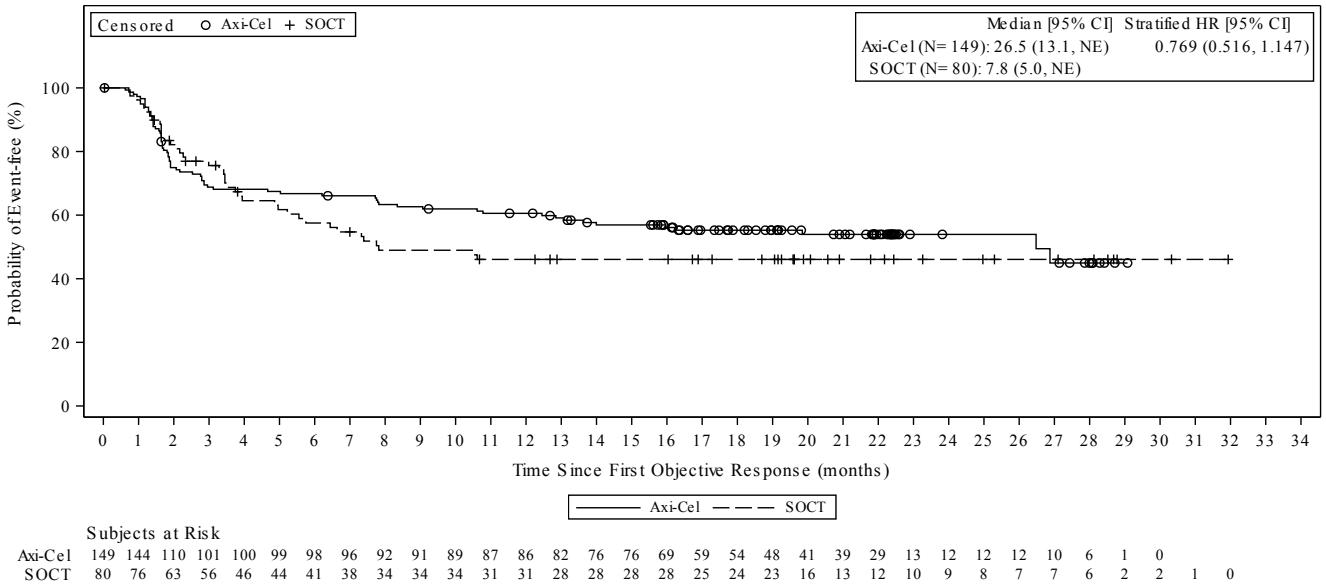
	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Event-free rate, % (95% CI) by KME		
3 month	68.8 (60.6, 75.6)	75.6 (64.4, 83.7)
6 month	66.8 (58.5, 73.7)	57.5 (45.5, 67.8)
9 month	62.6 (54.3, 69.9)	49.0 (37.1, 59.8)
12 month	60.6 (52.2, 67.9)	46.1 (34.4, 57.0)
15 month	56.9 (48.5, 64.5)	46.1 (34.4, 57.0)
18 month	55.3 (46.7, 62.9)	46.1 (34.4, 57.0)
21 month	53.9 (45.2, 61.8)	46.1 (34.4, 57.0)
24 month	53.9 (45.2, 61.8)	46.1 (34.4, 57.0)
27 month	44.9 (31.4, 57.6)	46.1 (34.4, 57.0)
30 month	NE (NE, NE)	46.1 (34.4, 57.0)
Median (95% CI) follow-up time (months) (reverse KM approach)	20.7 (18.8, 21.9)	19.6 (17.3, 21.8)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CR, complete response; DOR, duration of response; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; PR, partial response.
Note: Percentages are based on number of subjects in the analysis set with objective response.
Note: DOR is defined as the time from the first objective response to disease progression per Lugano Classification (Cheson et al, 2014) or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including stem cell transplant in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: Response assessments per Lugano Classification (Cheson et al, 2014).
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via IXRS.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care therapy. The Breslow method is used to handle the ties for the Cox regression models.

Data Source: ADSL, ADTTE Program Name: t_dor.sas Output Generated: 20210820T09:03

Abbildung 5 (Anhang): Kaplan-Meier Plot zu DOR nach Prüfarztbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Figure 14.2.3.1.2. Kaplan-Meier Plot of Duration of Response Per Investigator Assessment (Full Analysis Set)



Data Cutoff Date = 18MAR2021

Abbreviations: Axi-cel, axicabtagene ciloleucel; CI, confidence interval; HR, hazard ratio; NE, not estimable; SCT, stem cell transplant; SOCT, standard of care therapy.

Note: Duration of response is defined as the time from the first objective response to disease progression per Lugano Classification (Cheson et al, 2014) or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including SCT in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.

Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.

Note: Stratified Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care. The Breslow method is used to handle the ties for the Cox regression models.

Data Source: ADSL, ADTTE Program Name: f_km.sas Output Generated: 20210820T09:05

Tabelle 4-11 (Anhang): Ergebnisse zu DOR nach Zentralbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Table 14.2.3.1.1. Duration of Response Per Central Assessment (Full Analysis Set)

	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Number of objective responders (CR + PR)	150	90
Events, n (%)	66 (44)	37 (41)
Censored, n (%)	84 (56)	53 (59)
Stratified log-rank p-value	0.0695	NA
Hazard ratio (95% CI), stratified	0.736 (0.488, 1.108)	NA
Unstratified log-rank p-value	0.1442	NA
Hazard ratio (95% CI), unstratified	0.805 (0.537, 1.205)	NA
KM median (95% CI) DOR (months)	26.9 (13.6, NE)	8.9 (5.7, NE)
Min, Max DOR (months)	0, 29	0, 32
Events		
Disease progression, n (%)	58 (39)	34 (38)
Death from any cause, n (%)	8 (5)	3 (3)
Censoring reasons		
Response ongoing, n (%)	76 (51)	28 (31)
New lymphoma therapy, n (%)	6 (4)	23 (26)
Subsequent stem cell transplant, n (%)	0 (0)	1 (1)
Axicabtagene ciloleucel retreatment, n (%)	2 (1)	0 (0)
Lost to follow up, n (%)	0 (0)	1 (1)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CR, complete response; DOR, duration of response; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; PR, partial response.
Note: Percentages are based on number of subjects in the analysis set with objective response.
Note: DOR is defined as the time from the first objective response to disease progression per Lugano Classification (Cheson et al, 2014) or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including stem cell transplant in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: Response assessments per Lugano Classification (Cheson et al, 2014).
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via IXRS.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care.
Note: One-sided p-value from log rank test is presented.

Data Source: ADSL, ADTTE Program Name: t_dor.sas Output Generated: 20210820T09:03

Table 14.2.3.1.1. Duration of Response Per Central Assessment (Full Analysis Set)

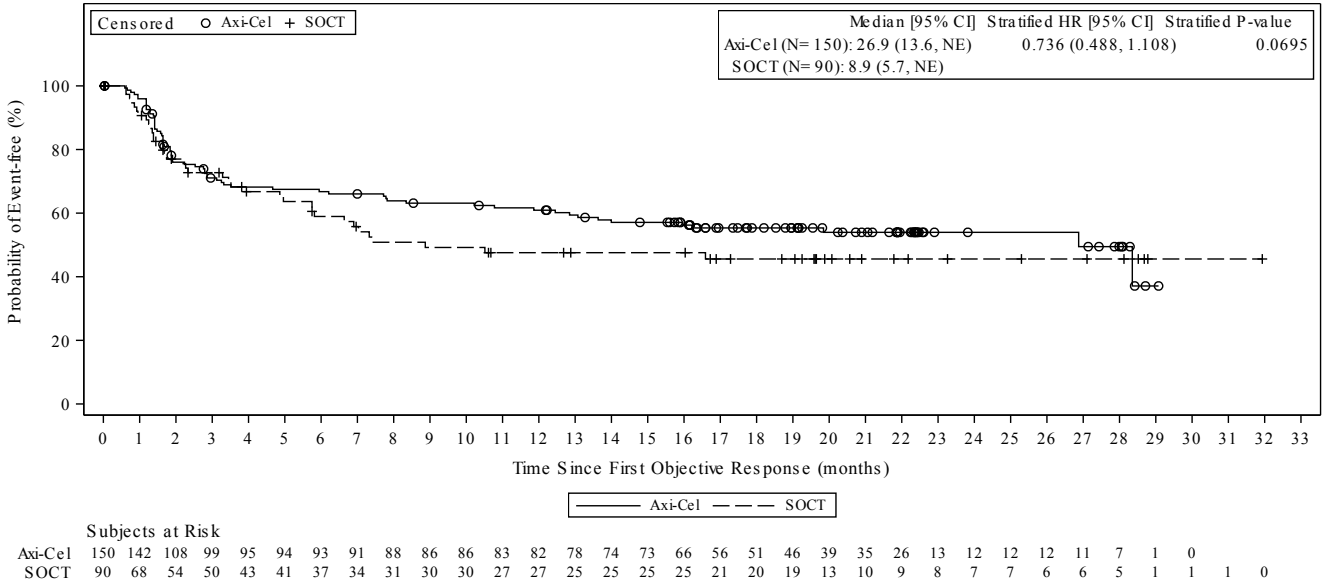
	Axicabtagene Ciloleucel (N = 180)	Standard of Care (N = 179)
Event-free rate, % (95% CI) by KME		
3 month	71.1 (62.9, 77.7)	72.7 (60.9, 81.5)
6 month	66.8 (58.4, 73.8)	58.9 (46.4, 69.5)
9 month	63.1 (54.7, 70.5)	49.2 (36.8, 60.5)
12 month	60.9 (52.4, 68.4)	47.6 (35.2, 58.9)
15 month	57.1 (48.5, 64.8)	47.6 (35.2, 58.9)
18 month	55.3 (46.7, 63.2)	45.6 (33.2, 57.1)
21 month	54.0 (45.1, 62.0)	45.6 (33.2, 57.1)
24 month	54.0 (45.1, 62.0)	45.6 (33.2, 57.1)
27 month	49.5 (37.6, 60.3)	45.6 (33.2, 57.1)
30 month	NE (NE, NE)	45.6 (33.2, 57.1)
Median (95% CI) follow-up time (months) (reverse KM approach)	19.5 (18.2, 21.7)	17.3 (12.7, 19.6)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CR, complete response; DOR, duration of response; KM, Kaplan-Meier; KME, Kaplan-Meier estimation; Max, maximum; Min, minimum; PR, partial response.
Note: Percentages are based on number of subjects in the analysis set with objective response.
Note: DOR is defined as the time from the first objective response to disease progression per Lugano Classification (Cheson et al, 2014) or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including stem cell transplant in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.
Note: Response assessments per Lugano Classification (Cheson et al, 2014).
Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via IXRS.
Note: Stratified (or unstratified) Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care.
Note: One-sided p-value from log rank test is presented.

Data Source: ADSL, ADTTE Program Name: t_dor.sas Output Generated: 20210820T09:03

Abbildung 6 (Anhang): Kaplan-Meier Plot zu DOR nach nach Zentralbeurteilung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Figure 14.2.3.1.1. Kaplan-Meier Plot of Duration of Response Per Central Assessment (Full Analysis Set)



Data Cutoff Date = 18MAR2021

Abbreviations: Axi-cel, axicabtagene ciloleucel; CI, confidence interval; HR, hazard ratio; NE, not estimable; SCT, stem cell transplant; SOCT, standard of care therapy.

Note: Duration of response is defined as the time from the first objective response to disease progression per Lugano Classification (Cheson et al, 2014) or death from any cause. Subjects not meeting the criteria by the analysis data cutoff date will be censored at their last evaluable disease assessment date prior to the data cutoff date or new lymphoma therapy start date (including SCT in the axicabtagene ciloleucel arm or retreatment of axicabtagene ciloleucel), whichever is earlier.

Note: The stratification factors are response to first-line therapy (primary refractory versus relapse ≤ 6 months of first-line therapy versus relapse > 6 and ≤ 12 months of first-line therapy) and second-line age-adjusted International Prognostic Index (0 to 1 versus 2 to 3) as collected via interactive voice/web response system.

Note: Stratified Cox regression models are used to provide the estimated hazard ratio and 2-sided 95% CIs for axicabtagene ciloleucel relative to standard of care. The Breslow method is used to handle the ties for the Cox regression models.

Note: One-sided p-value from log rank test is presented.

Data Source: ADSL, ADTTE Program Name: f_km.sas Output Generated: 20210820T09:05

Anhang 4-G2.5: Ergänzende Darstellung zu Symptomatik anhand EQ-5D VAS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-12 (Anhang): Rücklaufquoten nach Visite zu EQ-5D VAS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

PRO Tables
Protocol KTE-C19-107
Version: 1.0 (10Aug2021)

Table 1.2.2 EQ-5D-5L VAS Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	294 (99.3%)	165 (100.0%)	129 (98.5%)
Completed Study Day 50	Y	289 (97.6%)	163 (98.8%)	126 (96.2%)
Completed Study Day 100	Y	210 (70.9%)	145 (87.9%)	65 (49.6%)
Completed Study Day 150	Y	166 (56.1%)	110 (66.7%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	80 (48.5%)	32 (24.4%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	93 (31.4%)	70 (42.4%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	45 (15.2%)	33 (20.0%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	010111	1 (0.3%)	0 (0.0%)	1 (0.8%)
	011100	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	75 (25.3%)	17 (10.3%)	58 (44.3%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	5 (1.7%)	2 (1.2%)	3 (2.3%)
	111000	49 (16.6%)	35 (21.2%)	14 (10.7%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	2 (0.7%)	1 (0.6%)	1 (0.8%)

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PRO Tables
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Version: 1.0 (10Aug2021)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111100	32 (10.8%)	20 (12.1%)	12 (9.2%)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)
	111110	16 (5.4%)	10 (6.1%)	6 (4.6%)
	111111	96 (32.4%)	73 (44.2%)	23 (17.6%)
Pattern of Completion (Simplified)[a]	[0]Missing Screening	2 (0.7%)	0 (0.0%)	2 (1.5%)
	[1]Complete Screening, missing Study Day 50 (10XXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	85 (28.7%)	20 (12.1%)	65 (49.6%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	54 (18.2%)	38 (23.0%)	16 (12.2%)
	[4]Complete Screening through Day 150 (1111XX)	148 (50.0%)	105 (63.6%)	43 (32.8%)
Pattern of Completion through Month 24 (Simplified)[a]	[00]Missing Screening (0XXXXXXXXX)	2 (0.7%)	0 (0.0%)	2 (1.5%)
	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	85 (28.7%)	20 (12.1%)	65 (49.6%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	54 (18.2%)	38 (23.0%)	16 (12.2%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	36 (12.2%)	22 (13.3%)	14 (10.7%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	10 (6.1%)	6 (4.6%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	11 (3.7%)	7 (4.2%)	4 (3.1%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	23 (7.8%)	20 (12.1%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	8 (4.8%)	5 (3.8%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: QoL, quality of life; VAS, visual analog scale; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Tabelle 4-13 (Anhang): Mittelwert und Veränderung zu Screening zu EQ-5D VAS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Table 3.2.2 EQ-5D-5L VAS Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	294	165	129
	Mean (STDEV)	73.3 (19.3)	72.4 (18.7)	74.4 (20.1)
	Median (Q1, Q3)	80.0 (60.0, 90.0)	75.0 (60.0, 85.0)	80.0 (65.0, 90.0)
	Min, Max	10.0, 100.0	20.0, 100.0	10.0, 100.0
	95% CI	71.0, 75.5	69.5, 75.2	70.9, 77.9
Study Day 50				
Score at Study Day 50	n	289	163	126
	Mean (STDEV)	70.1 (20.2)	70.2 (19.8)	69.9 (20.9)
	Median (Q1, Q3)	75.0 (60.0, 85.0)	75.0 (60.0, 85.0)	70.0 (55.0, 90.0)
	Min, Max	5.0, 100.0	15.0, 100.0	5.0, 100.0
	95% CI	67.7, 72.4	67.1, 73.2	66.2, 73.6
Change from Screening at Study Day 50	n	287	163	124
	Mean (STDEV)	-3.0 (17.9)	-1.9 (18.7)	-4.4 (16.7)
	Median (Q1, Q3)	0.0 (-15.0, 5.0)	0.0 (-10.0, 10.0)	0.0 (-15.0, 5.0)
	Min, Max	-55.0, 60.0	-55.0, 60.0	-50.0, 50.0
	95% CI	-5.1, -0.9	-4.8, 1.0	-7.4, -1.5
Percent Improved, Stable, or Worsened at Study Day 50	Improved	65 (22.6%)	41 (25.2%)	24 (19.4%)
	Stable	121 (42.2%)	69 (42.3%)	52 (41.9%)
	Worsened	101 (35.2%)	53 (32.5%)	48 (38.7%)
Study Day 100				
Score at Study Day 100	n	210	145	65
	Mean (STDEV)	74.8 (18.8)	77.1 (18.2)	69.7 (19.2)
	Median (Q1, Q3)	80.0 (65.0, 90.0)	80.0 (70.0, 90.0)	70.0 (60.0, 85.0)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	10.0, 100.0	10.0, 100.0	20.0, 97.0
	95% CI	72.2, 77.3	74.1, 80.1	64.9, 74.4
Change from Screening at Study Day 100	n	209	145	64
	Mean (STDEV)	0.2 (19.6)	4.0 (18.4)	-8.2 (19.8)
	Median (Q1, Q3)	0.0 (-10.0, 10.0)	5.0 (-5.0, 15.0)	-5.0 (-20.0, 5.0)
	Min, Max	-70.0, 52.0	-70.0, 52.0	-70.0, 35.0
	95% CI	-2.4, 2.9	1.0, 7.0	-13.1, -3.3
Percent Improved, Stable, or Worsened at Study Day 100	Improved	70 (33.5%)	60 (41.4%)	10 (15.6%)
	Stable	84 (40.2%)	58 (40.0%)	26 (40.6%)
	Worsened	55 (26.3%)	27 (18.6%)	28 (43.8%)
Study Day 150				
Score at Study Day 150	n	166	110	56
	Mean (STDEV)	78.8 (17.4)	81.0 (15.3)	74.5 (20.2)
	Median (Q1, Q3)	80.0 (70.0, 90.0)	85.0 (75.0, 90.0)	80.0 (62.5, 90.0)
	Min, Max	6.0, 100.0	20.0, 100.0	6.0, 100.0
	95% CI	76.2, 81.5	78.1, 83.9	69.1, 79.9
Change from Screening at Study Day 150	n	164	110	54
	Mean (STDEV)	5.4 (21.0)	9.1 (19.4)	-2.2 (22.2)
	Median (Q1, Q3)	5.0 (-5.0, 15.0)	5.0 (-5.0, 20.0)	0.0 (-10.0, 10.0)
	Min, Max	-55.0, 56.0	-45.0, 56.0	-55.0, 53.0
	95% CI	2.2, 8.7	5.5, 12.8	-8.2, 3.9
Percent Improved, Stable, or Worsened at Study Day 150	Improved	72 (43.9%)	54 (49.1%)	18 (33.3%)
	Stable	56 (34.1%)	38 (34.5%)	18 (33.3%)
	Worsened	36 (22.0%)	18 (16.4%)	18 (33.3%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	81.1 (15.3)	81.3 (14.0)	80.8 (17.9)
	Median (Q1, Q3)	85.0 (75.0, 90.0)	85.0 (75.0, 90.0)	85.0 (77.5, 92.5)
	Min, Max	10.0, 100.0	40.0, 100.0	10.0, 100.0
	95% CI	78.5, 83.8	78.3, 84.2	75.1, 86.6
Change from Screening at Study Month 9	n	127	88	39
	Mean (STDEV)	9.3 (19.8)	11.4 (19.9)	4.4 (19.0)
	Median (Q1, Q3)	10.0 (0.0, 20.0)	10.0 (0.0, 20.0)	8.0 (0.0, 15.0)
	Min, Max	-50.0, 60.0	-45.0, 60.0	-50.0, 35.0
	95% CI	5.8, 12.7	7.2, 15.6	-1.8, 10.6
Percent Improved, Stable, or Worsened at Study Month 9	Improved	73 (57.5%)	53 (60.2%)	20 (51.3%)
	Stable	38 (29.9%)	25 (28.4%)	13 (33.3%)
	Worsened	16 (12.6%)	10 (11.4%)	6 (15.4%)
Study Month 12				
Score at Study Month 12	n	112	80	32
	Mean (STDEV)	81.2 (17.5)	80.7 (18.3)	82.5 (15.6)
	Median (Q1, Q3)	89.5 (75.0, 93.5)	85.0 (75.0, 93.5)	90.0 (77.5, 92.5)
	Min, Max	8.0, 100.0	8.0, 100.0	50.0, 100.0
	95% CI	77.9, 84.5	76.6, 84.8	76.9, 88.1
Change from Screening at Study Month 12	n	111	80	31
	Mean (STDEV)	9.1 (19.3)	10.1 (19.9)	6.6 (17.8)
	Median (Q1, Q3)	10.0 (0.0, 20.0)	10.0 (0.0, 20.0)	5.0 (-5.0, 15.0)
	Min, Max	-72.0, 60.0	-72.0, 60.0	-35.0, 40.0
	95% CI	5.5, 12.8	5.7, 14.6	0.0, 13.1
Percent Improved, Stable, or Worsened at Study Month 12	Improved	62 (55.9%)	47 (58.8%)	15 (48.4%)
	Stable	33 (29.7%)	24 (30.0%)	9 (29.0%)
	Worsened	16 (14.4%)	9 (11.3%)	7 (22.6%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	82.1 (17.5)	80.5 (19.0)	86.3 (12.5)
	Median (Q1, Q3)	90.0 (75.0, 95.0)	85.0 (75.0, 95.0)	90.0 (85.0, 95.0)
	Min, Max	20.0, 100.0	20.0, 100.0	50.0, 99.0
	95% CI	78.5, 85.7	75.9, 85.1	81.2, 91.3
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	10.0 (18.9)	10.7 (20.7)	8.2 (13.7)
	Median (Q1, Q3)	10.0 (0.0, 20.0)	10.0 (0.0, 20.0)	9.0 (-5.0, 15.0)
	Min, Max	-45.0, 60.0	-45.0, 60.0	-15.0, 40.0
	95% CI	6.1, 13.9	5.7, 15.8	2.6, 13.7
Percent Improved, Stable, or Worsened at Study Month 15	Improved	52 (55.9%)	38 (56.7%)	14 (53.8%)
	Stable	29 (31.2%)	20 (29.9%)	9 (34.6%)
	Worsened	12 (12.9%)	9 (13.4%)	3 (11.5%)
Study Month 18				
Score at Study Month 18	n	93	70	23
	Mean (STDEV)	85.1 (11.8)	85.2 (12.3)	84.6 (10.6)
	Median (Q1, Q3)	86.0 (80.0, 95.0)	90.0 (80.0, 95.0)	80.0 (80.0, 95.0)
	Min, Max	40.0, 100.0	40.0, 100.0	55.0, 100.0
	95% CI	82.6, 87.5	82.3, 88.2	80.0, 89.2
Change from Screening at Study Month 18	n	93	70	23
	Mean (STDEV)	13.7 (16.4)	15.1 (17.1)	9.3 (13.6)
	Median (Q1, Q3)	13.0 (0.0, 20.0)	11.5 (2.0, 22.0)	15.0 (-5.0, 20.0)
	Min, Max	-15.0, 70.0	-15.0, 70.0	-15.0, 30.0
	95% CI	10.3, 17.1	11.0, 19.2	3.4, 15.2
Percent Improved, Stable, or Worsened at Study Month 18	Improved	58 (62.4%)	45 (64.3%)	13 (56.5%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	29 (31.2%)	22 (31.4%)	7 (30.4%)
	Worsened	6 (6.5%)	3 (4.3%)	3 (13.0%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	86.1 (13.3)	85.8 (14.6)	86.7 (10.0)
	Median (Q1, Q3)	90.0 (80.0, 95.0)	90.0 (80.0, 95.0)	90.0 (79.5, 95.0)
	Min, Max	40.0, 100.0	40.0, 100.0	70.0, 99.0
	95% CI	82.8, 89.3	81.4, 90.2	82.0, 91.3
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	12.8 (16.3)	14.0 (17.2)	10.1 (14.3)
	Median (Q1, Q3)	10.0 (3.0, 20.0)	12.0 (2.0, 20.0)	9.5 (4.0, 17.5)
	Min, Max	-25.0, 60.0	-25.0, 60.0	-20.0, 45.0
	95% CI	8.7, 16.8	8.8, 19.1	3.4, 16.7
Percent Improved, Stable, or Worsened at Study Month 21	Improved	41 (63.1%)	29 (64.4%)	12 (60.0%)
	Stable	19 (29.2%)	13 (28.9%)	6 (30.0%)
	Worsened	5 (7.7%)	3 (6.7%)	2 (10.0%)
Study Month 24				
Score at Study Month 24	n	45	33	12
	Mean (STDEV)	85.2 (14.9)	82.8 (16.4)	91.9 (5.5)
	Median (Q1, Q3)	90.0 (80.0, 95.0)	85.0 (80.0, 95.0)	92.5 (90.0, 96.0)
	Min, Max	20.0, 100.0	20.0, 100.0	80.0, 99.0
	95% CI	80.8, 89.7	77.0, 88.6	88.4, 95.4
Change from Screening at Study Month 24	n	45	33	12
	Mean (STDEV)	11.2 (17.8)	10.9 (18.8)	12.2 (15.3)
	Median (Q1, Q3)	15.0 (0.0, 20.0)	15.0 (0.0, 20.0)	13.5 (1.5, 23.0)
	Min, Max	-45.0, 50.0	-45.0, 50.0	-15.0, 40.0

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	5.9, 16.6	4.2, 17.5	2.4, 21.9
Percent Improved, Stable, or Worsened at Study Month 24	Improved	28 (62.2%)	21 (63.6%)	7 (58.3%)
	Stable	12 (26.7%)	8 (24.2%)	4 (33.3%)
	Worsened	5 (11.1%)	4 (12.1%)	1 (8.3%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation; VAS, visual analog scale.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

Tabelle 4-14 (Anhang): Ergebnisse der MMRM Analyse zu EQ-5D VAS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

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Table 4.2.2 EQ-5D-5L VAS Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	998		
	Number of Observations Used	991		
	Number of Observations Not Used	7		
	Model Fit Statistics			
	-2 Res Log Likelihood	8056.7		
	AIC (Smaller is Better)	8098.7		
	AICC (Smaller is Better)	8099.7		
	BIC (Smaller is Better)	8176.2		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-3.0 (-6.7, 0.7)	-5.4 (-9.3, -1.4)
	Difference in Mean Change from Screening (95% CI)		2.4 (-1.8, 6.6)	nd
	Study Day 100 Mean Change from Screening (95% CI)		3.3 (-0.5, 7.2)	-10.3 (-15.2, -5.5)
	Difference in Mean Change from Screening (95% CI)		13.7 (8.5, 18.8)	nd
	Study Day 150 Mean Change from Screening (95% CI)		7.3 (3.1, 11.5)	-3.9 (-9.2, 1.4)
	Difference in Mean Change from Screening (95% CI)		11.3 (5.4, 17.1)	nd
	Study Month 9 Mean Change from Screening (95% CI)		8.3 (4.1, 12.6)	4.5 (-1.1, 10.1)
	Difference in Mean Change from Screening (95% CI)		3.8 (-2.3, 10.0)	nd
	Study Month 12 Mean Change from Screening (95% CI)		7.2 (2.9, 11.6)	7.0 (1.1, 12.9)
	Difference in Mean Change from Screening (95% CI)		0.3 (-6.3, 6.8)	nd
	Study Month 15 Mean Change from Screening (95% CI)		6.3 (1.7, 10.9)	9.7 (3.4, 16.0)
	Difference in Mean Change from Screening (95% CI)		-3.4 (-10.4, 3.6)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	998		
	Number of Observations Used	991		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	7		
	Model Fit Statistics			
	-2 Res Log Likelihood	8042.3		
	AIC (Smaller is Better)	8084.3		
	AICC (Smaller is Better)	8085.3		
	BIC (Smaller is Better)	8161.8		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-4.0 (-8.9, 0.9)	-5.9 (-10.9, -0.9)
	Difference in Mean Change from Screening (95% CI)		1.9 (-2.8, 6.5)	nd
	Study Day 100 Mean Change from Screening (95% CI)		2.3 (-2.7, 7.3)	-10.9 (-16.3, -5.6)
	Difference in Mean Change from Screening (95% CI)		13.2 (7.9, 18.6)	nd
	Study Day 150 Mean Change from Screening (95% CI)		6.2 (0.9, 11.6)	-4.5 (-10.4, 1.3)
	Difference in Mean Change from Screening (95% CI)		10.8 (4.7, 16.8)	nd
	Study Month 9 Mean Change from Screening (95% CI)		7.2 (1.8, 12.6)	3.8 (-2.3, 9.9)
	Difference in Mean Change from Screening (95% CI)		3.4 (-3.0, 9.7)	nd
	Study Month 12 Mean Change from Screening (95% CI)		6.1 (0.6, 11.6)	6.3 (-0.1, 12.7)
	Difference in Mean Change from Screening (95% CI)		-0.2 (-6.9, 6.5)	nd
	Study Month 15 Mean Change from Screening (95% CI)		5.2 (-0.5, 10.8)	9.1 (2.3, 15.9)
	Difference in Mean Change from Screening (95% CI)		-3.9 (-11.1, 3.3)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	998		
	Number of Observations Used	991		
	Number of Observations Not Used	7		
	Model Fit Statistics			
	-2 Res Log Likelihood	7945.5		
	AIC (Smaller is Better)	7987.5		
	AICC (Smaller is Better)	7988.5		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8065		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-7.1 (-14.6, 0.5)	-6.5 (-13.8, 0.7)
	Difference in Mean Change from Screening (95% CI)		-0.5 (-5.1, 4.1)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-0.7 (-8.4, 6.9)	-11.7 (-19.2, -4.1)
	Difference in Mean Change from Screening (95% CI)		10.9 (5.4, 16.4)	nd
	Study Day 150 Mean Change from Screening (95% CI)		3.1 (-4.7, 11.0)	-5.2 (-13.1, 2.6)
	Difference in Mean Change from Screening (95% CI)		8.4 (2.3, 14.5)	nd
	Study Month 9 Mean Change from Screening (95% CI)		4.0 (-3.8, 11.9)	3.0 (-5.0, 11.0)
	Difference in Mean Change from Screening (95% CI)		1.0 (-5.3, 7.3)	nd
	Study Month 12 Mean Change from Screening (95% CI)		2.9 (-5.0, 10.8)	5.5 (-2.9, 13.9)
	Difference in Mean Change from Screening (95% CI)		-2.6 (-9.4, 4.2)	nd
	Study Month 15 Mean Change from Screening (95% CI)		2.0 (-6.1, 10.0)	8.2 (-0.4, 16.9)
	Difference in Mean Change from Screening (95% CI)		-6.3 (-13.5, 1.0)	nd

Data cutoff date = 18MAR2021

Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; nd, not displayed; VAS, visual analog scale.

Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.

[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).

Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Abbildung 7 (Anhang): Verlaufskurven zu EQ-5D VAS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

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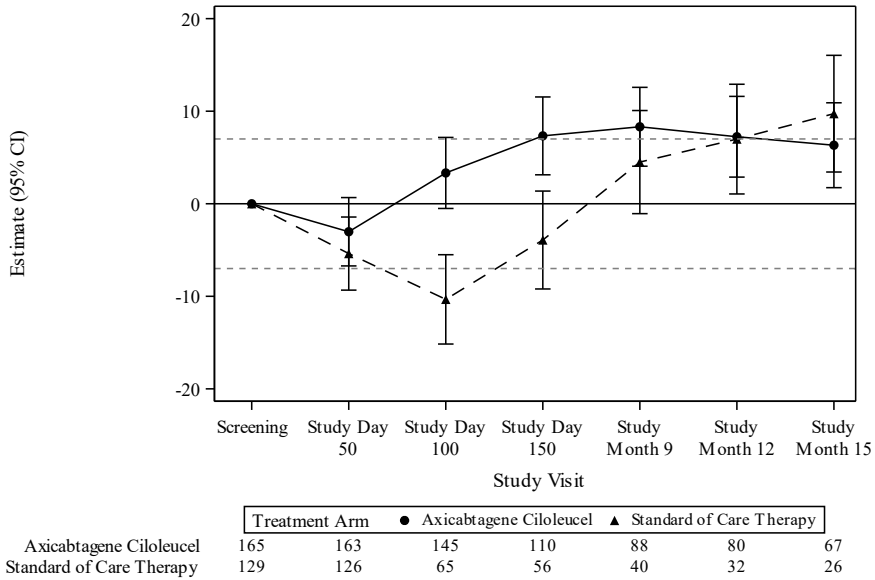
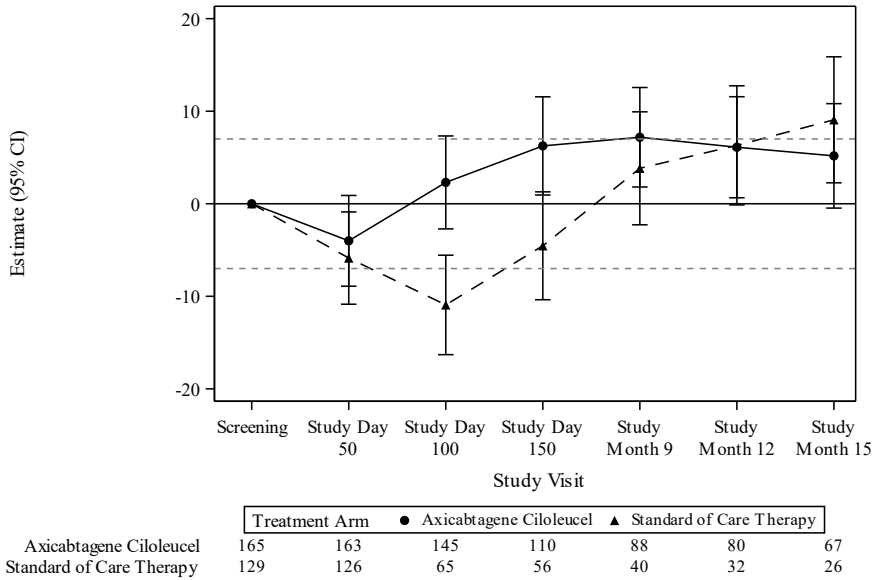
Figure 4.2.2.1 EQ-5D-5L VAS Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Axicabtagene Ciloleucel	165	163	145	110	88	80	67
Standard of Care Therapy	129	126	65	56	40	32	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; QoL, quality of life; VAS, visual analog scale.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.2.2. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Figure 4.2.2.2 EQ-5D-5L VAS Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; QoL, quality of life; VAS, visual analog scale.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.2.2. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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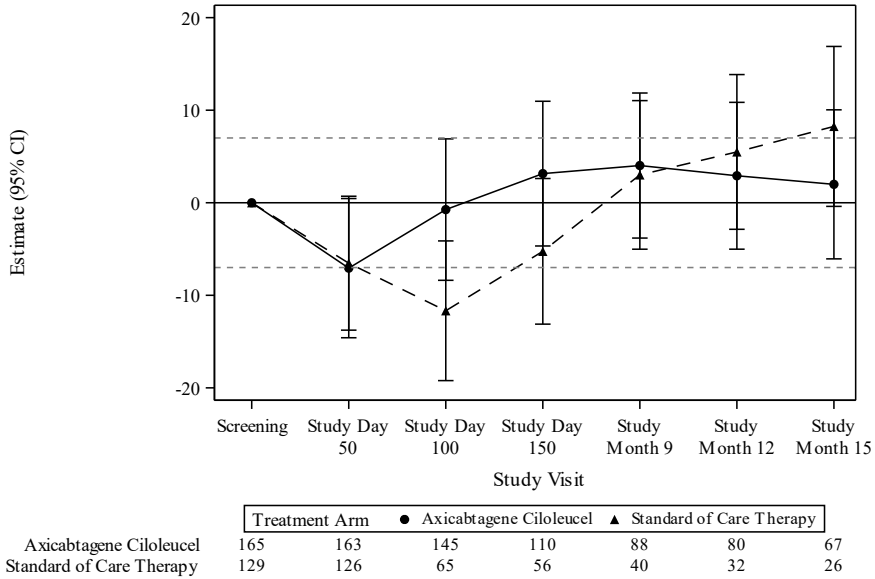
Figure 4.2.2.3 EQ-5D-5L VAS Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



	Screening	Study Day 50	Study Day 100	Study Day 150	Study Month 9	Study Month 12	Study Month 15
Axicabtagene Ciloleucel	165	163	145	110	88	80	67
Standard of Care Therapy	129	126	65	56	40	32	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; QoL, quality of life; VAS, visual analog scale.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.2.2. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Anhang 4-G2.6: Ergänzende Darstellung zu Symptomatik anhand EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-15 (Anhang): Rücklaufquoten nach Visite zu EORTC QLQ-C30 (Symptomatik) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Table 1.1.07 EORTC QLQ-C30 Fatigue Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	289 (97.6%)	163 (98.8%)	126 (96.2%)
Completed Study Day 100	Y	210 (70.9%)	146 (88.5%)	64 (48.9%)
Completed Study Day 150	Y	165 (55.7%)	109 (66.1%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	101000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	76 (25.7%)	17 (10.3%)	59 (45.0%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	5 (1.7%)	1 (0.6%)	4 (3.1%)
	111000	48 (16.2%)	35 (21.2%)	13 (9.9%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	3 (1.0%)	2 (1.2%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	96 (32.4%)	72 (43.6%)	24 (18.3%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	54 (18.2%)	39 (23.6%)	15 (11.5%)
	[4]Complete Screening through Day 150 (1111XX)	149 (50.3%)	105 (63.6%)	44 (33.6%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	54 (18.2%)	39 (23.6%)	15 (11.5%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	12 (4.1%)	8 (4.8%)	4 (3.1%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	22 (7.4%)	19 (11.5%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

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Version: 1.0 (10Aug2021)

Table 1.1.08 EORTC QLQ-C30 Nausea and Vomiting Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	289 (97.6%)	163 (98.8%)	126 (96.2%)
Completed Study Day 100	Y	210 (70.9%)	146 (88.5%)	64 (48.9%)
Completed Study Day 150	Y	165 (55.7%)	109 (66.1%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	101000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	76 (25.7%)	17 (10.3%)	59 (45.0%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	5 (1.7%)	1 (0.6%)	4 (3.1%)
	111000	48 (16.2%)	35 (21.2%)	13 (9.9%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	3 (1.0%)	2 (1.2%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	96 (32.4%)	72 (43.6%)	24 (18.3%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	54 (18.2%)	39 (23.6%)	15 (11.5%)
	[4]Complete Screening through Day 150 (1111XX)	149 (50.3%)	105 (63.6%)	44 (33.6%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	54 (18.2%)	39 (23.6%)	15 (11.5%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	12 (4.1%)	8 (4.8%)	4 (3.1%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	22 (7.4%)	19 (11.5%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Table 1.1.09 EORTC QLQ-C30 Pain Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	289 (97.6%)	163 (98.8%)	126 (96.2%)
Completed Study Day 100	Y	210 (70.9%)	146 (88.5%)	64 (48.9%)
Completed Study Day 150	Y	166 (56.1%)	110 (66.7%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	101000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	76 (25.7%)	17 (10.3%)	59 (45.0%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	5 (1.7%)	1 (0.6%)	4 (3.1%)
	111000	48 (16.2%)	35 (21.2%)	13 (9.9%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	97 (32.8%)	73 (44.2%)	24 (18.3%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	53 (17.9%)	38 (23.0%)	15 (11.5%)
	[4]Complete Screening through Day 150 (1111XX)	150 (50.7%)	106 (64.2%)	44 (33.6%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	53 (17.9%)	38 (23.0%)	15 (11.5%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	12 (4.1%)	8 (4.8%)	4 (3.1%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	23 (7.8%)	20 (12.1%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

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Table 1.1.10 EORTC QLQ-C30 Dyspnea Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	288 (97.3%)	163 (98.8%)	125 (95.4%)
Completed Study Day 100	Y	209 (70.6%)	145 (87.9%)	64 (48.9%)
Completed Study Day 150	Y	165 (55.7%)	109 (66.1%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	100000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	76 (25.7%)	18 (10.9%)	58 (44.3%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	5 (1.7%)	1 (0.6%)	4 (3.1%)
	111000	47 (15.9%)	34 (20.6%)	13 (9.9%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	3 (1.0%)	2 (1.2%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	96 (32.4%)	72 (43.6%)	24 (18.3%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	86 (29.1%)	20 (12.1%)	66 (50.4%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	53 (17.9%)	38 (23.0%)	15 (11.5%)
	[4]Complete Screening through Day 150 (1111XX)	149 (50.3%)	105 (63.6%)	44 (33.6%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	86 (29.1%)	20 (12.1%)	66 (50.4%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	53 (17.9%)	38 (23.0%)	15 (11.5%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	12 (4.1%)	8 (4.8%)	4 (3.1%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	22 (7.4%)	19 (11.5%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Table 1.1.11 EORTC QLQ-C30 Insomnia Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	288 (97.3%)	163 (98.8%)	125 (95.4%)
Completed Study Day 100	Y	210 (70.9%)	146 (88.5%)	64 (48.9%)
Completed Study Day 150	Y	165 (55.7%)	109 (66.1%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	101000	2 (0.7%)	0 (0.0%)	2 (1.5%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	76 (25.7%)	17 (10.3%)	59 (45.0%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	5 (1.7%)	1 (0.6%)	4 (3.1%)
	111000	47 (15.9%)	35 (21.2%)	12 (9.2%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	3 (1.0%)	2 (1.2%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	96 (32.4%)	72 (43.6%)	24 (18.3%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	53 (17.9%)	39 (23.6%)	14 (10.7%)
	[4]Complete Screening through Day 150 (1111XX)	149 (50.3%)	105 (63.6%)	44 (33.6%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	53 (17.9%)	39 (23.6%)	14 (10.7%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	12 (4.1%)	8 (4.8%)	4 (3.1%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	22 (7.4%)	19 (11.5%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

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Table 1.1.12 EORTC QLQ-C30 Appetite Loss Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	289 (97.6%)	163 (98.8%)	126 (96.2%)
Completed Study Day 100	Y	209 (70.6%)	146 (88.5%)	63 (48.1%)
Completed Study Day 150	Y	165 (55.7%)	109 (66.1%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	64 (21.6%)	44 (26.7%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	101000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	76 (25.7%)	17 (10.3%)	59 (45.0%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	6 (2.0%)	1 (0.6%)	5 (3.8%)
	111000	48 (16.2%)	35 (21.2%)	13 (9.9%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	3 (1.0%)	2 (1.2%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	95 (32.1%)	72 (43.6%)	23 (17.6%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	54 (18.2%)	39 (23.6%)	15 (11.5%)
	[4]Complete Screening through Day 150 (1111XX)	148 (50.0%)	105 (63.6%)	43 (32.8%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	54 (18.2%)	39 (23.6%)	15 (11.5%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	12 (4.1%)	8 (4.8%)	4 (3.1%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	23 (7.8%)	20 (12.1%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	11 (3.7%)	6 (3.6%)	5 (3.8%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Table 1.1.13 EORTC QLQ-C30 Constipation Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	289 (97.6%)	163 (98.8%)	126 (96.2%)
Completed Study Day 100	Y	209 (70.6%)	146 (88.5%)	63 (48.1%)
Completed Study Day 150	Y	165 (55.7%)	109 (66.1%)	56 (42.7%)
Completed Month 9	Y	127 (42.9%)	87 (52.7%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	101000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	77 (26.0%)	17 (10.3%)	60 (45.8%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	5 (1.7%)	1 (0.6%)	4 (3.1%)
	111000	47 (15.9%)	35 (21.2%)	12 (9.2%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	3 (1.0%)	2 (1.2%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)
	111101	5 (1.7%)	3 (1.8%)	2 (1.5%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	95 (32.1%)	71 (43.0%)	24 (18.3%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	53 (17.9%)	39 (23.6%)	14 (10.7%)
	[4]Complete Screening through Day 150 (1111XX)	149 (50.3%)	105 (63.6%)	44 (33.6%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	53 (17.9%)	39 (23.6%)	14 (10.7%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	38 (12.8%)	23 (13.9%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	19 (6.4%)	13 (7.9%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	12 (4.1%)	8 (4.8%)	4 (3.1%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	22 (7.4%)	19 (11.5%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

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Table 1.1.14 EORTC QLQ-C30 Diarrhea Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	287 (97.0%)	163 (98.8%)	124 (94.7%)
Completed Study Day 100	Y	209 (70.6%)	146 (88.5%)	63 (48.1%)
Completed Study Day 150	Y	166 (56.1%)	110 (66.7%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	101000	3 (1.0%)	0 (0.0%)	3 (2.3%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	76 (25.7%)	17 (10.3%)	59 (45.0%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	6 (2.0%)	1 (0.6%)	5 (3.8%)
	111000	46 (15.5%)	35 (21.2%)	11 (8.4%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	96 (32.4%)	73 (44.2%)	23 (17.6%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	9 (3.0%)	2 (1.2%)	7 (5.3%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	51 (17.2%)	38 (23.0%)	13 (9.9%)
	[4]Complete Screening through Day 150 (1111XX)	149 (50.3%)	106 (64.2%)	43 (32.8%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	9 (3.0%)	2 (1.2%)	7 (5.3%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	51 (17.2%)	38 (23.0%)	13 (9.9%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	11 (3.7%)	8 (4.8%)	3 (2.3%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	23 (7.8%)	20 (12.1%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Tabelle 4-16 (Anhang): Mittelwert und Veränderung zu Screening zu EORTC QLQ-C30 (Symptomatik) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Table 3.1.07 EORTC QLQ-C30 Fatigue Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	29.7 (23.5)	31.6 (23.9)	27.4 (22.9)
	Median (Q1, Q3)	22.2 (11.1, 33.3)	33.3 (11.1, 44.4)	22.2 (11.1, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	27.1, 32.4	27.9, 35.3	23.4, 31.4
Study Day 50				
Score at Study Day 50	n	289	163	126
	Mean (STDEV)	42.3 (26.1)	43.9 (27.9)	40.2 (23.6)
	Median (Q1, Q3)	33.3 (22.2, 66.7)	33.3 (33.3, 66.7)	33.3 (22.2, 55.6)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	39.2, 45.3	39.6, 48.2	36.0, 44.3
Change from Screening at Study Day 50	n	289	163	126
	Mean (STDEV)	12.2 (25.5)	12.2 (27.0)	12.2 (23.5)
	Median (Q1, Q3)	11.1 (0.0, 33.3)	11.1 (-11.1, 33.3)	11.1 (0.0, 22.2)
	Min, Max	-66.7, 88.9	-55.6, 88.9	-66.7, 66.7
	95% CI	9.2, 15.1	8.0, 16.3	8.1, 16.4
Percent Improved, Stable, or Worsened at Study Day 50	Improved	66 (22.8%)	43 (26.4%)	23 (18.3%)
	Stable	57 (19.7%)	31 (19.0%)	26 (20.6%)
	Worsened	166 (57.4%)	89 (54.6%)	77 (61.1%)
Study Day 100				
Score at Study Day 100	n	210	146	64
	Mean (STDEV)	32.9 (27.4)	29.1 (25.6)	41.5 (29.4)
	Median (Q1, Q3)	33.3 (11.1, 44.4)	33.3 (0.0, 44.4)	33.3 (22.2, 66.7)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	29.2, 36.6	25.0, 33.3	34.1, 48.8
Change from Screening at Study Day 100	n	210	146	64
	Mean (STDEV)	3.9 (24.4)	-2.5 (21.0)	18.6 (25.6)
	Median (Q1, Q3)	0.0 (-11.1, 22.2)	0.0 (-11.1, 11.1)	16.7 (0.0, 33.3)
	Min, Max	-66.7, 77.8	-55.6, 66.7	-66.7, 77.8
	95% CI	0.6, 7.3	-5.9, 1.0	12.2, 25.0
Percent Improved, Stable, or Worsened at Study Day 100	Improved	65 (31.0%)	57 (39.0%)	8 (12.5%)
	Stable	61 (29.0%)	48 (32.9%)	13 (20.3%)
	Worsened	84 (40.0%)	41 (28.1%)	43 (67.2%)
Study Day 150				
Score at Study Day 150	n	165	109	56
	Mean (STDEV)	27.7 (23.4)	24.6 (22.9)	33.9 (23.3)
	Median (Q1, Q3)	33.3 (11.1, 33.3)	22.2 (0.0, 33.3)	33.3 (22.2, 44.4)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	24.1, 31.3	20.2, 28.9	27.7, 40.2
Change from Screening at Study Day 150	n	165	109	56
	Mean (STDEV)	-1.7 (24.7)	-7.8 (22.9)	10.3 (23.8)
	Median (Q1, Q3)	0.0 (-11.1, 11.1)	-11.1 (-22.2, 0.0)	11.1 (0.0, 22.2)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-66.7, 66.7
	95% CI	-5.5, 2.1	-12.2, -3.5	4.0, 16.7
Percent Improved, Stable, or Worsened at Study Day 150	Improved	68 (41.2%)	58 (53.2%)	10 (17.9%)
	Stable	47 (28.5%)	30 (27.5%)	17 (30.4%)
	Worsened	50 (30.3%)	21 (19.3%)	29 (51.8%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	23.1 (21.9)	21.3 (22.2)	26.9 (21.2)
	Median (Q1, Q3)	22.2 (0.0, 33.3)	22.2 (0.0, 33.3)	22.2 (11.1, 38.9)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 77.8
	95% CI	19.3, 26.9	16.6, 26.0	20.2, 33.7
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	-8.0 (27.0)	-12.2 (23.6)	1.4 (31.4)
	Median (Q1, Q3)	-11.1 (-22.2, 0.0)	-11.1 (-22.2, 0.0)	0.0 (-22.2, 22.2)
	Min, Max	-66.7, 88.9	-66.7, 88.9	-66.7, 77.8
	95% CI	-12.7, -3.3	-17.3, -7.2	-8.7, 11.4
Percent Improved, Stable, or Worsened at Study Month 9	Improved	66 (51.6%)	51 (58.0%)	15 (37.5%)
	Stable	33 (25.8%)	23 (26.1%)	10 (25.0%)
	Worsened	29 (22.7%)	14 (15.9%)	15 (37.5%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	22.3 (23.6)	23.3 (24.4)	19.9 (21.8)
	Median (Q1, Q3)	22.2 (0.0, 33.3)	22.2 (0.0, 33.3)	11.1 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 88.9
	95% CI	17.9, 26.7	17.9, 28.8	12.1, 27.6
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	-9.6 (23.9)	-11.4 (21.3)	-5.4 (29.0)
	Median (Q1, Q3)	-11.1 (-22.2, 0.0)	-11.1 (-22.2, 0.0)	0.0 (-22.2, 11.1)
	Min, Max	-77.8, 66.7	-66.7, 33.3	-77.8, 66.7
	95% CI	-14.1, -5.2	-16.2, -6.6	-15.7, 4.9
Percent Improved, Stable, or Worsened at Study Month 12	Improved	63 (56.3%)	47 (59.5%)	16 (48.5%)
	Stable	25 (22.3%)	20 (25.3%)	5 (15.2%)
	Worsened	24 (21.4%)	12 (15.2%)	12 (36.4%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	21.6 (23.6)	23.2 (25.2)	17.5 (18.9)
	Median (Q1, Q3)	11.1 (0.0, 33.3)	11.1 (0.0, 33.3)	16.7 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	16.8, 26.5	17.1, 29.4	9.9, 25.2
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	-10.3 (23.9)	-12.3 (25.7)	-5.1 (17.8)
	Median (Q1, Q3)	-11.1 (-22.2, 0.0)	-11.1 (-22.2, 0.0)	0.0 (-11.1, 11.1)
	Min, Max	-66.7, 44.4	-66.7, 44.4	-55.6, 22.2
	95% CI	-15.2, -5.4	-18.5, -6.0	-12.3, 2.1
Percent Improved, Stable, or Worsened at Study Month 15	Improved	52 (55.9%)	41 (61.2%)	11 (42.3%)
	Stable	22 (23.7%)	14 (20.9%)	8 (30.8%)
	Worsened	19 (20.4%)	12 (17.9%)	7 (26.9%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	20.3 (21.5)	20.3 (23.4)	20.3 (14.5)
	Median (Q1, Q3)	22.2 (0.0, 33.3)	11.1 (0.0, 33.3)	22.2 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 44.4
	95% CI	15.9, 24.7	14.8, 25.9	14.0, 26.5
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	-11.1 (22.5)	-13.8 (22.7)	-2.9 (20.2)
	Median (Q1, Q3)	-11.1 (-22.2, 0.0)	-11.1 (-33.3, 0.0)	0.0 (-11.1, 11.1)
	Min, Max	-77.8, 33.3	-77.8, 33.3	-55.6, 33.3
	95% CI	-15.7, -6.5	-19.2, -8.4	-11.6, 5.8
Percent Improved, Stable, or Worsened at Study Month 18	Improved	50 (53.2%)	40 (56.3%)	10 (43.5%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	24 (25.5%)	20 (28.2%)	4 (17.4%)
	Worsened	20 (21.3%)	11 (15.5%)	9 (39.1%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	17.8 (20.2)	18.3 (22.4)	16.7 (14.6)
	Median (Q1, Q3)	11.1 (0.0, 33.3)	11.1 (0.0, 33.3)	22.2 (0.0, 27.8)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 44.4
	95% CI	12.8, 22.8	11.6, 25.0	9.8, 23.5
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	-14.0 (24.2)	-16.8 (24.1)	-7.8 (23.9)
	Median (Q1, Q3)	-11.1 (-22.2, 0.0)	-11.1 (-22.2, 0.0)	0.0 (-27.8, 11.1)
	Min, Max	-100.0, 33.3	-100.0, 33.3	-55.6, 33.3
	95% CI	-20.0, -8.0	-24.0, -9.5	-19.0, 3.4
Percent Improved, Stable, or Worsened at Study Month 21	Improved	36 (55.4%)	27 (60.0%)	9 (45.0%)
	Stable	19 (29.2%)	14 (31.1%)	5 (25.0%)
	Worsened	10 (15.4%)	4 (8.9%)	6 (30.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	19.4 (21.6)	21.9 (23.4)	13.0 (14.9)
	Median (Q1, Q3)	11.1 (0.0, 33.3)	16.7 (0.0, 33.3)	5.6 (0.0, 27.8)
	Min, Max	0.0, 77.8	0.0, 77.8	0.0, 33.3
	95% CI	12.9, 26.0	13.5, 30.3	3.5, 22.4
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	-12.6 (23.3)	-14.2 (25.6)	-8.3 (15.8)
	Median (Q1, Q3)	-11.1 (-22.2, 0.0)	-11.1 (-22.2, 0.0)	-5.6 (-22.2, 5.6)
	Min, Max	-88.9, 33.3	-88.9, 33.3	-33.3, 11.1

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	-19.7, -5.5	-23.5, -5.0	-18.4, 1.7
Percent Improved, Stable, or Worsened at Study Month 24	Improved	26 (59.1%)	20 (62.5%)	6 (50.0%)
	Stable	8 (18.2%)	5 (15.6%)	3 (25.0%)
	Worsened	10 (22.7%)	7 (21.9%)	3 (25.0%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

PRO Tables
Protocol KTE-C19-107
Version: 1.0 (10Aug2021)

Table 3.1.08 EORTC QLQ-C30 Nausea and Vomiting Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	4.8 (12.4)	5.8 (13.0)	3.6 (11.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 83.3	0.0, 66.7	0.0, 83.3
	95% CI	3.4, 6.2	3.8, 7.8	1.5, 5.6
Study Day 50				
Score at Study Day 50	n	289	163	126
	Mean (STDEV)	8.4 (15.7)	7.1 (14.5)	10.2 (17.0)
	Median (Q1, Q3)	0.0 (0.0, 16.7)	0.0 (0.0, 16.7)	0.0 (0.0, 16.7)
	Min, Max	0.0, 100.0	0.0, 83.3	0.0, 100.0
	95% CI	6.6, 10.2	4.8, 9.3	7.2, 13.2
Change from Screening at Study Day 50	n	289	163	126
	Mean (STDEV)	3.6 (18.9)	1.2 (18.3)	6.6 (19.2)
	Median (Q1, Q3)	0.0 (0.0, 16.7)	0.0 (0.0, 0.0)	0.0 (0.0, 16.7)
	Min, Max	-83.3, 83.3	-66.7, 83.3	-83.3, 83.3
	95% CI	1.4, 5.8	-1.6, 4.1	3.2, 10.0
Percent Improved, Stable, or Worsened at Study Day 50	Improved	34 (11.8%)	23 (14.1%)	11 (8.7%)
	Stable	176 (60.9%)	103 (63.2%)	73 (57.9%)
	Worsened	79 (27.3%)	37 (22.7%)	42 (33.3%)
Study Day 100				
Score at Study Day 100	n	210	146	64
	Mean (STDEV)	8.8 (19.4)	6.1 (16.4)	15.1 (23.9)
	Median (Q1, Q3)	0.0 (0.0, 16.7)	0.0 (0.0, 0.0)	0.0 (0.0, 16.7)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	6.2, 11.4	3.4, 8.7	9.1, 21.1
Change from Screening at Study Day 100	n	210	146	64
	Mean (STDEV)	4.0 (20.7)	0.7 (16.5)	11.7 (26.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 16.7)
	Min, Max	-83.3, 100.0	-50.0, 83.3	-83.3, 100.0
	95% CI	1.2, 6.9	-2.0, 3.4	5.1, 18.4
Percent Improved, Stable, or Worsened at Study Day 100	Improved	23 (11.0%)	20 (13.7%)	3 (4.7%)
	Stable	145 (69.0%)	109 (74.7%)	36 (56.3%)
	Worsened	42 (20.0%)	17 (11.6%)	25 (39.1%)
Study Day 150				
Score at Study Day 150	n	165	109	56
	Mean (STDEV)	5.9 (13.1)	4.6 (12.0)	8.3 (14.9)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 16.7)
	Min, Max	0.0, 66.7	0.0, 66.7	0.0, 66.7
	95% CI	3.8, 7.9	2.3, 6.9	4.3, 12.3
Change from Screening at Study Day 150	n	165	109	56
	Mean (STDEV)	1.5 (14.2)	-0.6 (12.2)	5.7 (16.9)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 16.7)
	Min, Max	-50.0, 66.7	-33.3, 33.3	-50.0, 66.7
	95% CI	-0.7, 3.7	-2.9, 1.7	1.1, 10.2
Percent Improved, Stable, or Worsened at Study Day 150	Improved	21 (12.7%)	17 (15.6%)	4 (7.1%)
	Stable	114 (69.1%)	78 (71.6%)	36 (64.3%)
	Worsened	30 (18.2%)	14 (12.8%)	16 (28.6%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	4.2 (10.9)	4.5 (11.8)	3.3 (8.6)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 66.7	0.0, 66.7	0.0, 33.3
	95% CI	2.3, 6.1	2.0, 7.0	0.6, 6.1
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	-1.7 (16.2)	-1.5 (15.3)	-2.1 (18.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-83.3, 66.7	-50.0, 66.7	-83.3, 33.3
	95% CI	-4.5, 1.1	-4.8, 1.7	-7.9, 3.7
Percent Improved, Stable, or Worsened at Study Month 9	Improved	21 (16.4%)	16 (18.2%)	5 (12.5%)
	Stable	95 (74.2%)	64 (72.7%)	31 (77.5%)
	Worsened	12 (9.4%)	8 (9.1%)	4 (10.0%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	4.5 (11.4)	4.4 (10.9)	4.5 (12.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 66.7	0.0, 66.7	0.0, 66.7
	95% CI	2.3, 6.6	2.0, 6.9	0.0, 9.0
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	-0.7 (14.2)	-1.5 (13.4)	1.0 (16.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-50.0, 66.7	-50.0, 33.3	-50.0, 66.7
	95% CI	-3.4, 1.9	-4.5, 1.5	-4.7, 6.7
Percent Improved, Stable, or Worsened at Study Month 12	Improved	16 (14.3%)	13 (16.5%)	3 (9.1%)
	Stable	83 (74.1%)	57 (72.2%)	26 (78.8%)
	Worsened	13 (11.6%)	9 (11.4%)	4 (12.1%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	3.8 (13.9)	4.5 (15.8)	1.9 (7.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	0.9, 6.6	0.6, 8.3	-1.0, 4.8
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	-0.2 (14.6)	-0.5 (16.9)	0.6 (5.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-50.0, 100.0	-50.0, 100.0	-16.7, 16.7
	95% CI	-3.2, 2.8	-4.6, 3.6	-1.7, 3.0
Percent Improved, Stable, or Worsened at Study Month 15	Improved	12 (12.9%)	11 (16.4%)	1 (3.8%)
	Stable	74 (79.6%)	51 (76.1%)	23 (88.5%)
	Worsened	7 (7.5%)	5 (7.5%)	2 (7.7%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	3.2 (11.8)	3.1 (12.1)	3.6 (11.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 66.7	0.0, 66.7	0.0, 50.0
	95% CI	0.8, 5.6	0.2, 5.9	-1.2, 8.5
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	-1.6 (11.2)	-2.1 (10.1)	0.0 (14.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-50.0, 33.3	-33.3, 33.3	-50.0, 33.3
	95% CI	-3.9, 0.7	-4.5, 0.3	-6.1, 6.1
Percent Improved, Stable, or Worsened at Study Month 18	Improved	13 (13.8%)	11 (15.5%)	2 (8.7%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	74 (78.7%)	56 (78.9%)	18 (78.3%)
	Worsened	7 (7.4%)	4 (5.6%)	3 (13.0%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	3.8 (14.7)	5.2 (17.3)	0.8 (3.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 16.7
	95% CI	0.2, 7.5	-0.0, 10.4	-0.9, 2.6
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	0.3 (16.0)	2.2 (16.9)	-4.2 (13.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-50.0, 100.0	-16.7, 100.0	-50.0, 16.7
	95% CI	-3.7, 4.2	-2.9, 7.3	-10.3, 2.0
Percent Improved, Stable, or Worsened at Study Month 21	Improved	8 (12.3%)	4 (8.9%)	4 (20.0%)
	Stable	52 (80.0%)	37 (82.2%)	15 (75.0%)
	Worsened	5 (7.7%)	4 (8.9%)	1 (5.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	3.4 (9.2)	4.2 (10.4)	1.4 (4.8)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 50.0	0.0, 50.0	0.0, 16.7
	95% CI	0.6, 6.2	0.4, 7.9	-1.7, 4.4
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	0.0 (12.5)	0.5 (14.3)	-1.4 (4.8)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-33.3, 50.0	-33.3, 50.0	-16.7, 0.0

PRO Tables
Protocol KTE-C19-107
Version: 1.0 (10Aug2021)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	-3.8, 3.8	-4.7, 5.7	-4.4, 1.7
Percent Improved, Stable, or Worsened at Study Month 24	Improved	7 (15.9%)	6 (18.8%)	1 (8.3%)
	Stable	31 (70.5%)	20 (62.5%)	11 (91.7%)
	Worsened	6 (13.6%)	6 (18.8%)	0 (0.0%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

PRO Tables
Protocol KTE-C19-107
Version: 1.0 (10Aug2021)

Table 3.1.09 EORTC QLQ-C30 Pain Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	26.0 (28.4)	25.9 (26.6)	26.1 (30.7)
	Median (Q1, Q3)	16.7 (0.0, 33.3)	16.7 (0.0, 33.3)	16.7 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	22.7, 29.2	21.8, 29.9	20.8, 31.4
Study Day 50				
Score at Study Day 50	n	289	163	126
	Mean (STDEV)	21.4 (26.3)	21.1 (25.8)	21.8 (27.0)
	Median (Q1, Q3)	16.7 (0.0, 33.3)	16.7 (0.0, 33.3)	16.7 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	18.3, 24.4	17.1, 25.1	17.1, 26.6
Change from Screening at Study Day 50	n	289	163	126
	Mean (STDEV)	-4.6 (26.8)	-4.9 (26.7)	-4.1 (27.0)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)
	Min, Max	-83.3, 100.0	-83.3, 83.3	-66.7, 100.0
	95% CI	-7.7, -1.5	-9.0, -0.8	-8.9, 0.7
Percent Improved, Stable, or Worsened at Study Day 50	Improved	106 (36.7%)	65 (39.9%)	41 (32.5%)
	Stable	118 (40.8%)	59 (36.2%)	59 (46.8%)
	Worsened	65 (22.5%)	39 (23.9%)	26 (20.6%)
Study Day 100				
Score at Study Day 100	n	210	146	64
	Mean (STDEV)	19.2 (26.3)	21.5 (28.0)	14.1 (21.5)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	16.7 (0.0, 33.3)	0.0 (0.0, 25.0)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	15.6, 22.8	16.9, 26.0	8.7, 19.4
Change from Screening at Study Day 100	n	210	146	64
	Mean (STDEV)	-4.5 (24.8)	-3.4 (23.6)	-7.0 (27.3)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)
	Min, Max	-83.3, 66.7	-66.7, 66.7	-83.3, 50.0
	95% CI	-7.9, -1.1	-7.3, 0.4	-13.9, -0.2
Percent Improved, Stable, or Worsened at Study Day 100	Improved	73 (34.8%)	50 (34.2%)	23 (35.9%)
	Stable	94 (44.8%)	64 (43.8%)	30 (46.9%)
	Worsened	43 (20.5%)	32 (21.9%)	11 (17.2%)
Study Day 150				
Score at Study Day 150	n	166	110	56
	Mean (STDEV)	16.5 (22.9)	19.1 (24.7)	11.3 (18.0)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	16.7 (0.0, 33.3)	0.0 (0.0, 16.7)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 83.3
	95% CI	13.0, 20.0	14.4, 23.8	6.5, 16.1
Change from Screening at Study Day 150	n	166	110	56
	Mean (STDEV)	-6.5 (26.5)	-4.5 (25.0)	-10.4 (29.1)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)
	Min, Max	-100.0, 83.3	-66.7, 83.3	-100.0, 33.3
	95% CI	-10.6, -2.5	-9.3, 0.2	-18.2, -2.6
Percent Improved, Stable, or Worsened at Study Day 150	Improved	59 (35.5%)	37 (33.6%)	22 (39.3%)
	Stable	71 (42.8%)	50 (45.5%)	21 (37.5%)
	Worsened	36 (21.7%)	23 (20.9%)	13 (23.2%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	15.8 (23.0)	18.0 (23.5)	10.8 (21.5)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	16.7 (0.0, 33.3)	0.0 (0.0, 16.7)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 83.3
	95% CI	11.7, 19.8	13.0, 23.0	3.9, 17.7
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	-8.9 (25.6)	-5.9 (24.1)	-15.4 (27.8)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-16.7, 8.3)	-16.7 (-33.3, 0.0)
	Min, Max	-83.3, 50.0	-66.7, 50.0	-83.3, 33.3
	95% CI	-13.3, -4.4	-11.0, -0.8	-24.3, -6.5
Percent Improved, Stable, or Worsened at Study Month 9	Improved	55 (43.0%)	33 (37.5%)	22 (55.0%)
	Stable	45 (35.2%)	33 (37.5%)	12 (30.0%)
	Worsened	28 (21.9%)	22 (25.0%)	6 (15.0%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	15.0 (22.8)	17.5 (25.2)	9.1 (14.5)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 16.7)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 50.0
	95% CI	10.8, 19.3	11.9, 23.1	4.0, 14.2
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	-9.4 (26.2)	-7.2 (25.7)	-14.6 (26.9)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)	-16.7 (-33.3, 0.0)
	Min, Max	-100.0, 66.7	-100.0, 66.7	-100.0, 33.3
	95% CI	-14.3, -4.5	-12.9, -1.4	-24.2, -5.1
Percent Improved, Stable, or Worsened at Study Month 12	Improved	48 (42.9%)	30 (38.0%)	18 (54.5%)
	Stable	46 (41.1%)	35 (44.3%)	11 (33.3%)
	Worsened	18 (16.1%)	14 (17.7%)	4 (12.1%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	13.8 (21.9)	16.9 (24.4)	5.8 (10.5)
	Median (Q1, Q3)	0.0 (0.0, 16.7)	0.0 (0.0, 33.3)	0.0 (0.0, 16.7)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	9.3, 18.3	11.0, 22.9	1.5, 10.0
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	-8.4 (27.4)	-5.2 (27.2)	-16.7 (26.7)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)	-8.3 (-33.3, 0.0)
	Min, Max	-100.0, 66.7	-100.0, 66.7	-100.0, 16.7
	95% CI	-14.1, -2.8	-11.9, 1.4	-27.4, -5.9
Percent Improved, Stable, or Worsened at Study Month 15	Improved	34 (36.6%)	21 (31.3%)	13 (50.0%)
	Stable	44 (47.3%)	33 (49.3%)	11 (42.3%)
	Worsened	15 (16.1%)	13 (19.4%)	2 (7.7%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	14.7 (20.7)	16.4 (22.6)	9.4 (12.1)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 16.7)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	10.5, 19.0	11.1, 21.8	4.2, 14.7
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	-9.4 (25.0)	-6.6 (23.7)	-18.1 (27.5)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)	-16.7 (-33.3, 0.0)
	Min, Max	-100.0, 33.3	-100.0, 33.3	-100.0, 16.7
	95% CI	-14.5, -4.3	-12.2, -1.0	-30.0, -6.2
Percent Improved, Stable, or Worsened at Study Month 18	Improved	39 (41.5%)	25 (35.2%)	14 (60.9%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	37 (39.4%)	32 (45.1%)	5 (21.7%)
	Worsened	18 (19.1%)	14 (19.7%)	4 (17.4%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	12.1 (19.4)	14.1 (21.9)	7.5 (11.4)
	Median (Q1, Q3)	0.0 (0.0, 16.7)	0.0 (0.0, 16.7)	0.0 (0.0, 16.7)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	7.2, 16.9	7.5, 20.7	2.1, 12.9
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	-13.8 (27.3)	-10.4 (25.7)	-21.7 (29.7)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-16.7, 0.0)	-16.7 (-41.7, 0.0)
	Min, Max	-100.0, 33.3	-100.0, 33.3	-100.0, 16.7
	95% CI	-20.6, -7.1	-18.1, -2.7	-35.6, -7.8
Percent Improved, Stable, or Worsened at Study Month 21	Improved	31 (47.7%)	19 (42.2%)	12 (60.0%)
	Stable	24 (36.9%)	18 (40.0%)	6 (30.0%)
	Worsened	10 (15.4%)	8 (17.8%)	2 (10.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	13.6 (20.7)	16.1 (22.6)	6.9 (13.2)
	Median (Q1, Q3)	0.0 (0.0, 25.0)	0.0 (0.0, 33.3)	0.0 (0.0, 8.3)
	Min, Max	0.0, 83.3	0.0, 83.3	0.0, 33.3
	95% CI	7.3, 19.9	8.0, 24.3	-1.5, 15.3
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	-11.7 (29.5)	-7.3 (31.7)	-23.6 (19.4)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)	-16.7 (-33.3, -16.7)
	Min, Max	-100.0, 83.3	-100.0, 83.3	-66.7, 0.0

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	-20.7, -2.8	-18.7, 4.1	-35.9, -11.3
Percent Improved, Stable, or Worsened at Study Month 24	Improved	21 (47.7%)	11 (34.4%)	10 (83.3%)
	Stable	18 (40.9%)	16 (50.0%)	2 (16.7%)
	Worsened	5 (11.4%)	5 (15.6%)	0 (0.0%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

PRO Tables
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Table 3.1.10 EORTC QLQ-C30 Dyspnea Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	13.1 (21.1)	15.6 (23.4)	9.9 (17.4)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	10.6, 15.5	12.0, 19.2	6.9, 12.9
Study Day 50				
Score at Study Day 50	n	288	163	125
	Mean (STDEV)	17.0 (22.4)	16.0 (21.4)	18.4 (23.7)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	14.4, 19.6	12.6, 19.3	14.2, 22.6
Change from Screening at Study Day 50	n	288	163	125
	Mean (STDEV)	3.6 (24.1)	0.2 (24.7)	8.0 (22.6)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-66.7, 100.0	-66.7, 66.7	-66.7, 100.0
	95% CI	0.8, 6.4	-3.6, 4.0	4.0, 12.0
Percent Improved, Stable, or Worsened at Study Day 50	Improved	38 (13.2%)	31 (19.0%)	7 (5.6%)
	Stable	185 (64.2%)	98 (60.1%)	87 (69.6%)
	Worsened	65 (22.6%)	34 (20.9%)	31 (24.8%)
Study Day 100				
Score at Study Day 100	n	209	145	64
	Mean (STDEV)	16.9 (25.1)	13.1 (22.0)	25.5 (29.5)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	33.3 (0.0, 33.3)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	13.5, 20.3	9.5, 16.7	18.1, 32.9
Change from Screening at Study Day 100	n	209	145	64
	Mean (STDEV)	3.2 (26.6)	-2.1 (22.3)	15.1 (31.4)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)
	Min, Max	-66.7, 100.0	-66.7, 100.0	-33.3, 100.0
	95% CI	-0.4, 6.8	-5.7, 1.6	7.3, 22.9
Percent Improved, Stable, or Worsened at Study Day 100	Improved	35 (16.7%)	28 (19.3%)	7 (10.9%)
	Stable	131 (62.7%)	100 (69.0%)	31 (48.4%)
	Worsened	43 (20.6%)	17 (11.7%)	26 (40.6%)
Study Day 150				
Score at Study Day 150	n	165	109	56
	Mean (STDEV)	15.6 (25.4)	12.5 (23.9)	21.4 (27.3)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	11.7, 19.5	8.0, 17.1	14.1, 28.7
Change from Screening at Study Day 150	n	165	109	56
	Mean (STDEV)	1.0 (29.5)	-3.7 (28.8)	10.1 (29.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 33.3)
	Min, Max	-66.7, 100.0	-66.7, 100.0	-66.7, 100.0
	95% CI	-3.5, 5.6	-9.1, 1.8	2.3, 17.9
Percent Improved, Stable, or Worsened at Study Day 150	Improved	32 (19.4%)	28 (25.7%)	4 (7.1%)
	Stable	104 (63.0%)	67 (61.5%)	37 (66.1%)
	Worsened	29 (17.6%)	14 (12.8%)	15 (26.8%)
Study Month 9				
Score at Study Month 9	n	128	88	40

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	12.0 (22.4)	9.1 (20.7)	18.3 (25.0)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	8.1, 15.9	4.7, 13.5	10.3, 26.3
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	-3.4 (26.1)	-8.0 (24.2)	6.7 (27.4)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 33.3)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-66.7, 66.7
	95% CI	-7.9, 1.2	-13.1, -2.8	-2.1, 15.4
Percent Improved, Stable, or Worsened at Study Month 9	Improved	30 (23.4%)	24 (27.3%)	6 (15.0%)
	Stable	79 (61.7%)	58 (65.9%)	21 (52.5%)
	Worsened	19 (14.8%)	6 (6.8%)	13 (32.5%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	10.7 (22.0)	12.7 (24.6)	6.1 (13.1)
	Median (Q1, Q3)	0.0 (0.0, 16.7)	0.0 (0.0, 33.3)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	6.6, 14.8	7.1, 18.2	1.4, 10.7
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	-4.5 (23.0)	-5.1 (24.5)	-3.0 (19.3)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-66.7, 100.0	-66.7, 100.0	-66.7, 33.3
	95% CI	-8.8, -0.2	-10.6, 0.4	-9.9, 3.8
Percent Improved, Stable, or Worsened at Study Month 12	Improved	25 (22.3%)	20 (25.3%)	5 (15.2%)
	Stable	77 (68.8%)	52 (65.8%)	25 (75.8%)
	Worsened	10 (8.9%)	7 (8.9%)	3 (9.1%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	11.8 (22.3)	12.9 (24.6)	9.0 (15.1)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	7.2, 16.4	6.9, 18.9	2.9, 15.1
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	-3.6 (27.1)	-6.0 (30.1)	2.6 (16.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 66.7	-100.0, 66.7	-33.3, 33.3
	95% CI	-9.2, 2.0	-13.3, 1.4	-3.9, 9.1
Percent Improved, Stable, or Worsened at Study Month 15	Improved	20 (21.5%)	18 (26.9%)	2 (7.7%)
	Stable	60 (64.5%)	40 (59.7%)	20 (76.9%)
	Worsened	13 (14.0%)	9 (13.4%)	4 (15.4%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	8.9 (18.4)	9.9 (19.8)	5.8 (12.9)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	5.1, 12.6	5.2, 14.6	0.2, 11.4
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	-8.2 (23.3)	-8.9 (23.9)	-5.8 (21.7)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-66.7, 33.3	-66.7, 33.3	-66.7, 33.3
	95% CI	-12.9, -3.4	-14.6, -3.3	-15.2, 3.6
Percent Improved, Stable, or Worsened at Study Month 18	Improved	25 (26.6%)	20 (28.2%)	5 (21.7%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	61 (64.9%)	45 (63.4%)	16 (69.6%)
	Worsened	8 (8.5%)	6 (8.5%)	2 (8.7%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	10.3 (20.3)	9.6 (20.9)	11.7 (19.6)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	5.2, 15.3	3.4, 15.9	2.5, 20.8
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	-7.2 (28.6)	-10.4 (28.3)	0.0 (28.6)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 66.7	-100.0, 66.7	-66.7, 66.7
	95% CI	-14.3, -0.1	-18.9, -1.9	-13.4, 13.4
Percent Improved, Stable, or Worsened at Study Month 21	Improved	19 (29.2%)	15 (33.3%)	4 (20.0%)
	Stable	38 (58.5%)	26 (57.8%)	12 (60.0%)
	Worsened	8 (12.3%)	4 (8.9%)	4 (20.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	10.6 (18.7)	13.5 (20.5)	2.8 (9.6)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 0.0)
	Min, Max	0.0, 66.7	0.0, 66.7	0.0, 33.3
	95% CI	4.9, 16.3	6.2, 20.9	-3.3, 8.9
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	-5.3 (24.8)	-7.3 (27.7)	0.0 (14.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (-16.7, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 33.3	-100.0, 33.3	-33.3, 33.3

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	-12.9, 2.3	-17.3, 2.7	-9.0, 9.0
Percent Improved, Stable, or Worsened at Study Month 24	Improved	9 (20.5%)	8 (25.0%)	1 (8.3%)
	Stable	30 (68.2%)	20 (62.5%)	10 (83.3%)
	Worsened	5 (11.4%)	4 (12.5%)	1 (8.3%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

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Table 3.1.11 EORTC QLQ-C30 Insomnia Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	26.2 (27.7)	27.7 (28.9)	24.4 (26.1)
	Median (Q1, Q3)	33.3 (0.0, 33.3)	33.3 (0.0, 33.3)	33.3 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	23.1, 29.4	23.2, 32.1	19.9, 28.9
Study Day 50				
Score at Study Day 50	n	288	163	125
	Mean (STDEV)	24.0 (26.7)	24.7 (27.1)	22.9 (26.2)
	Median (Q1, Q3)	33.3 (0.0, 33.3)	33.3 (0.0, 33.3)	33.3 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	20.9, 27.1	20.6, 28.9	18.3, 27.6
Change from Screening at Study Day 50	n	288	163	125
	Mean (STDEV)	-2.3 (30.1)	-3.1 (30.5)	-1.3 (29.8)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-100.0, 66.7	-66.7, 66.7	-100.0, 66.7
	95% CI	-5.8, 1.2	-7.8, 1.6	-6.6, 3.9
Percent Improved, Stable, or Worsened at Study Day 50	Improved	78 (27.1%)	41 (25.2%)	37 (29.6%)
	Stable	150 (52.1%)	89 (54.6%)	61 (48.8%)
	Worsened	60 (20.8%)	33 (20.2%)	27 (21.6%)
Study Day 100				
Score at Study Day 100	n	210	146	64
	Mean (STDEV)	24.0 (28.5)	22.6 (29.5)	27.1 (25.8)
	Median (Q1, Q3)	16.7 (0.0, 33.3)	0.0 (0.0, 33.3)	33.3 (0.0, 33.3)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	20.1, 27.8	17.8, 27.4	20.6, 33.5
Change from Screening at Study Day 100	n	210	146	64
	Mean (STDEV)	-2.5 (32.3)	-5.9 (33.4)	5.2 (28.6)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 33.3)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-66.7, 66.7
	95% CI	-6.9, 1.9	-11.4, -0.5	-1.9, 12.4
Percent Improved, Stable, or Worsened at Study Day 100	Improved	62 (29.5%)	51 (34.9%)	11 (17.2%)
	Stable	97 (46.2%)	66 (45.2%)	31 (48.4%)
	Worsened	51 (24.3%)	29 (19.9%)	22 (34.4%)
Study Day 150				
Score at Study Day 150	n	165	109	56
	Mean (STDEV)	21.0 (26.1)	20.8 (27.1)	21.4 (24.1)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	33.3 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	17.0, 25.0	15.6, 25.9	15.0, 27.9
Change from Screening at Study Day 150	n	165	109	56
	Mean (STDEV)	-6.3 (30.0)	-8.6 (29.9)	-1.8 (30.1)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-66.7, 66.7
	95% CI	-10.9, -1.6	-14.2, -2.9	-9.8, 6.3
Percent Improved, Stable, or Worsened at Study Day 150	Improved	53 (32.1%)	36 (33.0%)	17 (30.4%)
	Stable	83 (50.3%)	57 (52.3%)	26 (46.4%)
	Worsened	29 (17.6%)	16 (14.7%)	13 (23.2%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	18.2 (22.5)	18.9 (23.6)	16.7 (20.0)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	14.3, 22.2	13.9, 23.9	10.3, 23.1
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	-11.2 (27.8)	-11.0 (29.3)	-11.7 (24.5)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-100.0, 33.3	-100.0, 33.3	-66.7, 33.3
	95% CI	-16.1, -6.3	-17.2, -4.8	-19.5, -3.8
Percent Improved, Stable, or Worsened at Study Month 9	Improved	52 (40.6%)	36 (40.9%)	16 (40.0%)
	Stable	57 (44.5%)	37 (42.0%)	20 (50.0%)
	Worsened	19 (14.8%)	15 (17.0%)	4 (10.0%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	19.9 (27.4)	21.9 (28.2)	15.2 (25.1)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	14.8, 25.1	15.6, 28.3	6.2, 24.1
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	-9.8 (30.6)	-10.5 (30.9)	-8.1 (30.1)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-66.7, 66.7
	95% CI	-15.5, -4.1	-17.5, -3.6	-18.7, 2.6
Percent Improved, Stable, or Worsened at Study Month 12	Improved	44 (39.3%)	31 (39.2%)	13 (39.4%)
	Stable	51 (45.5%)	37 (46.8%)	14 (42.4%)
	Worsened	17 (15.2%)	11 (13.9%)	6 (18.2%)

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	18.3 (23.8)	19.9 (26.0)	14.1 (16.8)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	13.4, 23.2	13.6, 26.2	7.3, 20.9
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	-11.1 (27.5)	-11.9 (29.4)	-9.0 (22.2)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-66.7, 33.3
	95% CI	-16.8, -5.4	-19.1, -4.8	-18.0, 0.0
Percent Improved, Stable, or Worsened at Study Month 15	Improved	35 (37.6%)	27 (40.3%)	8 (30.8%)
	Stable	47 (50.5%)	31 (46.3%)	16 (61.5%)
	Worsened	11 (11.8%)	9 (13.4%)	2 (7.7%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	17.4 (24.8)	16.9 (25.7)	18.8 (22.1)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	12.3, 22.5	10.8, 23.0	9.3, 28.4
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	-12.1 (28.9)	-14.1 (30.2)	-5.8 (23.9)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-33.3, 66.7
	95% CI	-18.0, -6.1	-21.2, -6.9	-16.1, 4.5
Percent Improved, Stable, or Worsened at Study Month 18	Improved	37 (39.4%)	30 (42.3%)	7 (30.4%)

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	48 (51.1%)	34 (47.9%)	14 (60.9%)
	Worsened	9 (9.6%)	7 (9.9%)	2 (8.7%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	20.0 (27.5)	22.2 (29.3)	15.0 (22.9)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	13.2, 26.8	13.4, 31.0	4.3, 25.7
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	-14.4 (30.6)	-14.8 (33.0)	-13.3 (25.1)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	-33.3 (-33.3, 0.0)
	Min, Max	-100.0, 66.7	-100.0, 66.7	-33.3, 33.3
	95% CI	-21.9, -6.8	-24.7, -4.9	-25.1, -1.6
Percent Improved, Stable, or Worsened at Study Month 21	Improved	29 (44.6%)	18 (40.0%)	11 (55.0%)
	Stable	28 (43.1%)	22 (48.9%)	6 (30.0%)
	Worsened	8 (12.3%)	5 (11.1%)	3 (15.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	16.7 (24.4)	19.8 (26.6)	8.3 (15.1)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 16.7)
	Min, Max	0.0, 66.7	0.0, 66.7	0.0, 33.3
	95% CI	9.3, 24.1	10.2, 29.4	-1.2, 17.9
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	-13.6 (27.2)	-13.5 (30.4)	-13.9 (17.2)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-33.3, 0.0

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	-21.9, -5.4	-24.5, -2.6	-24.8, -3.0
Percent Improved, Stable, or Worsened at Study Month 24	Improved	19 (43.2%)	14 (43.8%)	5 (41.7%)
	Stable	23 (52.3%)	16 (50.0%)	7 (58.3%)
	Worsened	2 (4.5%)	2 (6.3%)	0 (0.0%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

PRO Tables
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Table 3.1.12 EORTC QLQ-C30 Appetite Loss Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	13.6 (22.8)	14.3 (22.8)	12.7 (22.8)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	11.0, 16.2	10.8, 17.8	8.8, 16.7
Study Day 50				
Score at Study Day 50	n	289	163	126
	Mean (STDEV)	24.9 (29.2)	28.6 (30.7)	20.1 (26.4)
	Median (Q1, Q3)	33.3 (0.0, 33.3)	33.3 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	21.5, 28.3	23.9, 33.4	15.5, 24.8
Change from Screening at Study Day 50	n	289	163	126
	Mean (STDEV)	11.1 (34.5)	14.3 (36.3)	6.9 (31.6)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-100.0, 100.0
	95% CI	7.1, 15.1	8.7, 19.9	1.3, 12.5
Percent Improved, Stable, or Worsened at Study Day 50	Improved	38 (13.1%)	22 (13.5%)	16 (12.7%)
	Stable	149 (51.6%)	76 (46.6%)	73 (57.9%)
	Worsened	102 (35.3%)	65 (39.9%)	37 (29.4%)
Study Day 100				
Score at Study Day 100	n	209	146	63
	Mean (STDEV)	18.2 (29.6)	13.2 (25.8)	29.6 (34.4)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	33.3 (0.0, 66.7)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	14.1, 22.2	9.0, 17.5	21.0, 38.3
Change from Screening at Study Day 100	n	209	146	63
	Mean (STDEV)	5.4 (30.0)	-0.9 (26.0)	20.1 (33.6)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-66.7, 100.0
	95% CI	1.3, 9.5	-5.2, 3.3	11.6, 28.6
Percent Improved, Stable, or Worsened at Study Day 100	Improved	32 (15.3%)	29 (19.9%)	3 (4.8%)
	Stable	125 (59.8%)	92 (63.0%)	33 (52.4%)
	Worsened	52 (24.9%)	25 (17.1%)	27 (42.9%)
Study Day 150				
Score at Study Day 150	n	165	109	56
	Mean (STDEV)	11.5 (22.6)	9.2 (21.2)	16.1 (24.6)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	8.0, 15.0	5.1, 13.2	9.5, 22.7
Change from Screening at Study Day 150	n	165	109	56
	Mean (STDEV)	-1.6 (25.5)	-5.8 (24.4)	6.5 (25.8)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 33.3)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-66.7, 66.7
	95% CI	-5.5, 2.3	-10.4, -1.2	-0.4, 13.4
Percent Improved, Stable, or Worsened at Study Day 150	Improved	36 (21.8%)	29 (26.6%)	7 (12.5%)
	Stable	102 (61.8%)	69 (63.3%)	33 (58.9%)
	Worsened	27 (16.4%)	11 (10.1%)	16 (28.6%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	7.6 (20.2)	5.7 (19.1)	11.7 (22.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 16.7)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	4.0, 11.1	1.6, 9.7	4.6, 18.7
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	-6.5 (28.1)	-8.7 (25.5)	-1.7 (32.9)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-100.0, 66.7
	95% CI	-11.4, -1.6	-14.1, -3.3	-12.2, 8.8
Percent Improved, Stable, or Worsened at Study Month 9	Improved	32 (25.0%)	24 (27.3%)	8 (20.0%)
	Stable	84 (65.6%)	59 (67.0%)	25 (62.5%)
	Worsened	12 (9.4%)	5 (5.7%)	7 (17.5%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	7.1 (18.1)	5.9 (17.5)	10.1 (19.5)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	3.7, 10.5	2.0, 9.8	3.2, 17.0
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	-6.5 (27.2)	-8.4 (26.4)	-2.0 (28.8)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 66.7	-100.0, 66.7	-100.0, 66.7
	95% CI	-11.6, -1.5	-14.4, -2.5	-12.2, 8.2
Percent Improved, Stable, or Worsened at Study Month 12	Improved	28 (25.0%)	21 (26.6%)	7 (21.2%)
	Stable	73 (65.2%)	53 (67.1%)	20 (60.6%)
	Worsened	11 (9.8%)	5 (6.3%)	6 (18.2%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	7.2 (20.2)	6.5 (20.3)	9.0 (20.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	3.0, 11.3	1.5, 11.4	0.8, 17.1
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	-6.1 (27.3)	-7.5 (26.5)	-2.6 (29.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-100.0, 66.7
	95% CI	-11.7, -0.5	-13.9, -1.0	-14.6, 9.4
Percent Improved, Stable, or Worsened at Study Month 15	Improved	22 (23.7%)	17 (25.4%)	5 (19.2%)
	Stable	64 (68.8%)	47 (70.1%)	17 (65.4%)
	Worsened	7 (7.5%)	3 (4.5%)	4 (15.4%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	6.4 (17.1)	6.1 (17.2)	7.2 (17.3)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	2.9, 9.9	2.0, 10.2	-0.2, 14.7
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	-8.2 (23.3)	-8.5 (20.9)	-7.2 (30.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-100.0, 66.7	-66.7, 33.3	-100.0, 66.7
	95% CI	-12.9, -3.4	-13.4, -3.5	-20.3, 5.8
Percent Improved, Stable, or Worsened at Study Month 18	Improved	23 (24.5%)	17 (23.9%)	6 (26.1%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	66 (70.2%)	51 (71.8%)	15 (65.2%)
	Worsened	5 (5.3%)	3 (4.2%)	2 (8.7%)
Study Month 21				
Score at Study Month 21	n	64	44	20
	Mean (STDEV)	2.6 (9.0)	3.0 (9.7)	1.7 (7.5)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 33.3	0.0, 33.3	0.0, 33.3
	95% CI	0.4, 4.9	0.1, 6.0	-1.8, 5.2
Change from Screening at Study Month 21	n	64	44	20
	Mean (STDEV)	-8.9 (23.2)	-6.1 (19.4)	-15.0 (29.6)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-100.0, 33.3	-66.7, 33.3	-100.0, 33.3
	95% CI	-14.6, -3.1	-12.0, -0.2	-28.8, -1.2
Percent Improved, Stable, or Worsened at Study Month 21	Improved	15 (23.4%)	8 (18.2%)	7 (35.0%)
	Stable	46 (71.9%)	34 (77.3%)	12 (60.0%)
	Worsened	3 (4.7%)	2 (4.5%)	1 (5.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	6.1 (19.4)	6.3 (19.7)	5.6 (19.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 66.7	0.0, 66.7	0.0, 66.7
	95% CI	0.2, 12.0	-0.9, 13.4	-6.7, 17.8
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	-5.3 (22.7)	-8.3 (25.4)	2.8 (9.6)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 33.3	-100.0, 33.3	0.0, 33.3

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	-12.2, 1.6	-17.5, 0.8	-3.3, 8.9
Percent Improved, Stable, or Worsened at Study Month 24	Improved	7 (15.9%)	7 (21.9%)	0 (0.0%)
	Stable	34 (77.3%)	23 (71.9%)	11 (91.7%)
	Worsened	3 (6.8%)	2 (6.3%)	1 (8.3%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

Table 3.1.13 EORTC QLQ-C30 Constipation Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	14.4 (25.1)	14.5 (24.8)	14.2 (25.5)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	11.5, 17.3	10.7, 18.4	9.8, 18.7
Study Day 50				
Score at Study Day 50	n	289	163	126
	Mean (STDEV)	11.9 (21.0)	7.6 (17.1)	17.5 (24.1)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	9.4, 14.3	4.9, 10.2	13.2, 21.7
Change from Screening at Study Day 50	n	289	163	126
	Mean (STDEV)	-2.9 (29.6)	-7.2 (27.7)	2.6 (31.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)	0.0 (0.0, 33.3)
	Min, Max	-100.0, 100.0	-100.0, 66.7	-100.0, 100.0
	95% CI	-6.3, 0.5	-11.4, -2.9	-2.8, 8.1
Percent Improved, Stable, or Worsened at Study Day 50	Improved	60 (20.8%)	42 (25.8%)	18 (14.3%)
	Stable	180 (62.3%)	104 (63.8%)	76 (60.3%)
	Worsened	49 (17.0%)	17 (10.4%)	32 (25.4%)
Study Day 100				
Score at Study Day 100	n	209	146	63
	Mean (STDEV)	9.6 (21.5)	10.5 (23.1)	7.4 (17.4)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	6.6, 12.5	6.7, 14.3	3.0, 11.8
Change from Screening at Study Day 100	n	209	146	63
	Mean (STDEV)	-3.7 (26.2)	-3.4 (27.0)	-4.2 (24.3)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-100.0, 66.7
	95% CI	-7.2, -0.1	-7.8, 1.0	-10.4, 1.9
Percent Improved, Stable, or Worsened at Study Day 100	Improved	44 (21.1%)	30 (20.5%)	14 (22.2%)
	Stable	142 (67.9%)	99 (67.8%)	43 (68.3%)
	Worsened	23 (11.0%)	17 (11.6%)	6 (9.5%)
Study Day 150				
Score at Study Day 150	n	165	109	56
	Mean (STDEV)	6.9 (17.5)	8.3 (19.9)	4.2 (11.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	4.2, 9.6	4.5, 12.0	1.2, 7.1
Change from Screening at Study Day 150	n	165	109	56
	Mean (STDEV)	-6.1 (24.2)	-4.3 (24.0)	-9.5 (24.4)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-100.0, 66.7	-66.7, 66.7	-100.0, 33.3
	95% CI	-9.8, -2.3	-8.8, 0.3	-16.1, -3.0
Percent Improved, Stable, or Worsened at Study Day 150	Improved	40 (24.2%)	24 (22.0%)	16 (28.6%)
	Stable	111 (67.3%)	75 (68.8%)	36 (64.3%)
	Worsened	14 (8.5%)	10 (9.2%)	4 (7.1%)
Study Month 9				
Score at Study Month 9	n	127	87	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	6.0 (17.5)	7.7 (20.1)	2.5 (8.9)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	3.0, 9.1	3.4, 12.0	-0.3, 5.3
Change from Screening at Study Month 9	n	127	87	40
	Mean (STDEV)	-7.6 (22.3)	-3.8 (17.9)	-15.8 (28.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-100.0, 66.7	-66.7, 66.7	-100.0, 33.3
	95% CI	-11.5, -3.7	-7.7, -0.0	-24.9, -6.8
Percent Improved, Stable, or Worsened at Study Month 9	Improved	29 (22.8%)	15 (17.2%)	14 (35.0%)
	Stable	92 (72.4%)	67 (77.0%)	25 (62.5%)
	Worsened	6 (4.7%)	5 (5.7%)	1 (2.5%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	5.7 (17.8)	6.8 (19.5)	3.0 (12.8)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	2.3, 9.0	2.4, 11.1	-1.5, 7.6
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	-7.4 (25.2)	-6.3 (25.1)	-10.1 (25.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-100.0, 66.7	-100.0, 66.7	-100.0, 33.3
	95% CI	-12.2, -2.7	-11.9, -0.7	-19.2, -1.0
Percent Improved, Stable, or Worsened at Study Month 12	Improved	27 (24.1%)	18 (22.8%)	9 (27.3%)
	Stable	77 (68.8%)	55 (69.6%)	22 (66.7%)
	Worsened	8 (7.1%)	6 (7.6%)	2 (6.1%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	7.2 (19.6)	9.0 (22.2)	2.6 (9.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	3.1, 11.2	3.6, 14.4	-1.1, 6.2
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	-5.4 (19.8)	-2.0 (17.3)	-14.1 (23.4)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-66.7, 33.3
	95% CI	-9.5, -1.3	-6.2, 2.2	-23.6, -4.6
Percent Improved, Stable, or Worsened at Study Month 15	Improved	18 (19.4%)	8 (11.9%)	10 (38.5%)
	Stable	70 (75.3%)	55 (82.1%)	15 (57.7%)
	Worsened	5 (5.4%)	4 (6.0%)	1 (3.8%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	5.3 (14.9)	3.8 (14.4)	10.1 (15.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	2.3, 8.4	0.3, 7.2	3.4, 16.9
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	-4.3 (19.1)	-4.7 (16.2)	-2.9 (26.4)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-66.7, 33.3	-66.7, 33.3	-66.7, 33.3
	95% CI	-8.2, -0.3	-8.5, -0.9	-14.3, 8.5
Percent Improved, Stable, or Worsened at Study Month 18	Improved	18 (19.1%)	12 (16.9%)	6 (26.1%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	68 (72.3%)	56 (78.9%)	12 (52.2%)
	Worsened	8 (8.5%)	3 (4.2%)	5 (21.7%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	8.7 (18.9)	9.6 (20.9)	6.7 (13.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	4.0, 13.4	3.4, 15.9	0.3, 13.1
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	-0.5 (22.4)	1.5 (23.5)	-5.0 (19.6)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (-16.7, 0.0)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-33.3, 33.3
	95% CI	-6.1, 5.0	-5.6, 8.5	-14.2, 4.2
Percent Improved, Stable, or Worsened at Study Month 21	Improved	9 (13.8%)	4 (8.9%)	5 (25.0%)
	Stable	48 (73.8%)	35 (77.8%)	13 (65.0%)
	Worsened	8 (12.3%)	6 (13.3%)	2 (10.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	5.3 (14.3)	4.2 (11.2)	8.3 (20.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 66.7	0.0, 33.3	0.0, 66.7
	95% CI	1.0, 9.6	0.1, 8.2	-4.8, 21.5
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	-3.0 (18.8)	-1.0 (15.8)	-8.3 (25.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (-16.7, 0.0)
	Min, Max	-66.7, 33.3	-66.7, 33.3	-66.7, 33.3

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	-8.7, 2.7	-6.7, 4.7	-24.3, 7.6
Percent Improved, Stable, or Worsened at Study Month 24	Improved	5 (11.4%)	2 (6.3%)	3 (25.0%)
	Stable	36 (81.8%)	28 (87.5%)	8 (66.7%)
	Worsened	3 (6.8%)	2 (6.3%)	1 (8.3%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

Table 3.1.14 EORTC QLQ-C30 Diarrhea Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	8.7 (17.7)	8.3 (16.2)	9.2 (19.4)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	6.6, 10.7	5.8, 10.8	5.8, 12.5
Study Day 50				
Score at Study Day 50	n	287	163	124
	Mean (STDEV)	9.6 (19.4)	8.8 (18.8)	10.8 (20.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	7.4, 11.9	5.9, 11.7	7.2, 14.3
Change from Screening at Study Day 50	n	287	163	124
	Mean (STDEV)	0.8 (23.9)	0.4 (22.5)	1.3 (25.6)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-100.0, 100.0
	95% CI	-2.0, 3.6	-3.1, 3.9	-3.2, 5.9
Percent Improved, Stable, or Worsened at Study Day 50	Improved	43 (15.0%)	25 (15.3%)	18 (14.5%)
	Stable	196 (68.3%)	114 (69.9%)	82 (66.1%)
	Worsened	48 (16.7%)	24 (14.7%)	24 (19.4%)
Study Day 100				
Score at Study Day 100	n	209	146	63
	Mean (STDEV)	12.9 (25.5)	7.1 (17.6)	26.5 (34.5)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	9.4, 16.4	4.2, 10.0	17.8, 35.1
Change from Screening at Study Day 100	n	209	146	63
	Mean (STDEV)	4.6 (29.3)	-0.7 (22.6)	16.9 (38.3)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-66.7, 100.0
	95% CI	0.6, 8.6	-4.4, 3.0	7.3, 26.6
Percent Improved, Stable, or Worsened at Study Day 100	Improved	29 (13.9%)	23 (15.8%)	6 (9.5%)
	Stable	139 (66.5%)	107 (73.3%)	32 (50.8%)
	Worsened	41 (19.6%)	16 (11.0%)	25 (39.7%)
Study Day 150				
Score at Study Day 150	n	166	110	56
	Mean (STDEV)	7.8 (18.3)	7.3 (18.8)	8.9 (17.4)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	5.0, 10.6	3.7, 10.8	4.3, 13.6
Change from Screening at Study Day 150	n	166	110	56
	Mean (STDEV)	0.6 (23.9)	-0.9 (26.1)	3.6 (18.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-66.7, 33.3
	95% CI	-3.1, 4.3	-5.8, 4.0	-1.4, 8.6
Percent Improved, Stable, or Worsened at Study Day 150	Improved	25 (15.1%)	21 (19.1%)	4 (7.1%)
	Stable	114 (68.7%)	73 (66.4%)	41 (73.2%)
	Worsened	27 (16.3%)	16 (14.5%)	11 (19.6%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	9.4 (20.9)	8.0 (18.2)	12.5 (25.8)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 16.7)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	5.7, 13.0	4.1, 11.8	4.2, 20.8
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	1.8 (25.6)	-0.0 (24.8)	5.8 (27.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-33.3, 100.0
	95% CI	-2.6, 6.3	-5.2, 5.2	-2.8, 14.5
Percent Improved, Stable, or Worsened at Study Month 9	Improved	19 (14.8%)	14 (15.9%)	5 (12.5%)
	Stable	89 (69.5%)	62 (70.5%)	27 (67.5%)
	Worsened	20 (15.6%)	12 (13.6%)	8 (20.0%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	7.4 (16.0)	6.8 (15.5)	9.1 (17.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 66.7	0.0, 66.7	0.0, 66.7
	95% CI	4.5, 10.4	3.3, 10.2	3.0, 15.2
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	-0.0 (20.5)	-1.7 (21.3)	4.0 (18.2)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 66.7	-100.0, 66.7	-33.3, 33.3
	95% CI	-3.8, 3.8	-6.5, 3.1	-2.4, 10.5
Percent Improved, Stable, or Worsened at Study Month 12	Improved	15 (13.4%)	12 (15.2%)	3 (9.1%)
	Stable	81 (72.3%)	58 (73.4%)	23 (69.7%)
	Worsened	16 (14.3%)	9 (11.4%)	7 (21.2%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	8.2 (18.2)	8.5 (18.7)	7.7 (17.1)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 66.7
	95% CI	4.5, 12.0	3.9, 13.0	0.8, 14.6
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	-0.0 (23.6)	-1.0 (25.3)	2.6 (18.7)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-33.3, 33.3
	95% CI	-4.9, 4.9	-7.2, 5.2	-5.0, 10.1
Percent Improved, Stable, or Worsened at Study Month 15	Improved	14 (15.1%)	11 (16.4%)	3 (11.5%)
	Stable	66 (71.0%)	48 (71.6%)	18 (69.2%)
	Worsened	13 (14.0%)	8 (11.9%)	5 (19.2%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	7.1 (16.1)	6.6 (16.5)	8.7 (15.0)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 33.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 33.3
	95% CI	3.8, 10.4	2.7, 10.5	2.2, 15.2
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	-0.7 (20.7)	-2.3 (22.1)	4.3 (15.3)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 33.3	-100.0, 33.3	-33.3, 33.3
	95% CI	-5.0, 3.5	-7.6, 2.9	-2.2, 10.9
Percent Improved, Stable, or Worsened at Study Month 18	Improved	14 (14.9%)	13 (18.3%)	1 (4.3%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	66 (70.2%)	48 (67.6%)	18 (78.3%)
	Worsened	14 (14.9%)	10 (14.1%)	4 (17.4%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	4.6 (13.0)	5.9 (14.7)	1.7 (7.5)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 66.7	0.0, 66.7	0.0, 33.3
	95% CI	1.4, 7.8	1.5, 10.3	-1.8, 5.2
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	-2.1 (19.4)	-0.7 (20.7)	-5.0 (16.3)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 33.3	-100.0, 33.3	-33.3, 33.3
	95% CI	-6.9, 2.8	-7.0, 5.5	-12.6, 2.6
Percent Improved, Stable, or Worsened at Study Month 21	Improved	8 (12.3%)	4 (8.9%)	4 (20.0%)
	Stable	51 (78.5%)	36 (80.0%)	15 (75.0%)
	Worsened	6 (9.2%)	5 (11.1%)	1 (5.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	3.0 (9.7)	4.2 (11.2)	0.0 (0.0)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	0.0, 33.3	0.0, 33.3	0.0, 0.0
	95% CI	0.1, 6.0	0.1, 8.2	nd
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	-3.8 (20.6)	-4.2 (23.6)	-2.8 (9.6)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
	Min, Max	-100.0, 33.3	-100.0, 33.3	-33.3, 0.0

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	-10.1, 2.5	-12.7, 4.3	-8.9, 3.3
Percent Improved, Stable, or Worsened at Study Month 24	Improved	6 (13.6%)	5 (15.6%)	1 (8.3%)
	Stable	35 (79.5%)	24 (75.0%)	11 (91.7%)
	Worsened	3 (6.8%)	3 (9.4%)	0 (0.0%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

Tabelle 4-17 (Anhang): Ergebnisse der MMRM Analyse zu EORTC QLQ-C30 (Symptomatik) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Table 4.1.07 EORTC QLQ-C30 Fatigue Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	997		
	Number of Observations Used	997		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8704.2		
	AIC (Smaller is Better)	8746.2		
	AICC (Smaller is Better)	8747.2		
	BIC (Smaller is Better)	8823.7		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		13.0 (8.0, 17.9)	13.1 (7.8, 18.5)
	Difference in Mean Change from Screening (95% CI)		-0.2 (-6.1, 5.7)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-2.5 (-7.2, 2.2)	17.9 (12.0, 23.8)
	Difference in Mean Change from Screening (95% CI)		-20.4 (-26.7, -14.1)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-7.3 (-12.4, -2.1)	7.1 (0.8, 13.5)
	Difference in Mean Change from Screening (95% CI)		-14.4 (-21.4, -7.4)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-11.5 (-17.3, -5.7)	-0.4 (-8.1, 7.4)
	Difference in Mean Change from Screening (95% CI)		-11.1 (-19.8, -2.4)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-9.8 (-15.5, -4.1)	-9.3 (-17.1, -1.4)
	Difference in Mean Change from Screening (95% CI)		-0.5 (-9.2, 8.2)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-8.9 (-14.8, -3.0)	-7.6 (-15.8, 0.7)
	Difference in Mean Change from Screening (95% CI)		-1.4 (-10.6, 7.9)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	997		
	Number of Observations Used	997		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8686.2		
	AIC (Smaller is Better)	8728.2		
	AICC (Smaller is Better)	8729.2		
	BIC (Smaller is Better)	8805.7		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		15.3 (9.1, 21.4)	16.5 (10.1, 22.9)
	Difference in Mean Change from Screening (95% CI)		-1.2 (-7.8, 5.3)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-0.4 (-6.5, 5.6)	20.0 (13.5, 26.5)
	Difference in Mean Change from Screening (95% CI)		-20.4 (-26.9, -14.0)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-5.0 (-11.4, 1.3)	9.7 (2.7, 16.6)
	Difference in Mean Change from Screening (95% CI)		-14.7 (-21.9, -7.5)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-9.3 (-16.2, -2.3)	2.1 (-6.1, 10.3)
	Difference in Mean Change from Screening (95% CI)		-11.4 (-20.3, -2.6)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-7.5 (-14.4, -0.6)	-6.8 (-15.2, 1.5)
	Difference in Mean Change from Screening (95% CI)		-0.7 (-9.6, 8.2)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-6.7 (-13.7, 0.3)	-5.0 (-13.8, 3.7)
	Difference in Mean Change from Screening (95% CI)		-1.7 (-11.1, 7.8)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	997		
	Number of Observations Used	997		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8587.4		
	AIC (Smaller is Better)	8629.4		
	AICC (Smaller is Better)	8630.3		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8706.9		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		17.2 (7.8, 26.6)	16.1 (6.9, 25.3)
	Difference in Mean Change from Screening (95% CI)		1.1 (-5.5, 7.7)	nd
	Study Day 100 Mean Change from Screening (95% CI)		1.5 (-7.8, 10.8)	19.5 (10.2, 28.8)
	Difference in Mean Change from Screening (95% CI)		-18.0 (-24.6, -11.4)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-3.1 (-12.6, 6.4)	9.1 (-0.4, 18.6)
	Difference in Mean Change from Screening (95% CI)		-12.1 (-19.2, -5.1)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-7.3 (-17.2, 2.7)	1.6 (-8.9, 12.0)
	Difference in Mean Change from Screening (95% CI)		-8.8 (-17.5, -0.1)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-5.3 (-15.3, 4.6)	-7.4 (-18.1, 3.3)
	Difference in Mean Change from Screening (95% CI)		2.0 (-6.9, 10.9)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-4.6 (-14.6, 5.4)	-5.6 (-16.6, 5.4)
	Difference in Mean Change from Screening (95% CI)		1.0 (-8.4, 10.4)	nd

Data cutoff date = 18MAR2021

Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.

Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.

[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).

Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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Table 4.1.08 EORTC QLQ-C30 Nausea and Vomiting Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	997		
	Number of Observations Used	997		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8055.3		
	AIC (Smaller is Better)	8097.3		
	AICC (Smaller is Better)	8098.3		
	BIC (Smaller is Better)	8174.8		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		2.9 (-0.6, 6.5)	8.2 (4.3, 12.0)
	Difference in Mean Change from Screening (95% CI)		-5.3 (-9.6, -1.0)	nd
	Study Day 100 Mean Change from Screening (95% CI)		1.8 (-2.1, 5.8)	13.9 (8.7, 19.0)
	Difference in Mean Change from Screening (95% CI)		-12.0 (-17.8, -6.2)	nd
	Study Day 150 Mean Change from Screening (95% CI)		1.3 (-1.9, 4.6)	4.3 (0.3, 8.4)
	Difference in Mean Change from Screening (95% CI)		-3.0 (-7.3, 1.3)	nd
	Study Month 9 Mean Change from Screening (95% CI)		0.2 (-3.3, 3.7)	-2.6 (-7.2, 2.0)
	Difference in Mean Change from Screening (95% CI)		2.8 (-2.2, 7.8)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-0.2 (-3.7, 3.3)	-0.2 (-5.0, 4.6)
	Difference in Mean Change from Screening (95% CI)		0.1 (-5.1, 5.2)	nd
	Study Month 15 Mean Change from Screening (95% CI)		0.1 (-3.8, 4.0)	-1.2 (-6.7, 4.2)
	Difference in Mean Change from Screening (95% CI)		1.3 (-4.7, 7.3)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	997		
	Number of Observations Used	997		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8042.4		
	AIC (Smaller is Better)	8084.4		
	AICC (Smaller is Better)	8085.3		
	BIC (Smaller is Better)	8161.9		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		2.3 (-2.0, 6.7)	7.4 (2.8, 12.0)
	Difference in Mean Change from Screening (95% CI)		-5.1 (-9.8, -0.3)	nd
	Study Day 100 Mean Change from Screening (95% CI)		1.3 (-3.4, 6.0)	13.3 (7.8, 18.8)
	Difference in Mean Change from Screening (95% CI)		-12.0 (-17.9, -6.1)	nd
	Study Day 150 Mean Change from Screening (95% CI)		0.7 (-3.5, 5.0)	3.7 (-0.8, 8.2)
	Difference in Mean Change from Screening (95% CI)		-3.0 (-7.5, 1.5)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-0.4 (-4.9, 4.1)	-3.3 (-8.4, 1.8)
	Difference in Mean Change from Screening (95% CI)		2.8 (-2.4, 8.0)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-0.8 (-5.3, 3.7)	-0.9 (-6.1, 4.4)
	Difference in Mean Change from Screening (95% CI)		0.1 (-5.2, 5.4)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-0.5 (-5.3, 4.3)	-1.9 (-7.7, 4.0)
	Difference in Mean Change from Screening (95% CI)		1.4 (-4.8, 7.5)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	997		
	Number of Observations Used	997		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	7967.9		
	AIC (Smaller is Better)	8009.9		
	AICC (Smaller is Better)	8010.9		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8087.4		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		2.9 (-3.9, 9.7)	7.5 (0.9, 14.2)
	Difference in Mean Change from Screening (95% CI)		-4.7 (-9.5, 0.2)	nd
	Study Day 100 Mean Change from Screening (95% CI)		1.7 (-5.3, 8.7)	13.5 (6.2, 20.8)
	Difference in Mean Change from Screening (95% CI)		-11.8 (-17.8, -5.8)	nd
	Study Day 150 Mean Change from Screening (95% CI)		1.2 (-5.6, 7.9)	4.0 (-2.7, 10.6)
	Difference in Mean Change from Screening (95% CI)		-2.8 (-7.4, 1.8)	nd
	Study Month 9 Mean Change from Screening (95% CI)		0.1 (-6.8, 7.0)	-3.0 (-10.0, 4.0)
	Difference in Mean Change from Screening (95% CI)		3.1 (-2.1, 8.4)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-0.1 (-7.0, 6.7)	-0.7 (-7.9, 6.5)
	Difference in Mean Change from Screening (95% CI)		0.5 (-4.8, 5.9)	nd
	Study Month 15 Mean Change from Screening (95% CI)		0.0 (-7.0, 7.1)	-1.6 (-9.2, 6.0)
	Difference in Mean Change from Screening (95% CI)		1.6 (-4.5, 7.8)	nd

Data cutoff date = 18MAR2021

Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.

Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.

[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).

Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Table 4.1.09 EORTC QLQ-C30 Pain Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	998		
	Number of Observations Used	998		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8735.5		
	AIC (Smaller is Better)	8777.5		
	AICC (Smaller is Better)	8778.5		
	BIC (Smaller is Better)	8855		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-4.1 (-9.4, 1.2)	-3.6 (-9.3, 2.1)
	Difference in Mean Change from Screening (95% CI)		-0.5 (-6.7, 5.6)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-3.4 (-8.6, 1.8)	-6.8 (-13.2, -0.3)
	Difference in Mean Change from Screening (95% CI)		3.4 (-3.4, 10.2)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-4.0 (-9.7, 1.7)	-10.2 (-17.2, -3.2)
	Difference in Mean Change from Screening (95% CI)		6.2 (-1.5, 14.0)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-5.7 (-11.3, -0.1)	-12.8 (-20.0, -5.5)
	Difference in Mean Change from Screening (95% CI)		7.0 (-0.9, 14.9)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-6.5 (-12.3, -0.6)	-13.5 (-21.2, -5.9)
	Difference in Mean Change from Screening (95% CI)		7.1 (-1.3, 15.5)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-6.3 (-12.5, -0.0)	-15.3 (-23.9, -6.8)
	Difference in Mean Change from Screening (95% CI)		9.0 (-0.5, 18.6)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	998		
	Number of Observations Used	998		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8719.9		
	AIC (Smaller is Better)	8761.9		
	AICC (Smaller is Better)	8762.9		
	BIC (Smaller is Better)	8839.4		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-5.3 (-12.1, 1.4)	-4.5 (-11.4, 2.5)
	Difference in Mean Change from Screening (95% CI)		-0.8 (-7.8, 6.1)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-4.6 (-11.3, 2.1)	-7.7 (-14.8, -0.5)
	Difference in Mean Change from Screening (95% CI)		3.0 (-4.1, 10.1)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-5.2 (-12.3, 2.0)	-11.0 (-18.8, -3.3)
	Difference in Mean Change from Screening (95% CI)		5.9 (-2.2, 13.9)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-6.9 (-14.0, 0.3)	-13.6 (-21.6, -5.6)
	Difference in Mean Change from Screening (95% CI)		6.7 (-1.5, 14.9)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-7.6 (-14.9, -0.3)	-14.3 (-22.7, -6.0)
	Difference in Mean Change from Screening (95% CI)		6.7 (-2.0, 15.4)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-7.4 (-15.0, 0.2)	-16.2 (-25.4, -6.9)
	Difference in Mean Change from Screening (95% CI)		8.7 (-1.1, 18.5)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	998		
	Number of Observations Used	998		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8627.2		
	AIC (Smaller is Better)	8669.2		
	AICC (Smaller is Better)	8670.1		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8746.7		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-7.6 (-18.2, 3.0)	-8.6 (-18.8, 1.6)
	Difference in Mean Change from Screening (95% CI)		1.0 (-6.0, 8.0)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-6.8 (-17.4, 3.7)	-11.9 (-22.3, -1.5)
	Difference in Mean Change from Screening (95% CI)		5.1 (-2.1, 12.3)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-7.4 (-18.1, 3.4)	-15.3 (-26.1, -4.5)
	Difference in Mean Change from Screening (95% CI)		8.0 (-0.2, 16.1)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-9.0 (-19.8, 1.9)	-17.8 (-28.8, -6.8)
	Difference in Mean Change from Screening (95% CI)		8.8 (0.4, 17.2)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-9.7 (-20.6, 1.3)	-18.4 (-29.7, -7.1)
	Difference in Mean Change from Screening (95% CI)		8.8 (-0.0, 17.6)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-9.5 (-20.7, 1.7)	-20.3 (-32.3, -8.3)
	Difference in Mean Change from Screening (95% CI)		10.8 (0.8, 20.7)	nd

Data cutoff date = 18MAR2021

Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.

Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.

[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).

Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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Table 4.1.10 EORTC QLQ-C30 Dyspnea Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	995		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8748.8		
	AIC (Smaller is Better)	8790.8		
	AICC (Smaller is Better)	8791.7		
	BIC (Smaller is Better)	8868.2		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		0.9 (-3.8, 5.6)	8.8 (3.7, 13.8)
	Difference in Mean Change from Screening (95% CI)		-7.8 (-13.4, -2.3)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-1.8 (-6.8, 3.3)	15.2 (8.6, 21.8)
	Difference in Mean Change from Screening (95% CI)		-16.9 (-24.2, -9.7)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-2.3 (-8.2, 3.6)	11.5 (3.9, 19.1)
	Difference in Mean Change from Screening (95% CI)		-13.8 (-22.5, -5.2)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-7.3 (-12.8, -1.8)	7.7 (0.5, 15.0)
	Difference in Mean Change from Screening (95% CI)		-15.0 (-23.1, -6.9)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-3.7 (-8.9, 1.6)	-3.3 (-10.4, 3.8)
	Difference in Mean Change from Screening (95% CI)		-0.4 (-8.1, 7.4)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-4.6 (-10.3, 1.1)	1.6 (-6.0, 9.2)
	Difference in Mean Change from Screening (95% CI)		-6.2 (-14.7, 2.4)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	995		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8728.8		
	AIC (Smaller is Better)	8770.8		
	AICC (Smaller is Better)	8771.8		
	BIC (Smaller is Better)	8848.3		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		5.6 (-0.6, 11.7)	12.8 (6.4, 19.1)
	Difference in Mean Change from Screening (95% CI)		-7.2 (-13.3, -1.0)	nd
	Study Day 100 Mean Change from Screening (95% CI)		2.9 (-3.6, 9.3)	18.6 (11.5, 25.8)
	Difference in Mean Change from Screening (95% CI)		-15.8 (-23.1, -8.4)	nd
	Study Day 150 Mean Change from Screening (95% CI)		2.3 (-4.7, 9.3)	15.0 (7.0, 23.0)
	Difference in Mean Change from Screening (95% CI)		-12.7 (-21.3, -4.0)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-2.5 (-9.3, 4.3)	11.5 (3.6, 19.4)
	Difference in Mean Change from Screening (95% CI)		-14.0 (-22.3, -5.7)	nd
	Study Month 12 Mean Change from Screening (95% CI)		1.2 (-5.4, 7.8)	0.5 (-7.2, 8.2)
	Difference in Mean Change from Screening (95% CI)		0.7 (-7.2, 8.6)	nd
	Study Month 15 Mean Change from Screening (95% CI)		0.0 (-6.9, 7.0)	5.2 (-3.1, 13.5)
	Difference in Mean Change from Screening (95% CI)		-5.1 (-14.0, 3.7)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	995		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8649.2		
	AIC (Smaller is Better)	8691.2		
	AICC (Smaller is Better)	8692.2		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8768.6		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		9.1 (-0.5, 18.7)	15.1 (5.8, 24.5)
	Difference in Mean Change from Screening (95% CI)		-6.0 (-12.4, 0.3)	nd
	Study Day 100 Mean Change from Screening (95% CI)		6.4 (-3.4, 16.1)	21.0 (11.1, 30.9)
	Difference in Mean Change from Screening (95% CI)		-14.6 (-22.1, -7.1)	nd
	Study Day 150 Mean Change from Screening (95% CI)		5.8 (-4.4, 16.0)	17.3 (6.8, 27.8)
	Difference in Mean Change from Screening (95% CI)		-11.5 (-20.3, -2.8)	nd
	Study Month 9 Mean Change from Screening (95% CI)		1.1 (-9.0, 11.1)	13.9 (3.5, 24.4)
	Difference in Mean Change from Screening (95% CI)		-12.9 (-21.2, -4.5)	nd
	Study Month 12 Mean Change from Screening (95% CI)		4.8 (-5.1, 14.6)	3.1 (-7.3, 13.5)
	Difference in Mean Change from Screening (95% CI)		1.7 (-6.4, 9.7)	nd
	Study Month 15 Mean Change from Screening (95% CI)		3.6 (-6.5, 13.8)	7.7 (-3.0, 18.4)
	Difference in Mean Change from Screening (95% CI)		-4.0 (-13.0, 4.9)	nd

Data cutoff date = 18MAR2021

Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.

Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.

[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).

Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Table 4.1.11 EORTC QLQ-C30 Insomnia Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	9082.5		
	AIC (Smaller is Better)	9124.5		
	AICC (Smaller is Better)	9125.4		
	BIC (Smaller is Better)	9202		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-1.1 (-7.2, 5.0)	0.1 (-6.5, 6.6)
	Difference in Mean Change from Screening (95% CI)		-1.1 (-8.2, 5.9)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-4.6 (-11.0, 1.8)	5.9 (-2.2, 14.1)
	Difference in Mean Change from Screening (95% CI)		-10.5 (-19.3, -1.7)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-6.0 (-12.6, 0.5)	-1.3 (-9.4, 6.8)
	Difference in Mean Change from Screening (95% CI)		-4.7 (-13.5, 4.1)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-7.7 (-14.2, -1.2)	-5.6 (-14.1, 2.9)
	Difference in Mean Change from Screening (95% CI)		-2.1 (-11.3, 7.1)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-4.8 (-11.9, 2.2)	-4.5 (-13.9, 5.0)
	Difference in Mean Change from Screening (95% CI)		-0.4 (-10.8, 10.1)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-7.0 (-13.7, -0.4)	-4.2 (-13.2, 4.8)
	Difference in Mean Change from Screening (95% CI)		-2.8 (-12.6, 6.9)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	9065		
	AIC (Smaller is Better)	9107		
	AICC (Smaller is Better)	9108		
	BIC (Smaller is Better)	9184.5		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		0.5 (-7.3, 8.3)	2.4 (-5.6, 10.3)
	Difference in Mean Change from Screening (95% CI)		-1.9 (-9.8, 6.0)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-3.2 (-11.2, 4.9)	7.6 (-1.2, 16.3)
	Difference in Mean Change from Screening (95% CI)		-10.7 (-19.9, -1.6)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-4.4 (-12.6, 3.8)	0.6 (-8.3, 9.4)
	Difference in Mean Change from Screening (95% CI)		-4.9 (-14.1, 4.2)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-6.0 (-14.3, 2.3)	-3.7 (-13.0, 5.5)
	Difference in Mean Change from Screening (95% CI)		-2.3 (-11.8, 7.2)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-3.2 (-11.8, 5.5)	-2.6 (-12.7, 7.5)
	Difference in Mean Change from Screening (95% CI)		-0.6 (-11.3, 10.2)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-5.3 (-13.7, 3.0)	-2.3 (-12.0, 7.5)
	Difference in Mean Change from Screening (95% CI)		-3.1 (-13.2, 7.1)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8981.1		
	AIC (Smaller is Better)	9023.1		
	AICC (Smaller is Better)	9024.1		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	9100.6		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		4.1 (-8.4, 16.5)	4.7 (-7.4, 16.7)
	Difference in Mean Change from Screening (95% CI)		-0.6 (-8.8, 7.6)	nd
	Study Day 100 Mean Change from Screening (95% CI)		0.4 (-12.2, 13.0)	10.0 (-2.5, 22.5)
	Difference in Mean Change from Screening (95% CI)		-9.5 (-18.9, -0.2)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-0.7 (-13.4, 12.1)	2.9 (-9.8, 15.5)
	Difference in Mean Change from Screening (95% CI)		-3.5 (-13.0, 5.9)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-2.2 (-15.0, 10.5)	-1.2 (-14.2, 11.7)
	Difference in Mean Change from Screening (95% CI)		-1.0 (-10.8, 8.8)	nd
	Study Month 12 Mean Change from Screening (95% CI)		0.6 (-12.4, 13.6)	-0.2 (-13.8, 13.4)
	Difference in Mean Change from Screening (95% CI)		0.8 (-10.3, 11.9)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-1.5 (-14.3, 11.3)	0.2 (-13.2, 13.6)
	Difference in Mean Change from Screening (95% CI)		-1.7 (-12.2, 8.7)	nd

Data cutoff date = 18MAR2021

Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.

Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.

[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).

Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Table 4.1.12 EORTC QLQ-C30 Appetite Loss Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	9034.9		
	AIC (Smaller is Better)	9076.9		
	AICC (Smaller is Better)	9077.9		
	BIC (Smaller is Better)	9154.4		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		17.1 (10.7, 23.5)	9.7 (2.8, 16.7)
	Difference in Mean Change from Screening (95% CI)		7.4 (-0.5, 15.3)	nd
	Study Day 100 Mean Change from Screening (95% CI)		1.2 (-4.7, 7.1)	23.6 (15.9, 31.3)
	Difference in Mean Change from Screening (95% CI)		-22.4 (-30.6, -14.2)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-1.7 (-7.4, 4.1)	5.8 (-1.4, 13.0)
	Difference in Mean Change from Screening (95% CI)		-7.5 (-15.1, 0.1)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-5.7 (-12.0, 0.7)	0.2 (-8.0, 8.4)
	Difference in Mean Change from Screening (95% CI)		-5.9 (-14.8, 3.1)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-5.8 (-12.0, 0.5)	-0.6 (-8.9, 7.7)
	Difference in Mean Change from Screening (95% CI)		-5.2 (-14.2, 3.8)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-3.2 (-9.8, 3.4)	-1.9 (-11.0, 7.2)
	Difference in Mean Change from Screening (95% CI)		-1.3 (-11.3, 8.7)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	9015.7		
	AIC (Smaller is Better)	9057.7		
	AICC (Smaller is Better)	9058.6		
	BIC (Smaller is Better)	9135.2		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		21.0 (13.2, 28.7)	11.8 (3.6, 20.0)
	Difference in Mean Change from Screening (95% CI)		9.2 (0.5, 17.9)	nd
	Study Day 100 Mean Change from Screening (95% CI)		5.3 (-2.2, 12.8)	26.3 (18.0, 34.6)
	Difference in Mean Change from Screening (95% CI)		-21.0 (-29.4, -12.6)	nd
	Study Day 150 Mean Change from Screening (95% CI)		2.6 (-4.8, 10.0)	8.6 (0.7, 16.5)
	Difference in Mean Change from Screening (95% CI)		-6.0 (-13.8, 1.9)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-1.3 (-9.2, 6.6)	3.0 (-6.0, 11.9)
	Difference in Mean Change from Screening (95% CI)		-4.3 (-13.6, 5.0)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-1.4 (-9.2, 6.5)	2.3 (-6.8, 11.3)
	Difference in Mean Change from Screening (95% CI)		-3.6 (-12.9, 5.7)	nd
	Study Month 15 Mean Change from Screening (95% CI)		1.2 (-6.9, 9.4)	1.0 (-8.8, 10.8)
	Difference in Mean Change from Screening (95% CI)		0.2 (-10.0, 10.5)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8928.4		
	AIC (Smaller is Better)	8970.4		
	AICC (Smaller is Better)	8971.4		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	9047.9		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		25.3 (13.3, 37.3)	15.0 (3.1, 26.8)
	Difference in Mean Change from Screening (95% CI)		10.3 (1.4, 19.3)	nd
	Study Day 100 Mean Change from Screening (95% CI)		9.4 (-2.4, 21.3)	29.6 (17.8, 41.5)
	Difference in Mean Change from Screening (95% CI)		-20.2 (-28.8, -11.7)	nd
	Study Day 150 Mean Change from Screening (95% CI)		6.9 (-4.9, 18.7)	11.5 (-0.1, 23.1)
	Difference in Mean Change from Screening (95% CI)		-4.6 (-12.8, 3.6)	nd
	Study Month 9 Mean Change from Screening (95% CI)		3.0 (-9.1, 15.1)	5.9 (-6.4, 18.3)
	Difference in Mean Change from Screening (95% CI)		-2.9 (-12.5, 6.6)	nd
	Study Month 12 Mean Change from Screening (95% CI)		3.1 (-9.0, 15.2)	5.1 (-7.5, 17.6)
	Difference in Mean Change from Screening (95% CI)		-2.0 (-11.6, 7.7)	nd
	Study Month 15 Mean Change from Screening (95% CI)		5.6 (-6.7, 17.9)	3.9 (-9.2, 16.9)
	Difference in Mean Change from Screening (95% CI)		1.8 (-8.6, 12.2)	nd

Data cutoff date = 18MAR2021

Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.

Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.

[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).

Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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Table 4.1.13 EORTC QLQ-C30 Constipation Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	995		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8564.1		
	AIC (Smaller is Better)	8606.1		
	AICC (Smaller is Better)	8607.1		
	BIC (Smaller is Better)	8683.6		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-6.1 (-11.6, -0.5)	3.7 (-2.3, 9.6)
	Difference in Mean Change from Screening (95% CI)		-9.8 (-16.5, -3.0)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-3.0 (-8.6, 2.5)	-6.2 (-13.0, 0.5)
	Difference in Mean Change from Screening (95% CI)		3.2 (-4.2, 10.6)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-4.2 (-9.6, 1.2)	-9.9 (-16.4, -3.3)
	Difference in Mean Change from Screening (95% CI)		5.7 (-1.5, 12.8)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-3.9 (-9.0, 1.1)	-13.8 (-20.0, -7.6)
	Difference in Mean Change from Screening (95% CI)		9.9 (3.3, 16.4)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-6.0 (-11.7, -0.3)	-12.9 (-20.1, -5.7)
	Difference in Mean Change from Screening (95% CI)		6.9 (-1.0, 14.8)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-2.6 (-7.5, 2.4)	-13.5 (-20.1, -6.9)
	Difference in Mean Change from Screening (95% CI)		10.9 (4.1, 17.8)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	995		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8546.2		
	AIC (Smaller is Better)	8588.2		
	AICC (Smaller is Better)	8589.2		
	BIC (Smaller is Better)	8665.7		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-4.5 (-11.3, 2.4)	6.3 (-0.7, 13.4)
	Difference in Mean Change from Screening (95% CI)		-10.8 (-18.2, -3.4)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-1.5 (-8.4, 5.4)	-4.1 (-11.6, 3.4)
	Difference in Mean Change from Screening (95% CI)		2.6 (-5.3, 10.4)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-2.8 (-9.7, 4.0)	-8.0 (-15.3, -0.7)
	Difference in Mean Change from Screening (95% CI)		5.1 (-2.4, 12.6)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-2.6 (-9.2, 4.1)	-11.9 (-19.0, -4.8)
	Difference in Mean Change from Screening (95% CI)		9.3 (2.4, 16.3)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-4.6 (-11.6, 2.5)	-10.8 (-18.8, -2.9)
	Difference in Mean Change from Screening (95% CI)		6.2 (-2.1, 14.6)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-1.3 (-7.9, 5.3)	-11.8 (-19.2, -4.3)
	Difference in Mean Change from Screening (95% CI)		10.5 (3.3, 17.6)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	995		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8458.6		
	AIC (Smaller is Better)	8500.6		
	AICC (Smaller is Better)	8501.6		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8578.1		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-4.3 (-15.0, 6.5)	5.5 (-5.0, 15.9)
	Difference in Mean Change from Screening (95% CI)		-9.7 (-17.3, -2.1)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-1.3 (-12.1, 9.6)	-4.8 (-15.5, 6.0)
	Difference in Mean Change from Screening (95% CI)		3.5 (-4.6, 11.6)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-2.5 (-13.3, 8.3)	-8.6 (-19.2, 2.0)
	Difference in Mean Change from Screening (95% CI)		6.1 (-1.5, 13.8)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-2.2 (-12.8, 8.5)	-12.5 (-22.9, -2.0)
	Difference in Mean Change from Screening (95% CI)		10.3 (3.2, 17.4)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-4.2 (-15.1, 6.7)	-11.5 (-22.6, -0.5)
	Difference in Mean Change from Screening (95% CI)		7.3 (-1.0, 15.6)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-0.7 (-11.4, 9.9)	-12.3 (-23.2, -1.4)
	Difference in Mean Change from Screening (95% CI)		11.5 (4.2, 18.9)	nd

Data cutoff date = 18MAR2021

Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.

Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.

[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).

Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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Table 4.1.14 EORTC QLQ-C30 Diarrhea Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	995		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8852.3		
	AIC (Smaller is Better)	8894.3		
	AICC (Smaller is Better)	8895.3		
	BIC (Smaller is Better)	8971.8		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-1.2 (-6.0, 3.5)	-0.3 (-5.4, 4.8)
	Difference in Mean Change from Screening (95% CI)		-0.9 (-6.5, 4.6)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-2.1 (-7.5, 3.3)	15.5 (8.4, 22.7)
	Difference in Mean Change from Screening (95% CI)		-17.6 (-25.5, -9.7)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-1.9 (-7.2, 3.3)	-0.1 (-6.7, 6.4)
	Difference in Mean Change from Screening (95% CI)		-1.8 (-9.1, 5.5)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-1.5 (-7.3, 4.2)	2.7 (-5.1, 10.5)
	Difference in Mean Change from Screening (95% CI)		-4.3 (-13.0, 4.5)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-3.1 (-8.2, 2.1)	0.4 (-6.7, 7.5)
	Difference in Mean Change from Screening (95% CI)		-3.5 (-11.2, 4.3)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-0.6 (-6.3, 5.2)	0.3 (-7.9, 8.5)
	Difference in Mean Change from Screening (95% CI)		-0.9 (-10.0, 8.2)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	995		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8834.5		
	AIC (Smaller is Better)	8876.5		
	AICC (Smaller is Better)	8877.4		
	BIC (Smaller is Better)	8954		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		1.2 (-4.8, 7.1)	-0.1 (-6.3, 6.1)
	Difference in Mean Change from Screening (95% CI)		1.3 (-5.0, 7.5)	nd
	Study Day 100 Mean Change from Screening (95% CI)		0.5 (-6.0, 7.0)	16.3 (8.8, 23.8)
	Difference in Mean Change from Screening (95% CI)		-15.8 (-24.0, -7.6)	nd
	Study Day 150 Mean Change from Screening (95% CI)		0.4 (-6.0, 6.9)	0.4 (-6.7, 7.6)
	Difference in Mean Change from Screening (95% CI)		0.0 (-7.6, 7.6)	nd
	Study Month 9 Mean Change from Screening (95% CI)		0.8 (-6.1, 7.8)	3.5 (-4.8, 11.7)
	Difference in Mean Change from Screening (95% CI)		-2.6 (-11.6, 6.3)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-0.7 (-7.2, 5.8)	1.2 (-6.4, 8.9)
	Difference in Mean Change from Screening (95% CI)		-2.0 (-10.0, 6.0)	nd
	Study Month 15 Mean Change from Screening (95% CI)		1.9 (-5.1, 8.8)	1.0 (-7.7, 9.6)
	Difference in Mean Change from Screening (95% CI)		0.9 (-8.5, 10.3)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	995		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8760.4		
	AIC (Smaller is Better)	8802.4		
	AICC (Smaller is Better)	8803.4		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8879.9		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		4.8 (-4.9, 14.5)	3.3 (-6.1, 12.6)
	Difference in Mean Change from Screening (95% CI)		1.5 (-4.9, 8.0)	nd
	Study Day 100 Mean Change from Screening (95% CI)		4.2 (-5.9, 14.2)	19.6 (9.3, 29.8)
	Difference in Mean Change from Screening (95% CI)		-15.4 (-23.8, -7.0)	nd
	Study Day 150 Mean Change from Screening (95% CI)		4.1 (-5.9, 14.2)	3.7 (-6.4, 13.7)
	Difference in Mean Change from Screening (95% CI)		0.5 (-7.5, 8.4)	nd
	Study Month 9 Mean Change from Screening (95% CI)		4.5 (-5.9, 14.8)	6.8 (-4.1, 17.7)
	Difference in Mean Change from Screening (95% CI)		-2.4 (-11.5, 6.8)	nd
	Study Month 12 Mean Change from Screening (95% CI)		2.9 (-7.1, 12.9)	4.7 (-5.9, 15.3)
	Difference in Mean Change from Screening (95% CI)		-1.8 (-10.1, 6.4)	nd
	Study Month 15 Mean Change from Screening (95% CI)		5.5 (-4.8, 15.8)	4.4 (-6.8, 15.6)
	Difference in Mean Change from Screening (95% CI)		1.1 (-8.4, 10.6)	nd

Data cutoff date = 18MAR2021

Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.

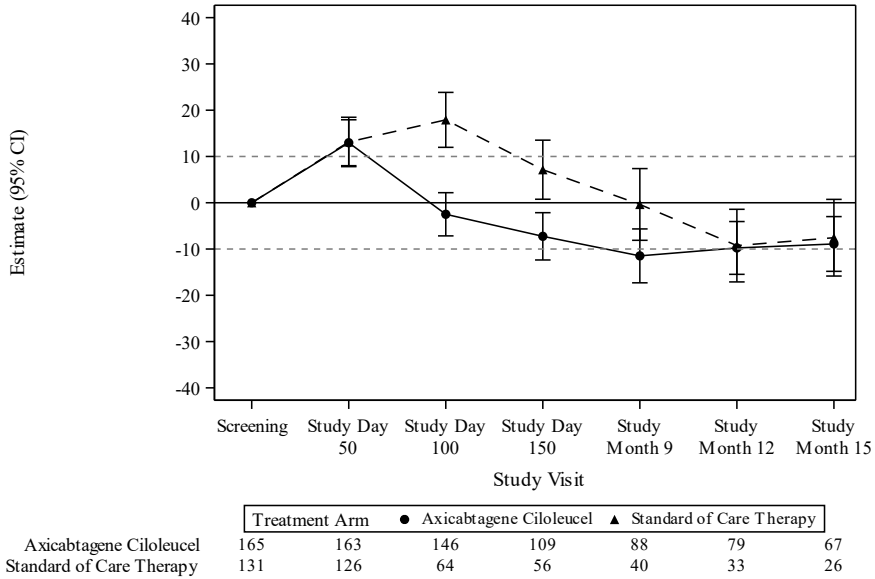
Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.

[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).

Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Abbildung 8 (Anhang): Verlaufskurven zu EORTC QLQ-C30 (Symptomatik) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Figure 4.1.07.1 EORTC QLQ-C30 Fatigue Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.07. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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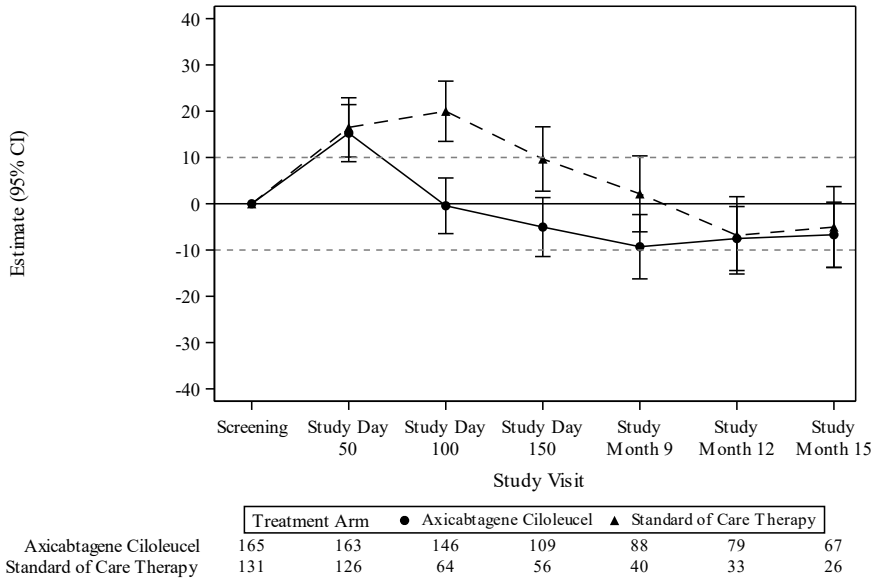
Figure 4.1.07.2 EORTC QLQ-C30 Fatigue Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Axicabtagene Ciloleucel	165	163	146	109	88	79	67
Standard of Care Therapy	131	126	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.07. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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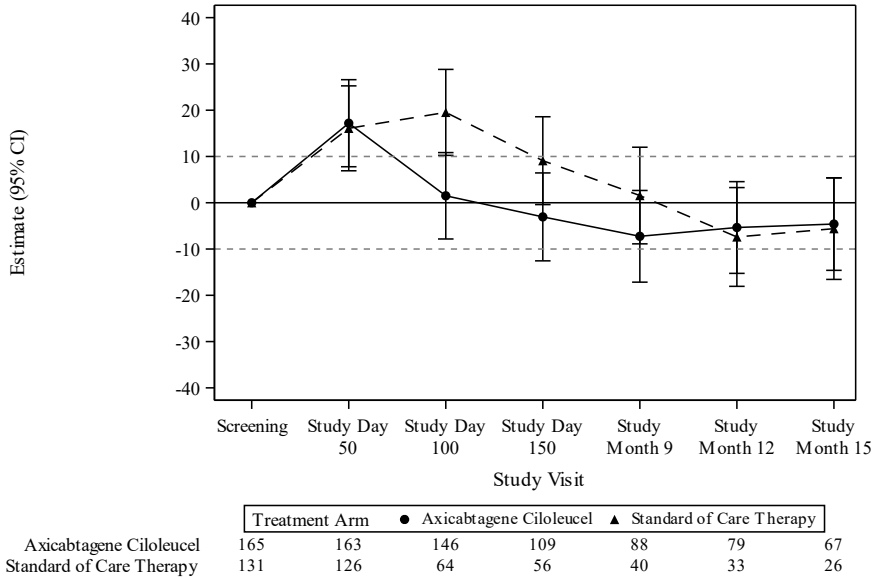
Figure 4.1.07.3 EORTC QLQ-C30 Fatigue Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Axicabtagene Ciloleucel	165	163	146	109	88	79	67
Standard of Care Therapy	131	126	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.07. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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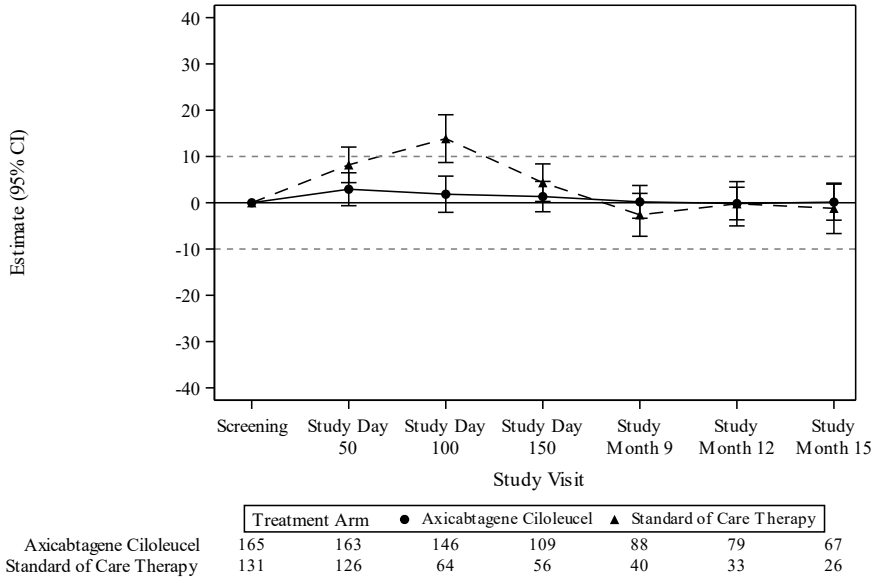
Figure 4.1.08.1 EORTC QLQ-C30 Nausea and Vomiting Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.08. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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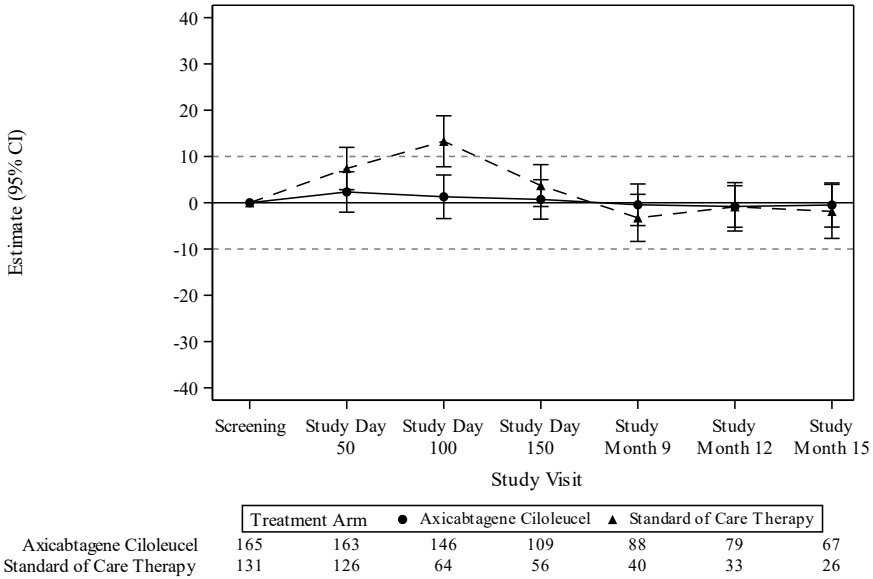
Figure 4.1.08.2 EORTC QLQ-C30 Nausea and Vomiting Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.08. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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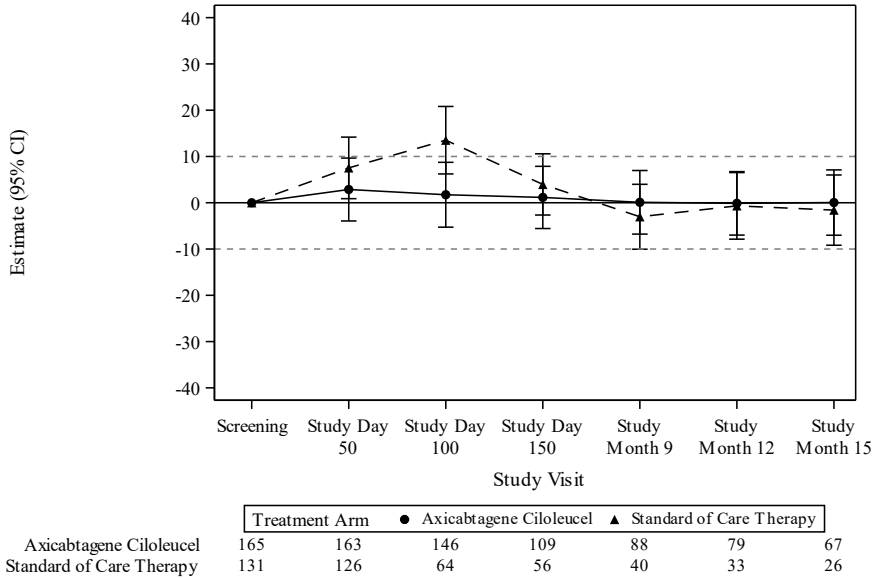
Figure 4.1.08.3 EORTC QLQ-C30 Nausea and Vomiting Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.08. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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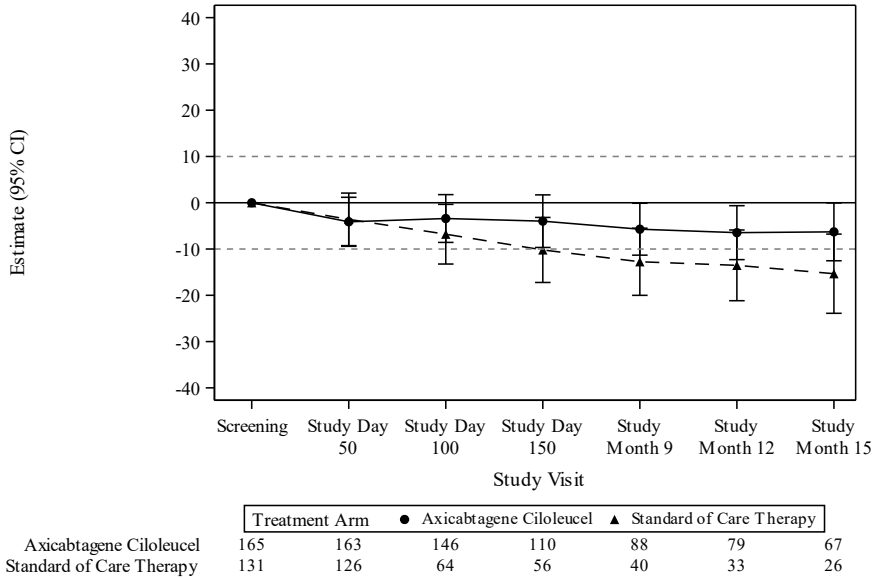
Figure 4.1.09.1 EORTC QLQ-C30 Pain Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.09. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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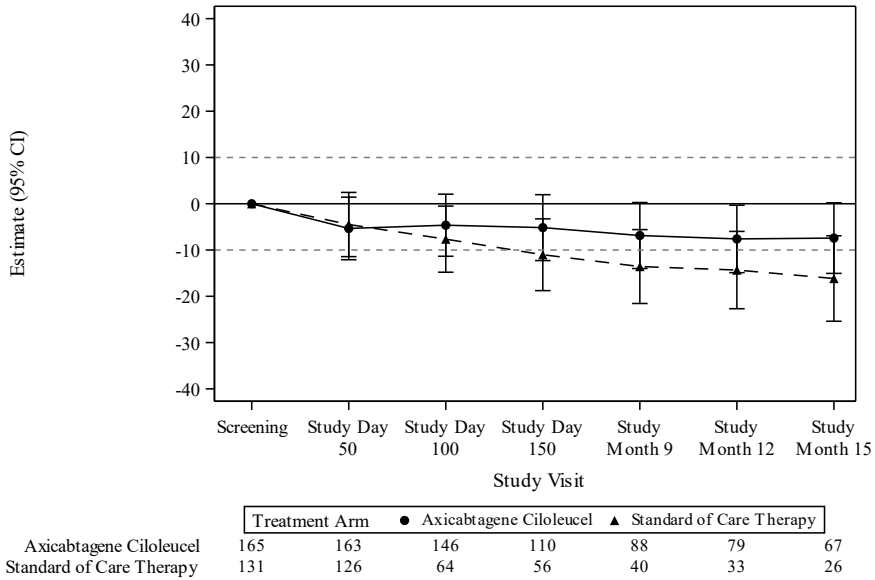
Figure 4.1.09.2 EORTC QLQ-C30 Pain Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.09. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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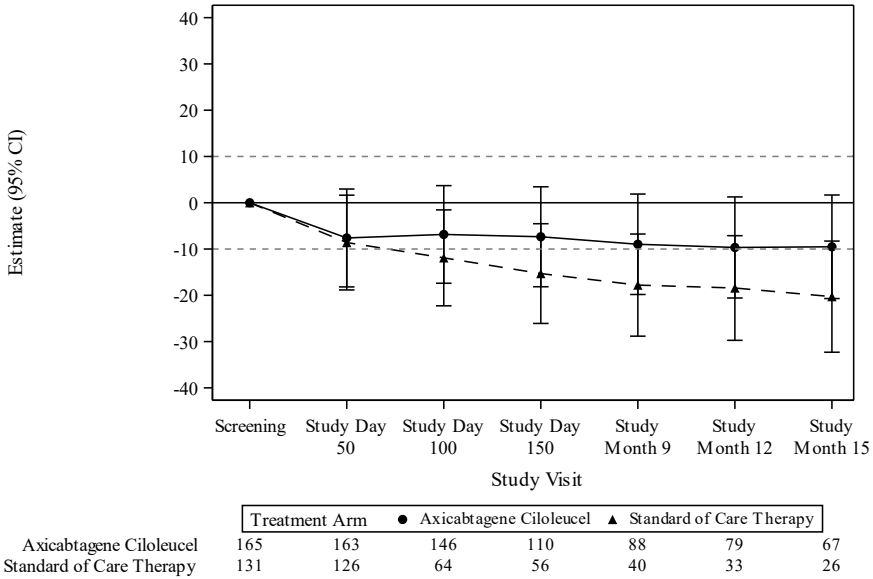
Figure 4.1.09.3 EORTC QLQ-C30 Pain Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.09. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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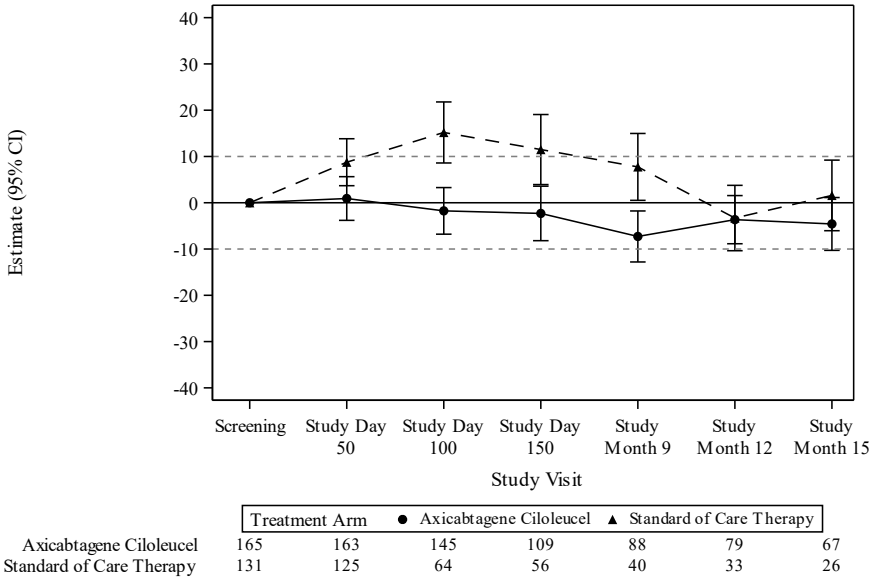
Figure 4.1.10.1 EORTC QLQ-C30 Dyspnea Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Axicabtagene Ciloleucel	165	163	145	109	88	79	67
Standard of Care Therapy	131	125	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.10. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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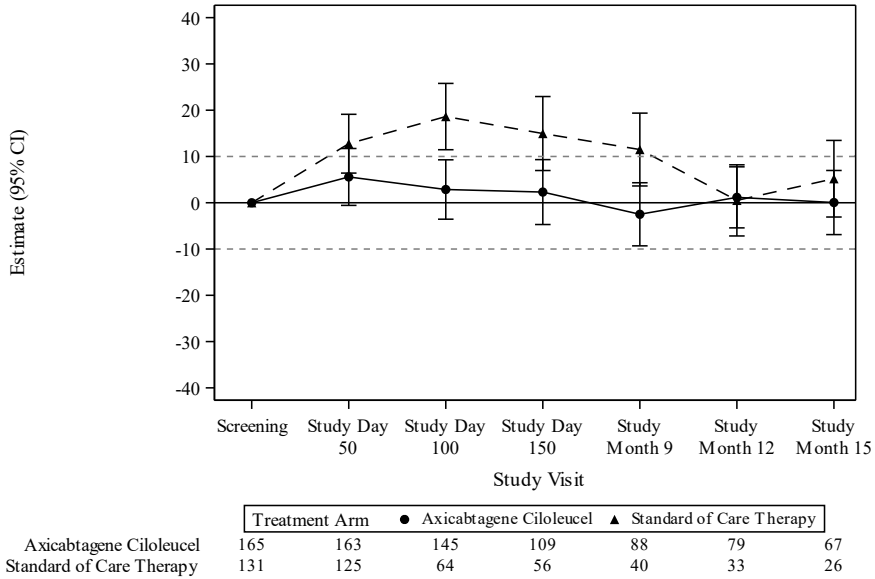
Figure 4.1.10.2 EORTC QLQ-C30 Dyspnea Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Axicabtagene Ciloleucel	165	163	145	109	88	79	67
Standard of Care Therapy	131	125	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.10. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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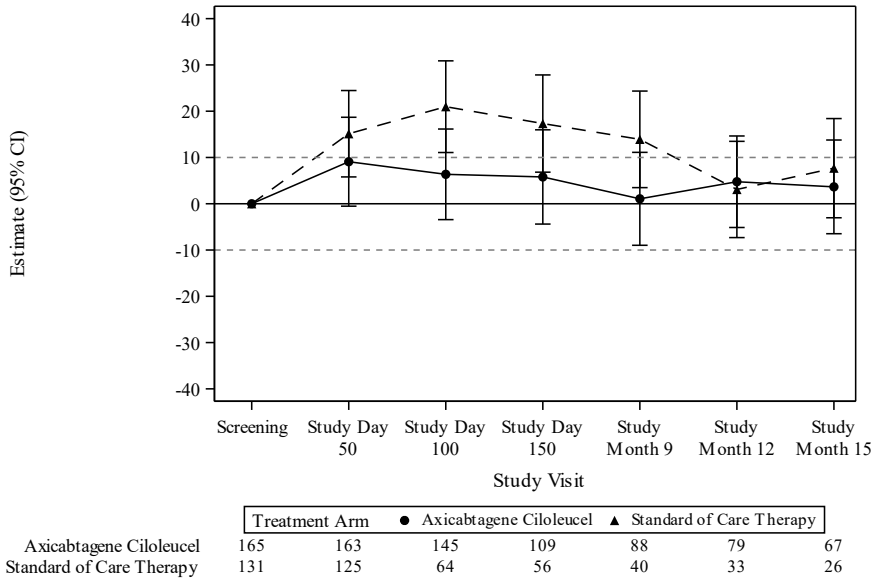
Version: 1.0 (10Aug2021)

Figure 4.1.10.3 EORTC QLQ-C30 Dyspnea Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Axicabtagene Ciloleucel	165	163	145	109	88	79	67
Standard of Care Therapy	131	125	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.10. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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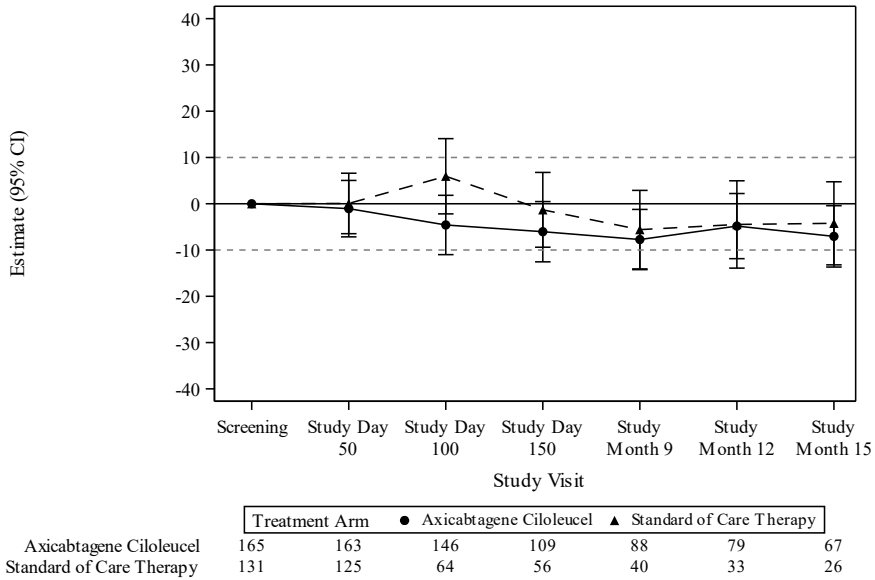
Version: 1.0 (10Aug2021)

Figure 4.1.11.1 EORTC QLQ-C30 Insomnia Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Axicabtagene Ciloleucel	165	163	146	109	88	79	67
Standard of Care Therapy	131	125	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.11. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

PRO Tables
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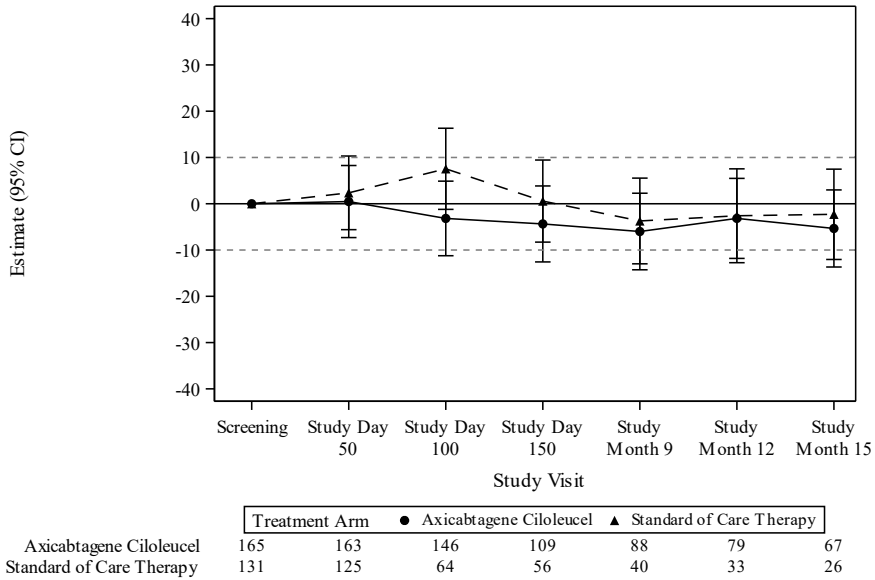
Version: 1.0 (10Aug2021)

Figure 4.1.11.2 EORTC QLQ-C30 Insomnia Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Axicabtagene Ciloleucel	165	163	146	109	88	79	67
Standard of Care Therapy	131	125	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.11. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

PRO Tables
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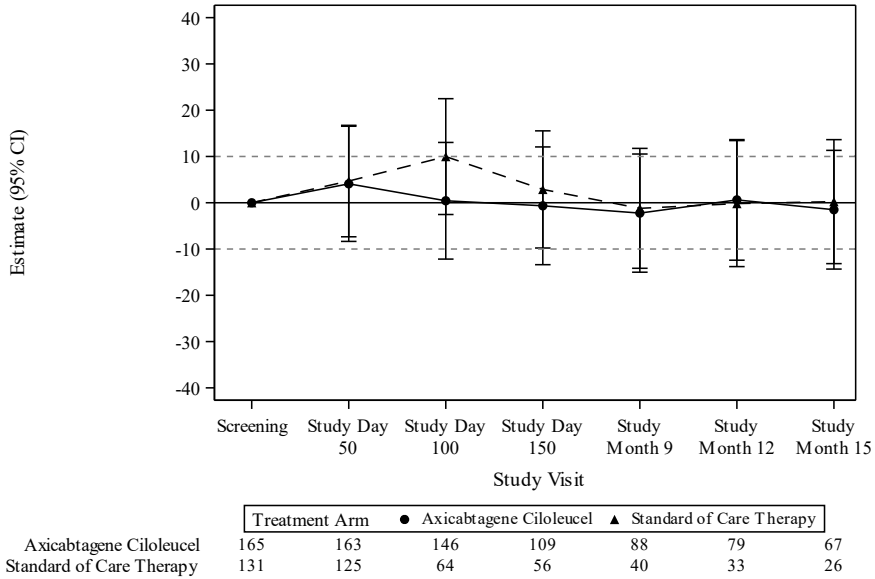
Version: 1.0 (10Aug2021)

Figure 4.1.11.3 EORTC QLQ-C30 Insomnia Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Axicabtagene Ciloleucel	165	163	146	109	88	79	67
Standard of Care Therapy	131	125	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.11. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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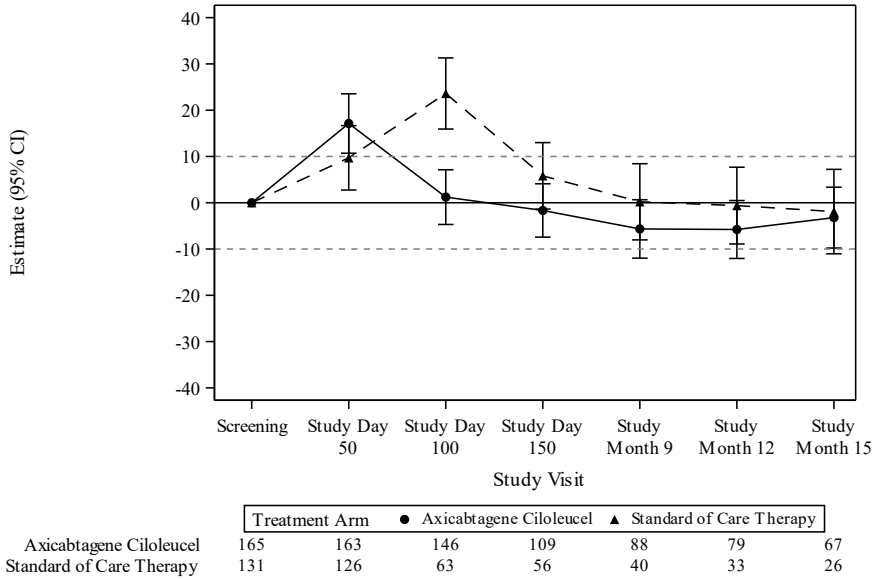
Version: 1.0 (10Aug2021)

Figure 4.1.12.1 EORTC QLQ-C30 Appetite Loss Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Axicabtagene Ciloleucel	165	163	146	109	88	79	67
Standard of Care Therapy	131	126	63	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.12. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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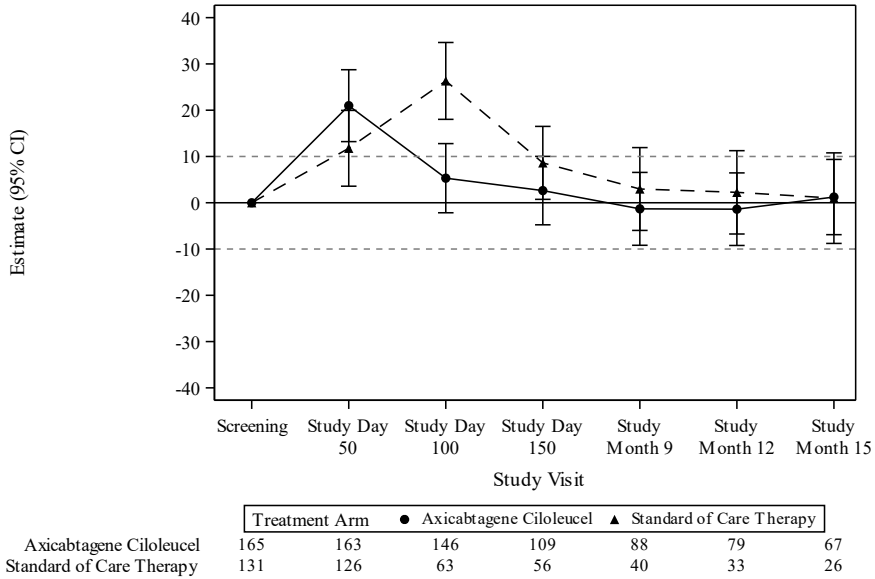
Protocol KTE-C19-107
Version: 1.0 (10Aug2021)

Figure 4.1.12.2 EORTC QLQ-C30 Appetite Loss Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Axicabtagene Ciloleucel	165	163	146	109	88	79	67
Standard of Care Therapy	131	126	63	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.12. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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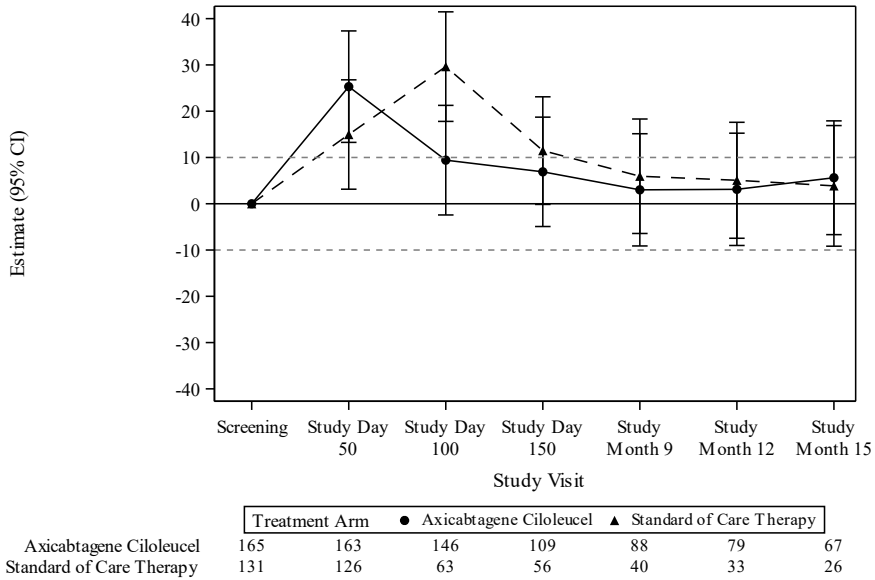
Version: 1.0 (10Aug2021)

Figure 4.1.12.3 EORTC QLQ-C30 Appetite Loss Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Axicabtagene Ciloleucel	165	163	146	109	88	79	67
Standard of Care Therapy	131	126	63	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.12. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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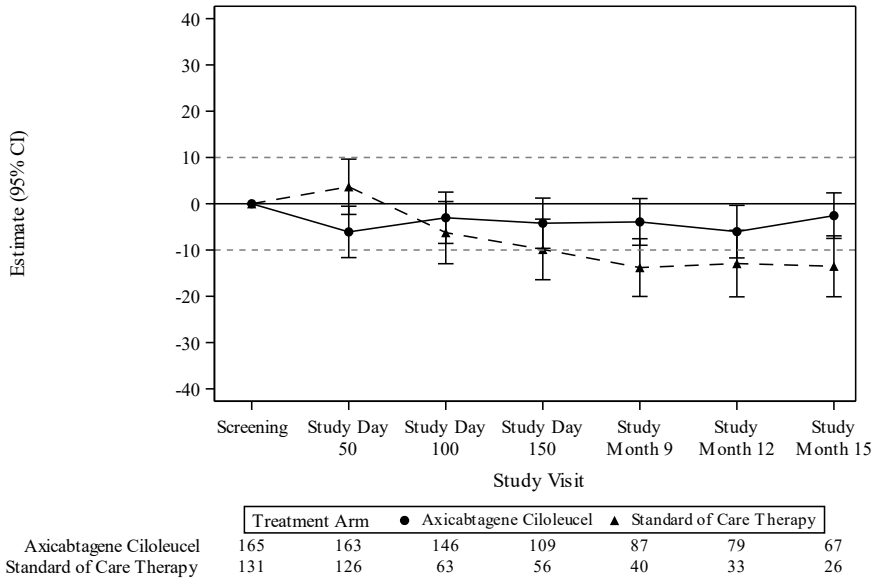
Figure 4.1.13.1 EORTC QLQ-C30 Constipation Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Axicabtagene Ciloleucel	165	163	146	109	87	79	67
Standard of Care Therapy	131	126	63	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.13. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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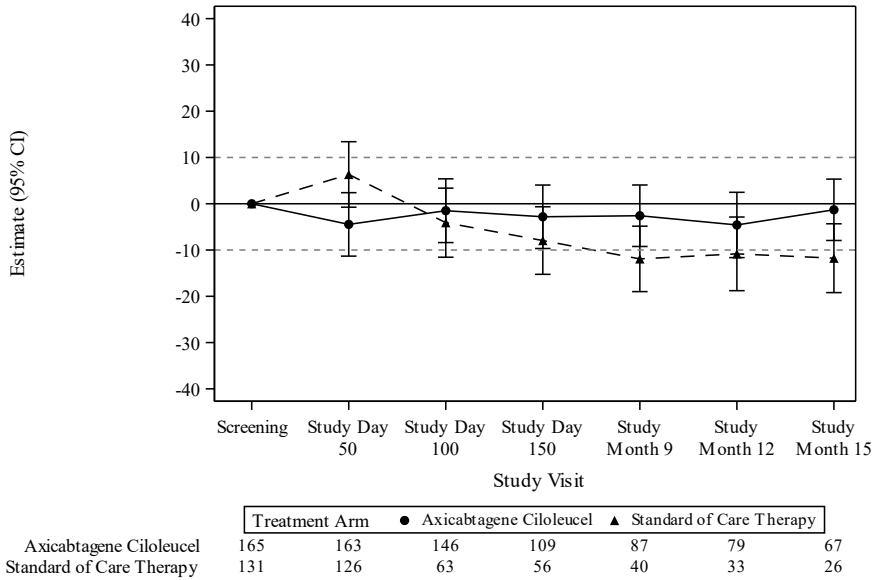
Figure 4.1.13.2 EORTC QLQ-C30 Constipation Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.13. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

PRO Tables
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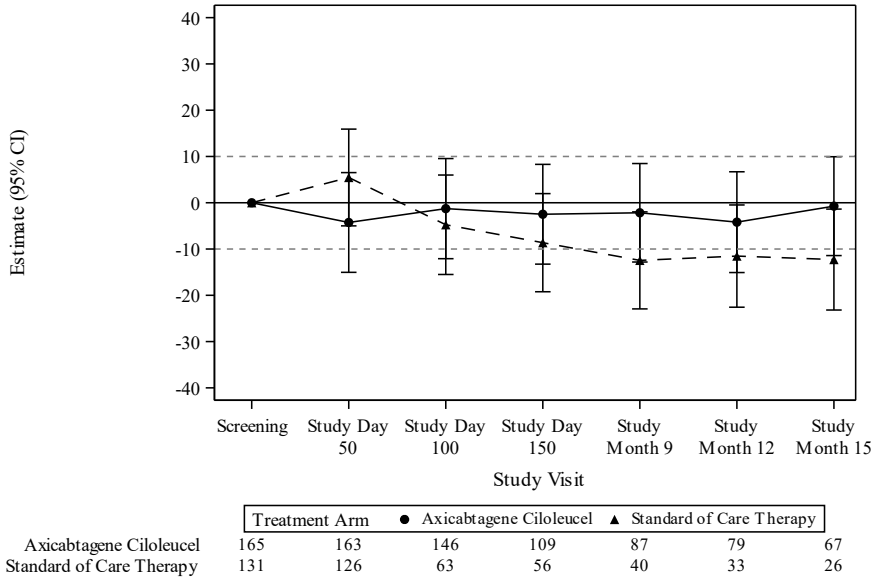
Figure 4.1.13.3 EORTC QLQ-C30 Constipation Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Axicabtagene Ciloleucel	165	163	146	109	87	79	67
Standard of Care Therapy	131	126	63	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.13. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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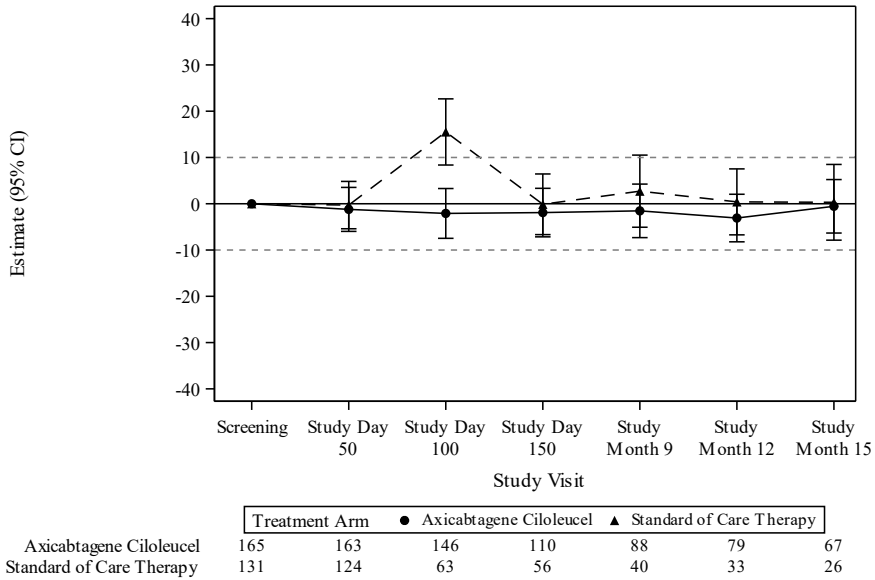
Figure 4.1.14.1 EORTC QLQ-C30 Diarrhea Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.14. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

PRO Tables
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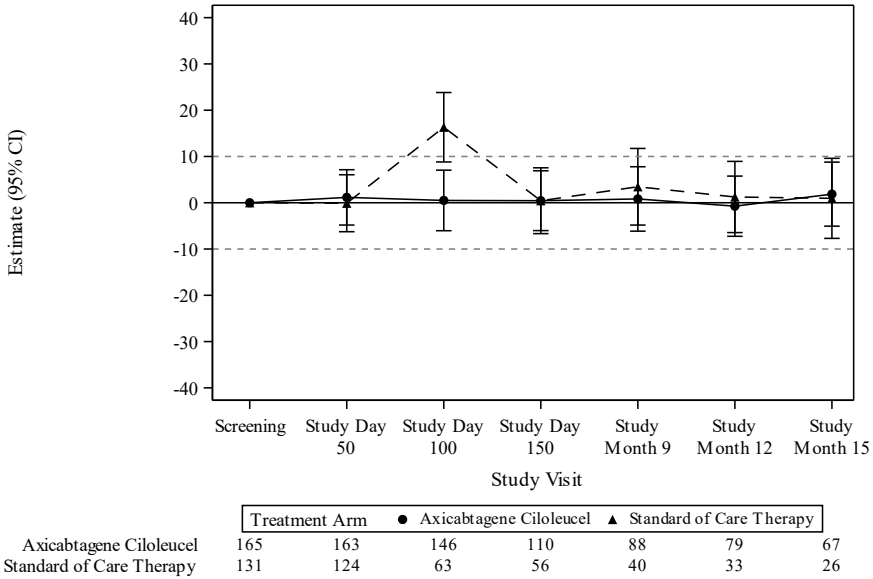
Version: 1.0 (10Aug2021)

Figure 4.1.14.2 EORTC QLQ-C30 Diarrhea Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.14. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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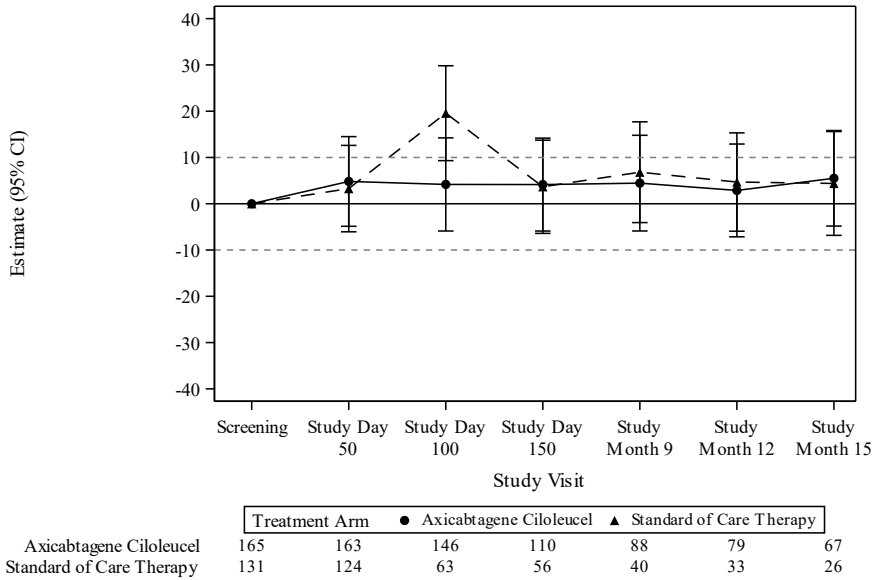
Figure 4.1.14.3 EORTC QLQ-C30 Diarrhea Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.14. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Anhang 4-G2.7: Ergänzende Darstellung zu gesundheitsbezogene Lebensqualität anhand EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-18 (Anhang): Rücklaufquoten nach Visite zu EORTC QLQ-C30 (gesundheitsbezogene Lebensqualität) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Table 1.1.01 EORTC QLQ-C30 Global Health Status/QoL Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	295 (99.7%)	165 (100.0%)	130 (99.2%)
Completed Study Day 50	Y	288 (97.3%)	163 (98.8%)	125 (95.4%)
Completed Study Day 100	Y	208 (70.3%)	146 (88.5%)	62 (47.3%)
Completed Study Day 150	Y	166 (56.1%)	110 (66.7%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	010000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101000	2 (0.7%)	0 (0.0%)	2 (1.5%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	75 (25.3%)	17 (10.3%)	58 (44.3%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	7 (2.4%)	1 (0.6%)	6 (4.6%)
	111000	47 (15.9%)	35 (21.2%)	12 (9.2%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	95 (32.1%)	73 (44.2%)	22 (16.8%)
Pattern of Completion (Simplified)[a]	[0]Missing Screening	1 (0.3%)	0 (0.0%)	1 (0.8%)
	[1]Complete Screening, missing Study Day 50 (10XXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	52 (17.6%)	38 (23.0%)	14 (10.7%)
	[4]Complete Screening through Day 150 (1111XX)	148 (50.0%)	106 (64.2%)	42 (32.1%)
Pattern of Completion through Month 24 (Simplified)[a]	[00]Missing Screening (0XXXXXXXXX)	1 (0.3%)	0 (0.0%)	1 (0.8%)
	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	52 (17.6%)	38 (23.0%)	14 (10.7%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	19 (6.4%)	14 (8.5%)	5 (3.8%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	11 (3.7%)	8 (4.8%)	3 (2.3%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	23 (7.8%)	20 (12.1%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

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Table 1.1.02 EORTC QLQ-C30 Physical Functioning Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	295 (99.7%)	164 (99.4%)	131 (100.0%)
Completed Study Day 50	Y	289 (97.6%)	163 (98.8%)	126 (96.2%)
Completed Study Day 100	Y	210 (70.9%)	146 (88.5%)	64 (48.9%)
Completed Study Day 150	Y	165 (55.7%)	109 (66.1%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	010000	1 (0.3%)	1 (0.6%)	0 (0.0%)
	101000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	75 (25.3%)	16 (9.7%)	59 (45.0%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	5 (1.7%)	1 (0.6%)	4 (3.1%)
	111000	48 (16.2%)	35 (21.2%)	13 (9.9%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	3 (1.0%)	2 (1.2%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	96 (32.4%)	72 (43.6%)	24 (18.3%)
Pattern of Completion (Simplified)[a]	[0]Missing Screening	1 (0.3%)	1 (0.6%)	0 (0.0%)
	[1]Complete Screening, missing Study Day 50 (10XXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	85 (28.7%)	18 (10.9%)	67 (51.1%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	54 (18.2%)	39 (23.6%)	15 (11.5%)
	[4]Complete Screening through Day 150 (1111XX)	149 (50.3%)	105 (63.6%)	44 (33.6%)
Pattern of Completion through Month 24 (Simplified)[a]	[00]Missing Screening (0XXXXXXXXX)	1 (0.3%)	1 (0.6%)	0 (0.0%)
	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	85 (28.7%)	18 (10.9%)	67 (51.1%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	54 (18.2%)	39 (23.6%)	15 (11.5%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	12 (4.1%)	8 (4.8%)	4 (3.1%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	22 (7.4%)	19 (11.5%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

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Table 1.1.03 EORTC QLQ-C30 Role Functioning Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	289 (97.6%)	163 (98.8%)	126 (96.2%)
Completed Study Day 100	Y	210 (70.9%)	146 (88.5%)	64 (48.9%)
Completed Study Day 150	Y	166 (56.1%)	110 (66.7%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	101000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	76 (25.7%)	17 (10.3%)	59 (45.0%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	5 (1.7%)	1 (0.6%)	4 (3.1%)
	111000	48 (16.2%)	35 (21.2%)	13 (9.9%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	97 (32.8%)	73 (44.2%)	24 (18.3%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	53 (17.9%)	38 (23.0%)	15 (11.5%)
	[4]Complete Screening through Day 150 (1111XX)	150 (50.7%)	106 (64.2%)	44 (33.6%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	7 (2.4%)	2 (1.2%)	5 (3.8%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	53 (17.9%)	38 (23.0%)	15 (11.5%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	12 (4.1%)	8 (4.8%)	4 (3.1%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	23 (7.8%)	20 (12.1%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Table 1.1.04 EORTC QLQ-C30 Emotional Functioning Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	288 (97.3%)	163 (98.8%)	125 (95.4%)
Completed Study Day 100	Y	209 (70.6%)	146 (88.5%)	63 (48.1%)
Completed Study Day 150	Y	166 (56.1%)	110 (66.7%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	101000	2 (0.7%)	0 (0.0%)	2 (1.5%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	76 (25.7%)	17 (10.3%)	59 (45.0%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	6 (2.0%)	1 (0.6%)	5 (3.8%)
	111000	47 (15.9%)	35 (21.2%)	12 (9.2%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	96 (32.4%)	73 (44.2%)	23 (17.6%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	52 (17.6%)	38 (23.0%)	14 (10.7%)
	[4]Complete Screening through Day 150 (1111XX)	149 (50.3%)	106 (64.2%)	43 (32.8%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	52 (17.6%)	38 (23.0%)	14 (10.7%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	11 (3.7%)	8 (4.8%)	3 (2.3%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	23 (7.8%)	20 (12.1%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

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Table 1.1.05 EORTC QLQ-C30 Cognitive Functioning Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	296 (100.0%)	165 (100.0%)	131 (100.0%)
Completed Study Day 50	Y	288 (97.3%)	163 (98.8%)	125 (95.4%)
Completed Study Day 100	Y	209 (70.6%)	146 (88.5%)	63 (48.1%)
Completed Study Day 150	Y	166 (56.1%)	110 (66.7%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	101000	2 (0.7%)	0 (0.0%)	2 (1.5%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	76 (25.7%)	17 (10.3%)	59 (45.0%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	6 (2.0%)	1 (0.6%)	5 (3.8%)
	111000	47 (15.9%)	35 (21.2%)	12 (9.2%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	96 (32.4%)	73 (44.2%)	23 (17.6%)
Pattern of Completion (Simplified)[a]	[1]Complete Screening, missing Study Day 50 (10XXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	52 (17.6%)	38 (23.0%)	14 (10.7%)
	[4]Complete Screening through Day 150 (1111XX)	149 (50.3%)	106 (64.2%)	43 (32.8%)
Pattern of Completion through Month 24 (Simplified)[a]	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	87 (29.4%)	19 (11.5%)	68 (51.9%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	52 (17.6%)	38 (23.0%)	14 (10.7%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	11 (3.7%)	8 (4.8%)	3 (2.3%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	23 (7.8%)	20 (12.1%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

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Table 1.1.06 EORTC QLQ-C30 Social Functioning Score Completion by Visit (QoL Analysis Set)

Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
Completed Screening	Y	295 (99.7%)	165 (100.0%)	130 (99.2%)
Completed Study Day 50	Y	288 (97.3%)	163 (98.8%)	125 (95.4%)
Completed Study Day 100	Y	209 (70.6%)	146 (88.5%)	63 (48.1%)
Completed Study Day 150	Y	166 (56.1%)	110 (66.7%)	56 (42.7%)
Completed Month 9	Y	128 (43.2%)	88 (53.3%)	40 (30.5%)
Completed Month 12	Y	112 (37.8%)	79 (47.9%)	33 (25.2%)
Completed Month 15	Y	93 (31.4%)	67 (40.6%)	26 (19.8%)
Completed Month 18	Y	94 (31.8%)	71 (43.0%)	23 (17.6%)
Completed Month 21	Y	65 (22.0%)	45 (27.3%)	20 (15.3%)
Completed Month 24	Y	44 (14.9%)	32 (19.4%)	12 (9.2%)
Pattern of Completion for Day 50 through Month 12 Visits[a]	010000	1 (0.3%)	0 (0.0%)	1 (0.8%)
	101000	2 (0.7%)	0 (0.0%)	2 (1.5%)
	101100	3 (1.0%)	1 (0.6%)	2 (1.5%)
	101111	3 (1.0%)	1 (0.6%)	2 (1.5%)
	110000	75 (25.3%)	17 (10.3%)	58 (44.3%)
	110100	2 (0.7%)	1 (0.6%)	1 (0.8%)
	110110	3 (1.0%)	0 (0.0%)	3 (2.3%)
	110111	6 (2.0%)	1 (0.6%)	5 (3.8%)
	111000	47 (15.9%)	35 (21.2%)	12 (9.2%)
	111001	1 (0.3%)	1 (0.6%)	0 (0.0%)
	111010	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111011	2 (0.7%)	1 (0.6%)	1 (0.8%)
	111100	33 (11.1%)	20 (12.1%)	13 (9.9%)

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Variable	Category	Overall (%) (N = 296)	Axicabtagene Ciloleucel (%) (N = 165)	Standard of Care Therapy (%) (N = 131)
	111101	4 (1.4%)	2 (1.2%)	2 (1.5%)
	111110	16 (5.4%)	11 (6.7%)	5 (3.8%)
	111111	96 (32.4%)	73 (44.2%)	23 (17.6%)
Pattern of Completion (Simplified)[a]	[0]Missing Screening	1 (0.3%)	0 (0.0%)	1 (0.8%)
	[1]Complete Screening, missing Study Day 50 (10XXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[2]Complete Screening through Day 50, missing Day 100 (110XXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[3]Complete Screening through Day 100, missing Day 150 (1110XX)	52 (17.6%)	38 (23.0%)	14 (10.7%)
	[4]Complete Screening through Day 150 (1111XX)	149 (50.3%)	106 (64.2%)	43 (32.8%)
Pattern of Completion through Month 24 (Simplified)[a]	[00]Missing Screening (0XXXXXXXXX)	1 (0.3%)	0 (0.0%)	1 (0.8%)
	[01]Complete Screening, missing Day 50 (10XXXXXXXX)	8 (2.7%)	2 (1.2%)	6 (4.6%)
	[02]Complete Screening through Day 50, missing Day 100 (110XXXXXXX)	86 (29.1%)	19 (11.5%)	67 (51.1%)
	[03]Complete Screening through Day 100, missing Day 150 (1110XXXXXX)	52 (17.6%)	38 (23.0%)	14 (10.7%)
	[04]Complete Screening through Day 150, missing Month 9 (11110XXXXX)	37 (12.5%)	22 (13.3%)	15 (11.5%)
	[05]Complete Screening through Month 9, missing Month 12 (111110XXXX)	16 (5.4%)	11 (6.7%)	5 (3.8%)
	[06]Complete Screening through Month 12, missing Month 15 (1111110XXX)	20 (6.8%)	14 (8.5%)	6 (4.6%)
	[07]Complete Screening through Month 15, missing Month 18 (11111110XX)	11 (3.7%)	8 (4.8%)	3 (2.3%)
	[08]Complete Screening through Month 18, missing Month 21 (111111110X)	23 (7.8%)	20 (12.1%)	3 (2.3%)
	[09]Complete Screening through Month 21, missing Month 24 (1111111110)	13 (4.4%)	7 (4.2%)	6 (4.6%)
	[10]Complete through Month 24 (1111111111)	29 (9.8%)	24 (14.5%)	5 (3.8%)

Data cutoff date = 18MAR2021
Abbreviations: EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life; Y, yes.
Note: Percentages are based on total evaluable in the QoL Analysis Set.
[a] Completion pattern groups are mutually exclusive and require all values to be non-missing prior to the visit in question. Vectors of completion are listed as ABCDEF or ABCDEFGHIJ where 1 represents completion and 0 missing at A: Screening, B: Day 50, C: Day 100, D: Day 150, E: Month 9, F: Month 12, G: Month 15, H: Month 18, I: Month 21, J: Month 24. Only combinations that exist in the data will be summarized.
Data Source: ADPRO, ADQSCOMP Program Name: Tables 1.X.X - Completion Rates by Visit v8 2021.07.01.sas Output Generated: 09AUG2021

Tabelle 4-19 (Anhang): Mittelwert und Veränderung zu Screening zu EORTC QLQ-C30 (gesundheitsbezogene Lebensqualität) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Table 3.1.01 EORTC QLQ-C30 Global Health Status/QoL Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	295	165	130
	Mean (STDEV)	69.3 (21.3)	68.6 (19.9)	70.1 (23.1)
	Median (Q1, Q3)	75.0 (50.0, 83.3)	66.7 (50.0, 83.3)	75.0 (50.0, 83.3)
	Min, Max	0.0, 100.0	16.7, 100.0	0.0, 100.0
	95% CI	66.8, 71.7	65.6, 71.7	66.1, 74.1
Study Day 50				
Score at Study Day 50	n	288	163	125
	Mean (STDEV)	61.1 (21.8)	60.9 (21.2)	61.3 (22.7)
	Median (Q1, Q3)	66.7 (50.0, 83.3)	66.7 (50.0, 75.0)	58.3 (41.7, 83.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	58.6, 63.6	57.7, 64.2	57.3, 65.3
Change from Screening at Study Day 50	n	287	163	124
	Mean (STDEV)	-7.9 (21.3)	-7.4 (20.2)	-8.5 (22.7)
	Median (Q1, Q3)	-8.3 (-16.7, 0.0)	-8.3 (-16.7, 8.3)	-8.3 (-25.0, 0.0)
	Min, Max	-66.7, 66.7	-66.7, 58.3	-66.7, 66.7
	95% CI	-10.4, -5.4	-10.5, -4.3	-12.6, -4.5
Percent Improved, Stable, or Worsened at Study Day 50	Improved	50 (17.4%)	31 (19.0%)	19 (15.3%)
	Stable	119 (41.5%)	62 (38.0%)	57 (46.0%)
	Worsened	118 (41.1%)	70 (42.9%)	48 (38.7%)
Study Day 100				
Score at Study Day 100	n	208	146	62
	Mean (STDEV)	66.5 (22.0)	70.4 (21.0)	57.1 (21.8)
	Median (Q1, Q3)	66.7 (50.0, 83.3)	75.0 (58.3, 83.3)	62.5 (41.7, 75.0)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	16.7, 91.7
	95% CI	63.5, 69.5	67.0, 73.9	51.6, 62.7
Change from Screening at Study Day 100	n	208	146	62
	Mean (STDEV)	-3.6 (21.9)	1.3 (19.6)	-15.3 (22.7)
	Median (Q1, Q3)	0.0 (-16.7, 8.3)	0.0 (-8.3, 16.7)	-16.7 (-33.3, 0.0)
	Min, Max	-75.0, 83.3	-58.3, 83.3	-75.0, 33.3
	95% CI	-6.6, -0.7	-1.9, 4.5	-21.1, -9.5
Percent Improved, Stable, or Worsened at Study Day 100	Improved	46 (22.1%)	39 (26.7%)	7 (11.3%)
	Stable	95 (45.7%)	73 (50.0%)	22 (35.5%)
	Worsened	67 (32.2%)	34 (23.3%)	33 (53.2%)
Study Day 150				
Score at Study Day 150	n	166	110	56
	Mean (STDEV)	72.2 (19.8)	74.4 (19.8)	68.0 (19.1)
	Median (Q1, Q3)	75.0 (66.7, 83.3)	83.3 (66.7, 83.3)	66.7 (58.3, 83.3)
	Min, Max	0.0, 100.0	0.0, 100.0	16.7, 100.0
	95% CI	69.2, 75.3	70.6, 78.1	62.9, 73.1
Change from Screening at Study Day 150	n	166	110	56
	Mean (STDEV)	2.5 (24.9)	5.9 (24.9)	-4.2 (23.7)
	Median (Q1, Q3)	0.0 (-8.3, 16.7)	0.0 (-8.3, 16.7)	0.0 (-25.0, 8.3)
	Min, Max	-100.0, 83.3	-100.0, 83.3	-50.0, 50.0
	95% CI	-1.3, 6.3	1.2, 10.6	-10.5, 2.2
Percent Improved, Stable, or Worsened at Study Day 150	Improved	48 (28.9%)	36 (32.7%)	12 (21.4%)
	Stable	85 (51.2%)	59 (53.6%)	26 (46.4%)
	Worsened	33 (19.9%)	15 (13.6%)	18 (32.1%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	74.7 (21.0)	75.1 (20.9)	73.8 (21.2)
	Median (Q1, Q3)	83.3 (66.7, 83.3)	83.3 (66.7, 87.5)	79.2 (66.7, 83.3)
	Min, Max	0.0, 100.0	0.0, 100.0	16.7, 100.0
	95% CI	71.0, 78.3	70.7, 79.5	67.0, 80.5
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	6.6 (23.0)	8.0 (22.7)	3.5 (23.7)
	Median (Q1, Q3)	8.3 (0.0, 16.7)	8.3 (0.0, 20.8)	8.3 (-8.3, 16.7)
	Min, Max	-66.7, 58.3	-66.7, 58.3	-66.7, 50.0
	95% CI	2.6, 10.6	3.2, 12.8	-4.0, 11.1
Percent Improved, Stable, or Worsened at Study Month 9	Improved	53 (41.4%)	38 (43.2%)	15 (37.5%)
	Stable	53 (41.4%)	38 (43.2%)	15 (37.5%)
	Worsened	22 (17.2%)	12 (13.6%)	10 (25.0%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	76.4 (20.3)	75.3 (23.0)	79.0 (11.8)
	Median (Q1, Q3)	83.3 (66.7, 83.3)	83.3 (66.7, 91.7)	83.3 (66.7, 83.3)
	Min, Max	0.0, 100.0	0.0, 100.0	50.0, 100.0
	95% CI	72.6, 80.2	70.2, 80.5	74.9, 83.2
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	8.8 (23.5)	8.6 (24.9)	9.1 (20.2)
	Median (Q1, Q3)	8.3 (0.0, 16.7)	8.3 (0.0, 16.7)	8.3 (-8.3, 16.7)
	Min, Max	-66.7, 83.3	-66.7, 83.3	-16.7, 50.0
	95% CI	4.4, 13.2	3.1, 14.2	1.9, 16.3
Percent Improved, Stable, or Worsened at Study Month 12	Improved	49 (43.8%)	35 (44.3%)	14 (42.4%)
	Stable	46 (41.1%)	33 (41.8%)	13 (39.4%)
	Worsened	17 (15.2%)	11 (13.9%)	6 (18.2%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	76.6 (19.9)	74.4 (21.0)	82.4 (15.3)
	Median (Q1, Q3)	83.3 (66.7, 83.3)	75.0 (66.7, 83.3)	83.3 (83.3, 91.7)
	Min, Max	0.0, 100.0	0.0, 100.0	33.3, 100.0
	95% CI	72.5, 80.7	69.2, 79.5	76.2, 88.6
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	9.2 (21.3)	9.0 (22.3)	9.9 (18.9)
	Median (Q1, Q3)	8.3 (0.0, 16.7)	8.3 (0.0, 16.7)	12.5 (0.0, 25.0)
	Min, Max	-50.0, 66.7	-50.0, 66.7	-25.0, 41.7
	95% CI	4.8, 13.6	3.5, 14.4	2.3, 17.6
Percent Improved, Stable, or Worsened at Study Month 15	Improved	40 (43.0%)	27 (40.3%)	13 (50.0%)
	Stable	41 (44.1%)	32 (47.8%)	9 (34.6%)
	Worsened	12 (12.9%)	8 (11.9%)	4 (15.4%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	77.6 (16.0)	78.1 (16.3)	76.1 (15.3)
	Median (Q1, Q3)	83.3 (66.7, 83.3)	83.3 (66.7, 83.3)	75.0 (66.7, 83.3)
	Min, Max	33.3, 100.0	33.3, 100.0	50.0, 100.0
	95% CI	74.3, 80.9	74.2, 81.9	69.5, 82.7
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	9.3 (20.9)	10.2 (20.9)	6.5 (21.3)
	Median (Q1, Q3)	8.3 (0.0, 16.7)	8.3 (0.0, 16.7)	0.0 (-8.3, 16.7)
	Min, Max	-41.7, 66.7	-41.7, 66.7	-33.3, 50.0
	95% CI	5.0, 13.6	5.3, 15.2	-2.7, 15.7
Percent Improved, Stable, or Worsened at Study Month 18	Improved	40 (42.6%)	30 (42.3%)	10 (43.5%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	40 (42.6%)	32 (45.1%)	8 (34.8%)
	Worsened	14 (14.9%)	9 (12.7%)	5 (21.7%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	82.3 (16.2)	81.7 (17.5)	83.8 (13.4)
	Median (Q1, Q3)	83.3 (75.0, 91.7)	83.3 (75.0, 91.7)	83.3 (79.2, 91.7)
	Min, Max	33.3, 100.0	33.3, 100.0	50.0, 100.0
	95% CI	78.3, 86.3	76.4, 86.9	77.5, 90.0
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	11.5 (20.9)	10.0 (21.5)	15.0 (19.6)
	Median (Q1, Q3)	8.3 (0.0, 25.0)	8.3 (0.0, 16.7)	16.7 (0.0, 25.0)
	Min, Max	-33.3, 66.7	-33.3, 66.7	-16.7, 50.0
	95% CI	6.4, 16.7	3.5, 16.5	5.8, 24.2
Percent Improved, Stable, or Worsened at Study Month 21	Improved	29 (44.6%)	18 (40.0%)	11 (55.0%)
	Stable	30 (46.2%)	23 (51.1%)	7 (35.0%)
	Worsened	6 (9.2%)	4 (8.9%)	2 (10.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	79.5 (20.1)	76.0 (21.9)	88.9 (10.3)
	Median (Q1, Q3)	83.3 (66.7, 91.7)	83.3 (66.7, 91.7)	87.5 (83.3, 100.0)
	Min, Max	8.3, 100.0	8.3, 100.0	66.7, 100.0
	95% CI	73.4, 85.7	68.2, 83.9	82.4, 95.4
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	9.8 (20.0)	8.6 (21.0)	13.2 (17.2)
	Median (Q1, Q3)	8.3 (-4.2, 16.7)	8.3 (-8.3, 16.7)	12.5 (0.0, 20.8)
	Min, Max	-33.3, 50.0	-33.3, 50.0	-8.3, 50.0

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	3.8, 15.9	1.0, 16.2	2.3, 24.1
Percent Improved, Stable, or Worsened at Study Month 24	Improved	20 (45.5%)	14 (43.8%)	6 (50.0%)
	Stable	18 (40.9%)	12 (37.5%)	6 (50.0%)
	Worsened	6 (13.6%)	6 (18.8%)	0 (0.0%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

PRO Tables
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Table 3.1.02 EORTC QLQ-C30 Physical Functioning Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	295	164	131
	Mean (STDEV)	84.3 (18.2)	83.5 (17.7)	85.3 (18.9)
	Median (Q1, Q3)	86.7 (80.0, 100.0)	86.7 (80.0, 100.0)	93.3 (80.0, 100.0)
	Min, Max	6.7, 100.0	6.7, 100.0	6.7, 100.0
	95% CI	82.2, 86.4	80.8, 86.2	82.0, 88.6
Study Day 50				
Score at Study Day 50	n	289	163	126
	Mean (STDEV)	73.6 (22.6)	70.7 (24.5)	77.3 (19.5)
	Median (Q1, Q3)	80.0 (60.0, 93.3)	73.3 (53.3, 86.7)	80.0 (66.7, 93.3)
	Min, Max	0.0, 100.0	0.0, 100.0	13.3, 100.0
	95% CI	71.0, 76.2	66.9, 74.5	73.9, 80.7
Change from Screening at Study Day 50	n	288	162	126
	Mean (STDEV)	-10.9 (20.1)	-12.9 (21.7)	-8.3 (17.5)
	Median (Q1, Q3)	-6.7 (-20.0, 0.0)	-6.7 (-26.7, 0.0)	-6.7 (-20.0, 0.0)
	Min, Max	-93.3, 40.0	-93.3, 33.3	-73.3, 40.0
	95% CI	-13.2, -8.6	-16.3, -9.5	-11.4, -5.2
Percent Improved, Stable, or Worsened at Study Day 50	Improved	28 (9.7%)	20 (12.3%)	8 (6.3%)
	Stable	135 (46.9%)	64 (39.5%)	71 (56.3%)
	Worsened	125 (43.4%)	78 (48.1%)	47 (37.3%)
Study Day 100				
Score at Study Day 100	n	210	146	64
	Mean (STDEV)	79.5 (21.3)	82.0 (20.9)	74.0 (21.4)
	Median (Q1, Q3)	86.7 (66.7, 100.0)	86.7 (73.3, 100.0)	80.0 (60.0, 93.3)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	20.0, 100.0
	95% CI	76.6, 82.4	78.5, 85.4	68.7, 79.4
Change from Screening at Study Day 100	n	210	146	64
	Mean (STDEV)	-5.8 (19.1)	-1.8 (17.8)	-15.0 (19.1)
	Median (Q1, Q3)	0.0 (-13.3, 6.7)	0.0 (-6.7, 6.7)	-13.3 (-30.0, 0.0)
	Min, Max	-93.3, 53.3	-93.3, 53.3	-66.7, 26.7
	95% CI	-8.4, -3.2	-4.7, 1.1	-19.8, -10.3
Percent Improved, Stable, or Worsened at Study Day 100	Improved	32 (15.2%)	29 (19.9%)	3 (4.7%)
	Stable	108 (51.4%)	81 (55.5%)	27 (42.2%)
	Worsened	70 (33.3%)	36 (24.7%)	34 (53.1%)
Study Day 150				
Score at Study Day 150	n	165	109	56
	Mean (STDEV)	83.9 (18.9)	84.4 (19.7)	82.9 (17.3)
	Median (Q1, Q3)	86.7 (80.0, 100.0)	86.7 (80.0, 100.0)	86.7 (80.0, 93.3)
	Min, Max	0.0, 100.0	0.0, 100.0	20.0, 100.0
	95% CI	81.0, 86.8	80.7, 88.1	78.2, 87.5
Change from Screening at Study Day 150	n	165	109	56
	Mean (STDEV)	-0.9 (19.9)	1.3 (18.9)	-5.2 (21.3)
	Median (Q1, Q3)	0.0 (-6.7, 6.7)	0.0 (-6.7, 6.7)	0.0 (-13.3, 0.0)
	Min, Max	-73.3, 73.3	-66.7, 53.3	-73.3, 73.3
	95% CI	-4.0, 2.1	-2.3, 4.9	-10.9, 0.5
Percent Improved, Stable, or Worsened at Study Day 150	Improved	30 (18.2%)	26 (23.9%)	4 (7.1%)
	Stable	98 (59.4%)	64 (58.7%)	34 (60.7%)
	Worsened	37 (22.4%)	19 (17.4%)	18 (32.1%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	85.9 (17.5)	86.4 (17.3)	84.7 (18.1)
	Median (Q1, Q3)	93.3 (80.0, 100.0)	93.3 (80.0, 100.0)	91.1 (80.0, 93.3)
	Min, Max	6.7, 100.0	6.7, 100.0	26.7, 100.0
	95% CI	82.8, 88.9	82.7, 90.1	78.9, 90.5
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	2.0 (19.5)	4.1 (17.1)	-2.4 (23.5)
	Median (Q1, Q3)	0.0 (-6.7, 13.3)	0.0 (0.0, 13.3)	0.0 (-6.7, 1.1)
	Min, Max	-73.3, 73.3	-53.3, 53.3	-73.3, 73.3
	95% CI	-1.4, 5.4	0.4, 7.7	-10.0, 5.1
Percent Improved, Stable, or Worsened at Study Month 9	Improved	35 (27.3%)	28 (31.8%)	7 (17.5%)
	Stable	75 (58.6%)	49 (55.7%)	26 (65.0%)
	Worsened	18 (14.1%)	11 (12.5%)	7 (17.5%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	86.0 (20.1)	84.7 (22.1)	89.1 (14.1)
	Median (Q1, Q3)	93.3 (83.3, 100.0)	93.3 (80.0, 100.0)	93.3 (86.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	33.3, 100.0
	95% CI	82.2, 89.7	79.7, 89.6	84.1, 94.1
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	2.5 (20.6)	3.4 (20.8)	0.4 (20.3)
	Median (Q1, Q3)	0.0 (0.0, 13.3)	3.3 (0.0, 13.3)	0.0 (-6.7, 6.7)
	Min, Max	-73.3, 73.3	-73.3, 46.7	-66.7, 73.3
	95% CI	-1.3, 6.4	-1.3, 8.1	-6.8, 7.6
Percent Improved, Stable, or Worsened at Study Month 12	Improved	36 (32.1%)	29 (36.7%)	7 (21.2%)
	Stable	56 (50.0%)	36 (45.6%)	20 (60.6%)
	Worsened	20 (17.9%)	14 (17.7%)	6 (18.2%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	87.2 (19.2)	85.2 (21.5)	92.1 (10.0)
	Median (Q1, Q3)	93.3 (86.7, 100.0)	93.3 (80.0, 100.0)	93.3 (86.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	60.0, 100.0
	95% CI	83.2, 91.1	80.0, 90.5	88.1, 96.2
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	3.2 (18.4)	3.9 (19.3)	1.6 (16.1)
	Median (Q1, Q3)	0.0 (-6.7, 13.3)	0.0 (0.0, 13.3)	0.0 (-6.7, 6.7)
	Min, Max	-60.0, 66.7	-60.0, 53.3	-25.0, 66.7
	95% CI	-0.6, 7.0	-0.9, 8.6	-4.9, 8.1
Percent Improved, Stable, or Worsened at Study Month 15	Improved	29 (31.2%)	25 (37.3%)	4 (15.4%)
	Stable	50 (53.8%)	32 (47.8%)	18 (69.2%)
	Worsened	14 (15.1%)	10 (14.9%)	4 (15.4%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	88.0 (15.7)	86.9 (17.0)	91.3 (10.3)
	Median (Q1, Q3)	93.3 (86.7, 100.0)	93.3 (86.7, 100.0)	93.3 (86.7, 100.0)
	Min, Max	6.7, 100.0	6.7, 100.0	60.0, 100.0
	95% CI	84.8, 91.2	82.9, 91.0	86.8, 95.8
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	4.5 (15.8)	5.0 (15.1)	3.2 (17.9)
	Median (Q1, Q3)	0.0 (0.0, 13.3)	0.0 (0.0, 13.3)	0.0 (-6.7, 6.7)
	Min, Max	-33.3, 60.0	-26.7, 46.7	-33.3, 60.0
	95% CI	1.3, 7.8	1.4, 8.6	-4.5, 10.9
Percent Improved, Stable, or Worsened at Study Month 18	Improved	26 (27.7%)	21 (29.6%)	5 (21.7%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	60 (63.8%)	44 (62.0%)	16 (69.6%)
	Worsened	8 (8.5%)	6 (8.5%)	2 (8.7%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	90.0 (17.3)	88.8 (19.4)	92.7 (11.2)
	Median (Q1, Q3)	100.0 (86.7, 100.0)	100.0 (86.7, 100.0)	100.0 (90.0, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	66.7, 100.0
	95% CI	85.7, 94.3	83.0, 94.6	87.4, 97.9
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	5.5 (17.7)	6.0 (16.1)	4.3 (21.4)
	Median (Q1, Q3)	0.0 (0.0, 13.3)	0.0 (0.0, 13.3)	0.0 (-3.3, 10.0)
	Min, Max	-33.3, 73.3	-26.7, 60.0	-33.3, 73.3
	95% CI	1.1, 9.9	1.2, 10.8	-5.7, 14.4
Percent Improved, Stable, or Worsened at Study Month 21	Improved	20 (30.8%)	15 (33.3%)	5 (25.0%)
	Stable	40 (61.5%)	27 (60.0%)	13 (65.0%)
	Worsened	5 (7.7%)	3 (6.7%)	2 (10.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	88.9 (17.6)	85.8 (19.7)	97.2 (4.5)
	Median (Q1, Q3)	93.3 (86.7, 100.0)	93.3 (83.3, 100.0)	100.0 (93.3, 100.0)
	Min, Max	26.7, 100.0	26.7, 100.0	86.7, 100.0
	95% CI	83.6, 94.3	78.7, 92.9	94.4, 100.1
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	4.2 (14.6)	3.7 (16.5)	5.6 (8.0)
	Median (Q1, Q3)	0.0 (0.0, 13.3)	0.0 (-3.3, 10.0)	3.3 (0.0, 13.3)
	Min, Max	-26.7, 60.0	-26.7, 60.0	-6.7, 20.0

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	-0.2, 8.7	-2.2, 9.7	0.5, 10.6
Percent Improved, Stable, or Worsened at Study Month 24	Improved	12 (27.3%)	8 (25.0%)	4 (33.3%)
	Stable	27 (61.4%)	19 (59.4%)	8 (66.7%)
	Worsened	5 (11.4%)	5 (15.6%)	0 (0.0%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

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Table 3.1.03 EORTC QLQ-C30 Role Functioning Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	77.5 (26.7)	78.4 (25.0)	76.3 (28.8)
	Median (Q1, Q3)	83.3 (66.7, 100.0)	83.3 (66.7, 100.0)	83.3 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	74.4, 80.5	74.5, 82.2	71.4, 81.3
Study Day 50				
Score at Study Day 50	n	289	163	126
	Mean (STDEV)	60.9 (31.5)	58.0 (33.2)	64.7 (28.9)
	Median (Q1, Q3)	66.7 (33.3, 83.3)	66.7 (33.3, 83.3)	66.7 (50.0, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	57.3, 64.5	52.8, 63.1	59.6, 69.8
Change from Screening at Study Day 50	n	289	163	126
	Mean (STDEV)	-16.6 (31.8)	-20.2 (31.7)	-11.9 (31.5)
	Median (Q1, Q3)	-16.7 (-33.3, 0.0)	-16.7 (-33.3, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-100.0, 83.3	-100.0, 50.0	-83.3, 83.3
	95% CI	-20.3, -12.9	-25.1, -15.3	-17.5, -6.4
Percent Improved, Stable, or Worsened at Study Day 50	Improved	46 (15.9%)	22 (13.5%)	24 (19.0%)
	Stable	93 (32.2%)	53 (32.5%)	40 (31.7%)
	Worsened	150 (51.9%)	88 (54.0%)	62 (49.2%)
Study Day 100				
Score at Study Day 100	n	210	146	64
	Mean (STDEV)	70.0 (31.7)	75.7 (28.3)	57.0 (35.4)
	Median (Q1, Q3)	83.3 (50.0, 100.0)	83.3 (66.7, 100.0)	66.7 (33.3, 83.3)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	65.7, 74.3	71.1, 80.3	48.2, 65.9
Change from Screening at Study Day 100	n	210	146	64
	Mean (STDEV)	-9.8 (29.8)	-3.5 (24.7)	-24.0 (35.2)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-16.7, 0.0)	-16.7 (-50.0, 0.0)
	Min, Max	-100.0, 50.0	-100.0, 50.0	-100.0, 33.3
	95% CI	-13.8, -5.7	-7.6, 0.5	-32.8, -15.2
Percent Improved, Stable, or Worsened at Study Day 100	Improved	44 (21.0%)	36 (24.7%)	8 (12.5%)
	Stable	84 (40.0%)	66 (45.2%)	18 (28.1%)
	Worsened	82 (39.0%)	44 (30.1%)	38 (59.4%)
Study Day 150				
Score at Study Day 150	n	166	110	56
	Mean (STDEV)	77.9 (27.4)	82.9 (26.1)	68.2 (27.6)
	Median (Q1, Q3)	83.3 (66.7, 100.0)	100.0 (66.7, 100.0)	66.7 (50.0, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	73.7, 82.1	78.0, 87.8	60.8, 75.5
Change from Screening at Study Day 150	n	166	110	56
	Mean (STDEV)	-1.3 (29.8)	4.8 (27.3)	-13.4 (30.9)
	Median (Q1, Q3)	0.0 (-16.7, 16.7)	0.0 (0.0, 16.7)	-16.7 (-33.3, 0.0)
	Min, Max	-83.3, 100.0	-83.3, 100.0	-83.3, 100.0
	95% CI	-5.9, 3.3	-0.3, 10.0	-21.7, -5.1
Percent Improved, Stable, or Worsened at Study Day 150	Improved	49 (29.5%)	41 (37.3%)	8 (14.3%)
	Stable	64 (38.6%)	45 (40.9%)	19 (33.9%)
	Worsened	53 (31.9%)	24 (21.8%)	29 (51.8%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	80.3 (26.3)	82.0 (26.0)	76.7 (26.9)
	Median (Q1, Q3)	100.0 (66.7, 100.0)	100.0 (66.7, 100.0)	83.3 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	16.7, 100.0
	95% CI	75.7, 84.9	76.5, 87.5	68.1, 85.3
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	3.0 (30.8)	5.7 (28.1)	-2.9 (35.6)
	Median (Q1, Q3)	0.0 (-8.3, 16.7)	0.0 (0.0, 16.7)	0.0 (-33.3, 16.7)
	Min, Max	-100.0, 100.0	-100.0, 66.7	-66.7, 100.0
	95% CI	-2.4, 8.4	-0.3, 11.6	-14.3, 8.5
Percent Improved, Stable, or Worsened at Study Month 9	Improved	47 (36.7%)	35 (39.8%)	12 (30.0%)
	Stable	49 (38.3%)	34 (38.6%)	15 (37.5%)
	Worsened	32 (25.0%)	19 (21.6%)	13 (32.5%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	81.5 (26.9)	79.1 (29.8)	87.4 (17.2)
	Median (Q1, Q3)	100.0 (66.7, 100.0)	100.0 (66.7, 100.0)	100.0 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	33.3, 100.0
	95% CI	76.5, 86.6	72.4, 85.8	81.3, 93.5
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	4.8 (29.2)	4.2 (28.1)	6.1 (32.2)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (-16.7, 33.3)
	Min, Max	-100.0, 100.0	-100.0, 66.7	-33.3, 100.0
	95% CI	-0.7, 10.2	-2.1, 10.5	-5.4, 17.5
Percent Improved, Stable, or Worsened at Study Month 12	Improved	37 (33.0%)	27 (34.2%)	10 (30.3%)
	Stable	49 (43.8%)	36 (45.6%)	13 (39.4%)
	Worsened	26 (23.2%)	16 (20.3%)	10 (30.3%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	83.5 (24.9)	82.3 (27.0)	86.5 (18.3)
	Median (Q1, Q3)	100.0 (66.7, 100.0)	100.0 (66.7, 100.0)	100.0 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	50.0, 100.0
	95% CI	78.4, 88.6	75.7, 88.9	79.2, 93.9
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	5.4 (29.4)	5.2 (27.9)	5.8 (33.6)
	Median (Q1, Q3)	0.0 (0.0, 16.7)	0.0 (0.0, 33.3)	0.0 (0.0, 16.7)
	Min, Max	-83.3, 100.0	-83.3, 66.7	-50.0, 100.0
	95% CI	-0.7, 11.4	-1.6, 12.0	-7.8, 19.4
Percent Improved, Stable, or Worsened at Study Month 15	Improved	32 (34.4%)	25 (37.3%)	7 (26.9%)
	Stable	41 (44.1%)	28 (41.8%)	13 (50.0%)
	Worsened	20 (21.5%)	14 (20.9%)	6 (23.1%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	85.3 (22.9)	85.0 (24.1)	86.2 (19.2)
	Median (Q1, Q3)	100.0 (66.7, 100.0)	100.0 (66.7, 100.0)	100.0 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	33.3, 100.0
	95% CI	80.6, 90.0	79.3, 90.7	77.9, 94.5
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	8.7 (30.4)	8.5 (27.7)	9.4 (38.2)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (-16.7, 33.3)
	Min, Max	-83.3, 100.0	-83.3, 83.3	-66.7, 100.0
	95% CI	2.5, 14.9	1.9, 15.0	-7.1, 25.9
Percent Improved, Stable, or Worsened at Study Month 18	Improved	38 (40.4%)	27 (38.0%)	11 (47.8%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	36 (38.3%)	30 (42.3%)	6 (26.1%)
	Worsened	20 (21.3%)	14 (19.7%)	6 (26.1%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	88.5 (20.4)	87.4 (22.8)	90.8 (13.8)
	Median (Q1, Q3)	100.0 (66.7, 100.0)	100.0 (66.7, 100.0)	100.0 (83.3, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	66.7, 100.0
	95% CI	83.4, 93.5	80.6, 94.3	84.4, 97.3
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	11.8 (28.8)	11.5 (26.3)	12.5 (34.6)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	-33.3, 100.0	-33.3, 100.0	-33.3, 100.0
	95% CI	4.7, 18.9	3.6, 19.4	-3.7, 28.7
Percent Improved, Stable, or Worsened at Study Month 21	Improved	28 (43.1%)	20 (44.4%)	8 (40.0%)
	Stable	27 (41.5%)	19 (42.2%)	8 (40.0%)
	Worsened	10 (15.4%)	6 (13.3%)	4 (20.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	88.6 (21.2)	84.9 (23.7)	98.6 (4.8)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (66.7, 100.0)	100.0 (100.0, 100.0)
	Min, Max	16.7, 100.0	16.7, 100.0	83.3, 100.0
	95% CI	82.2, 95.1	76.3, 93.4	95.6, 101.7
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	11.7 (27.7)	10.4 (29.3)	15.3 (24.1)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	-33.3, 100.0	-33.3, 100.0	0.0, 66.7

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	3.3, 20.2	-0.1, 21.0	-0.0, 30.6
Percent Improved, Stable, or Worsened at Study Month 24	Improved	16 (36.4%)	12 (37.5%)	4 (33.3%)
	Stable	22 (50.0%)	14 (43.8%)	8 (66.7%)
	Worsened	6 (13.6%)	6 (18.8%)	0 (0.0%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

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Table 3.1.04 EORTC QLQ-C30 Emotional Functioning Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	77.3 (20.9)	76.9 (20.4)	77.9 (21.4)
	Median (Q1, Q3)	83.3 (66.7, 91.7)	83.3 (66.7, 91.7)	83.3 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	8.3, 100.0
	95% CI	74.9, 79.7	73.7, 80.0	74.2, 81.6
Study Day 50				
Score at Study Day 50	n	288	163	125
	Mean (STDEV)	77.8 (22.1)	79.5 (22.2)	75.6 (21.8)
	Median (Q1, Q3)	83.3 (66.7, 100.0)	83.3 (66.7, 100.0)	75.0 (66.7, 91.7)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	75.2, 80.3	76.1, 82.9	71.7, 79.4
Change from Screening at Study Day 50	n	288	163	125
	Mean (STDEV)	0.6 (20.3)	2.8 (21.6)	-2.3 (18.2)
	Median (Q1, Q3)	0.0 (-8.3, 8.3)	0.0 (-8.3, 16.7)	0.0 (-16.7, 8.3)
	Min, Max	-66.7, 66.7	-66.7, 66.7	-50.0, 50.0
	95% CI	-1.8, 3.0	-0.5, 6.2	-5.5, 0.9
Percent Improved, Stable, or Worsened at Study Day 50	Improved	67 (23.3%)	44 (27.0%)	23 (18.4%)
	Stable	158 (54.9%)	89 (54.6%)	69 (55.2%)
	Worsened	63 (21.9%)	30 (18.4%)	33 (26.4%)
Study Day 100				
Score at Study Day 100	n	209	146	63
	Mean (STDEV)	81.3 (20.2)	82.3 (20.6)	79.0 (19.1)
	Median (Q1, Q3)	83.3 (66.7, 100.0)	91.7 (75.0, 100.0)	83.3 (66.7, 100.0)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	25.0, 100.0
	95% CI	78.6, 84.1	79.0, 85.7	74.2, 83.8
Change from Screening at Study Day 100	n	209	146	63
	Mean (STDEV)	3.6 (21.0)	5.3 (21.5)	-0.6 (19.5)
	Median (Q1, Q3)	0.0 (-8.3, 16.7)	8.3 (-8.3, 16.7)	0.0 (-8.3, 8.3)
	Min, Max	-58.3, 66.7	-58.3, 66.7	-41.7, 66.7
	95% CI	0.7, 6.4	1.8, 8.9	-5.5, 4.3
Percent Improved, Stable, or Worsened at Study Day 100	Improved	59 (28.2%)	48 (32.9%)	11 (17.5%)
	Stable	111 (53.1%)	73 (50.0%)	38 (60.3%)
	Worsened	39 (18.7%)	25 (17.1%)	14 (22.2%)
Study Day 150				
Score at Study Day 150	n	166	110	56
	Mean (STDEV)	83.6 (18.6)	85.0 (18.0)	80.8 (19.4)
	Median (Q1, Q3)	91.7 (75.0, 100.0)	91.7 (75.0, 100.0)	83.3 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	8.3, 100.0
	95% CI	80.8, 86.4	81.6, 88.4	75.6, 86.0
Change from Screening at Study Day 150	n	166	110	56
	Mean (STDEV)	6.9 (18.0)	7.9 (18.6)	4.9 (16.6)
	Median (Q1, Q3)	8.3 (0.0, 16.7)	8.3 (0.0, 16.7)	8.3 (0.0, 8.3)
	Min, Max	-58.3, 50.0	-58.3, 50.0	-36.1, 50.0
	95% CI	4.1, 9.6	4.4, 11.4	0.4, 9.3
Percent Improved, Stable, or Worsened at Study Day 150	Improved	49 (29.5%)	38 (34.5%)	11 (19.6%)
	Stable	102 (61.4%)	64 (58.2%)	38 (67.9%)
	Worsened	15 (9.0%)	8 (7.3%)	7 (12.5%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	84.6 (18.5)	86.7 (16.8)	80.0 (21.4)
	Median (Q1, Q3)	91.7 (75.0, 100.0)	91.7 (79.2, 100.0)	83.3 (70.8, 100.0)
	Min, Max	8.3, 100.0	8.3, 100.0	8.3, 100.0
	95% CI	81.4, 87.9	83.2, 90.3	73.2, 86.8
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	9.9 (18.5)	11.3 (19.1)	6.8 (16.9)
	Median (Q1, Q3)	8.3 (0.0, 16.7)	8.3 (0.0, 16.7)	8.3 (0.0, 16.7)
	Min, Max	-50.0, 83.3	-33.3, 83.3	-50.0, 50.0
	95% CI	6.6, 13.1	7.2, 15.3	1.4, 12.2
Percent Improved, Stable, or Worsened at Study Month 9	Improved	44 (34.4%)	33 (37.5%)	11 (27.5%)
	Stable	76 (59.4%)	51 (58.0%)	25 (62.5%)
	Worsened	8 (6.3%)	4 (4.5%)	4 (10.0%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	85.0 (19.6)	84.2 (20.7)	87.1 (16.7)
	Median (Q1, Q3)	91.7 (75.0, 100.0)	91.7 (75.0, 100.0)	91.7 (75.0, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	33.3, 100.0
	95% CI	81.4, 88.7	79.5, 88.8	81.2, 93.0
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	9.7 (21.2)	8.9 (22.4)	11.8 (18.0)
	Median (Q1, Q3)	8.3 (0.0, 25.0)	8.3 (-8.3, 16.7)	8.3 (0.0, 25.0)
	Min, Max	-33.3, 66.7	-33.3, 66.7	-16.7, 58.3
	95% CI	5.8, 13.7	3.8, 13.9	5.4, 18.2
Percent Improved, Stable, or Worsened at Study Month 12	Improved	42 (37.5%)	28 (35.4%)	14 (42.4%)
	Stable	57 (50.9%)	41 (51.9%)	16 (48.5%)
	Worsened	13 (11.6%)	10 (12.7%)	3 (9.1%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	84.1 (19.8)	82.3 (20.9)	88.8 (16.0)
	Median (Q1, Q3)	91.7 (75.0, 100.0)	83.3 (75.0, 100.0)	95.8 (83.3, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	33.3, 100.0
	95% CI	80.1, 88.2	77.2, 87.4	82.3, 95.2
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	10.8 (20.2)	9.8 (21.7)	13.5 (15.6)
	Median (Q1, Q3)	8.3 (0.0, 25.0)	8.3 (0.0, 25.0)	8.3 (0.0, 25.0)
	Min, Max	-41.7, 58.3	-41.7, 58.3	-16.7, 41.7
	95% CI	6.7, 15.0	4.5, 15.1	7.1, 19.8
Percent Improved, Stable, or Worsened at Study Month 15	Improved	36 (38.7%)	25 (37.3%)	11 (42.3%)
	Stable	48 (51.6%)	34 (50.7%)	14 (53.8%)
	Worsened	9 (9.7%)	8 (11.9%)	1 (3.8%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	86.6 (15.9)	86.6 (16.7)	86.6 (13.2)
	Median (Q1, Q3)	91.7 (75.0, 100.0)	91.7 (75.0, 100.0)	91.7 (75.0, 100.0)
	Min, Max	16.7, 100.0	16.7, 100.0	66.7, 100.0
	95% CI	83.3, 89.8	82.6, 90.5	80.9, 92.3
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	12.8 (19.3)	13.6 (19.9)	10.4 (17.5)
	Median (Q1, Q3)	8.3 (0.0, 25.0)	8.3 (0.0, 25.0)	0.0 (0.0, 25.0)
	Min, Max	-25.0, 58.3	-25.0, 58.3	-16.7, 41.7
	95% CI	8.8, 16.7	8.9, 18.3	2.8, 18.0
Percent Improved, Stable, or Worsened at Study Month 18	Improved	42 (44.7%)	33 (46.5%)	9 (39.1%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	47 (50.0%)	34 (47.9%)	13 (56.5%)
	Worsened	5 (5.3%)	4 (5.6%)	1 (4.3%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	86.2 (18.9)	85.9 (20.4)	86.7 (15.4)
	Median (Q1, Q3)	91.7 (83.3, 100.0)	91.7 (83.3, 100.0)	91.7 (79.2, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	41.7, 100.0
	95% CI	81.5, 90.8	79.8, 92.1	79.5, 93.9
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	13.0 (18.9)	12.4 (20.1)	14.4 (16.2)
	Median (Q1, Q3)	8.3 (0.0, 25.0)	8.3 (0.0, 25.0)	16.7 (4.2, 25.0)
	Min, Max	-25.0, 58.3	-25.0, 58.3	-16.7, 41.7
	95% CI	8.4, 17.7	6.4, 18.4	6.9, 22.0
Percent Improved, Stable, or Worsened at Study Month 21	Improved	30 (46.2%)	19 (42.2%)	11 (55.0%)
	Stable	30 (46.2%)	23 (51.1%)	7 (35.0%)
	Worsened	5 (7.7%)	3 (6.7%)	2 (10.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	86.6 (17.1)	83.9 (18.6)	93.8 (9.5)
	Median (Q1, Q3)	95.8 (75.0, 100.0)	91.7 (66.7, 100.0)	100.0 (83.3, 100.0)
	Min, Max	25.0, 100.0	25.0, 100.0	75.0, 100.0
	95% CI	81.4, 91.7	77.2, 90.5	87.7, 99.8
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	13.4 (20.7)	11.5 (21.4)	18.8 (18.8)
	Median (Q1, Q3)	8.3 (0.0, 29.2)	8.3 (-8.3, 25.0)	25.0 (0.0, 33.3)
	Min, Max	-25.0, 58.3	-25.0, 58.3	-16.7, 41.7

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	7.1, 19.8	3.8, 19.2	6.8, 30.7
Percent Improved, Stable, or Worsened at Study Month 24	Improved	21 (47.7%)	13 (40.6%)	8 (66.7%)
	Stable	19 (43.2%)	16 (50.0%)	3 (25.0%)
	Worsened	4 (9.1%)	3 (9.4%)	1 (8.3%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

Table 3.1.05 EORTC QLQ-C30 Cognitive Functioning Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	296	165	131
	Mean (STDEV)	87.9 (17.2)	88.1 (16.4)	87.7 (18.2)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)
	Min, Max	16.7, 100.0	16.7, 100.0	33.3, 100.0
	95% CI	85.9, 89.9	85.6, 90.6	84.5, 90.8
Study Day 50				
Score at Study Day 50	n	288	163	125
	Mean (STDEV)	84.0 (20.7)	85.8 (19.7)	81.7 (21.8)
	Median (Q1, Q3)	83.3 (66.7, 100.0)	100.0 (83.3, 100.0)	83.3 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	81.6, 86.4	82.7, 88.8	77.9, 85.6
Change from Screening at Study Day 50	n	288	163	125
	Mean (STDEV)	-3.8 (17.8)	-2.4 (17.3)	-5.7 (18.3)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)	0.0 (-16.7, 0.0)
	Min, Max	-66.7, 66.7	-50.0, 66.7	-66.7, 33.3
	95% CI	-5.9, -1.8	-5.0, 0.3	-9.0, -2.5
Percent Improved, Stable, or Worsened at Study Day 50	Improved	51 (17.7%)	30 (18.4%)	21 (16.8%)
	Stable	153 (53.1%)	91 (55.8%)	62 (49.6%)
	Worsened	84 (29.2%)	42 (25.8%)	42 (33.6%)
Study Day 100				
Score at Study Day 100	n	209	146	63
	Mean (STDEV)	85.9 (19.3)	87.0 (20.2)	83.3 (16.9)
	Median (Q1, Q3)	100.0 (66.7, 100.0)	100.0 (83.3, 100.0)	83.3 (66.7, 100.0)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	33.3, 100.0
	95% CI	83.3, 88.5	83.7, 90.3	79.1, 87.6
Change from Screening at Study Day 100	n	209	146	63
	Mean (STDEV)	-2.3 (18.9)	-0.6 (18.3)	-6.3 (19.7)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (0.0, 0.0)	0.0 (-16.7, 0.0)
	Min, Max	-50.0, 66.7	-50.0, 66.7	-50.0, 50.0
	95% CI	-4.9, 0.3	-3.6, 2.4	-11.3, -1.4
Percent Improved, Stable, or Worsened at Study Day 100	Improved	42 (20.1%)	30 (20.5%)	12 (19.0%)
	Stable	108 (51.7%)	84 (57.5%)	24 (38.1%)
	Worsened	59 (28.2%)	32 (21.9%)	27 (42.9%)
Study Day 150				
Score at Study Day 150	n	166	110	56
	Mean (STDEV)	86.9 (17.4)	88.8 (17.9)	83.3 (15.9)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)	83.3 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	33.3, 100.0
	95% CI	84.3, 89.6	85.4, 92.2	79.1, 87.6
Change from Screening at Study Day 150	n	166	110	56
	Mean (STDEV)	-0.4 (17.6)	1.7 (17.3)	-4.5 (17.5)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (0.0, 0.0)	0.0 (-16.7, 0.0)
	Min, Max	-50.0, 66.7	-50.0, 66.7	-33.3, 50.0
	95% CI	-3.1, 2.3	-1.6, 4.9	-9.2, 0.2
Percent Improved, Stable, or Worsened at Study Day 150	Improved	36 (21.7%)	27 (24.5%)	9 (16.1%)
	Stable	86 (51.8%)	60 (54.5%)	26 (46.4%)
	Worsened	44 (26.5%)	23 (20.9%)	21 (37.5%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	86.3 (20.2)	87.3 (21.4)	84.2 (17.3)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)	83.3 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	33.3, 100.0
	95% CI	82.8, 89.9	82.8, 91.9	78.6, 89.7
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	-0.4 (20.1)	0.6 (20.1)	-2.5 (20.2)
	Median (Q1, Q3)	0.0 (-16.7, 0.0)	0.0 (-8.3, 16.7)	0.0 (-16.7, 0.0)
	Min, Max	-50.0, 66.7	-50.0, 66.7	-50.0, 50.0
	95% CI	-3.9, 3.1	-3.7, 4.8	-8.9, 3.9
Percent Improved, Stable, or Worsened at Study Month 9	Improved	30 (23.4%)	23 (26.1%)	7 (17.5%)
	Stable	62 (48.4%)	43 (48.9%)	19 (47.5%)
	Worsened	36 (28.1%)	22 (25.0%)	14 (35.0%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	86.8 (21.4)	86.1 (23.3)	88.4 (15.9)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	50.0, 100.0
	95% CI	82.8, 90.8	80.8, 91.3	82.8, 94.0
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	0.4 (20.9)	0.4 (21.0)	0.5 (21.0)
	Median (Q1, Q3)	0.0 (-8.3, 16.7)	0.0 (0.0, 16.7)	0.0 (-16.7, 0.0)
	Min, Max	-50.0, 66.7	-50.0, 66.7	-33.3, 66.7
	95% CI	-3.5, 4.4	-4.3, 5.1	-7.0, 8.0
Percent Improved, Stable, or Worsened at Study Month 12	Improved	29 (25.9%)	22 (27.8%)	7 (21.2%)
	Stable	55 (49.1%)	38 (48.1%)	17 (51.5%)
	Worsened	28 (25.0%)	19 (24.1%)	9 (27.3%)

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	87.8 (20.0)	88.3 (21.3)	86.5 (16.3)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)	91.7 (83.3, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	50.0, 100.0
	95% CI	83.7, 91.9	83.1, 93.5	79.9, 93.1
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	2.7 (20.0)	4.0 (19.3)	-0.6 (21.8)
	Median (Q1, Q3)	0.0 (0.0, 16.7)	0.0 (0.0, 16.7)	0.0 (-16.7, 0.0)
	Min, Max	-50.0, 66.7	-50.0, 66.7	-33.3, 66.7
	95% CI	-1.4, 6.8	-0.7, 8.7	-9.5, 8.2
Percent Improved, Stable, or Worsened at Study Month 15	Improved	25 (26.9%)	20 (29.9%)	5 (19.2%)
	Stable	50 (53.8%)	38 (56.7%)	12 (46.2%)
	Worsened	18 (19.4%)	9 (13.4%)	9 (34.6%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	88.7 (17.8)	89.4 (18.3)	86.2 (16.4)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)	83.3 (83.3, 100.0)
	Min, Max	16.7, 100.0	16.7, 100.0	50.0, 100.0
	95% CI	85.0, 92.3	85.1, 93.8	79.1, 93.3
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	1.8 (19.5)	3.5 (18.9)	-3.6 (20.7)
	Median (Q1, Q3)	0.0 (-16.7, 16.7)	0.0 (0.0, 16.7)	0.0 (-16.7, 0.0)
	Min, Max	-33.3, 66.7	-33.3, 66.7	-33.3, 50.0
	95% CI	-2.2, 5.8	-0.9, 8.0	-12.6, 5.3
Percent Improved, Stable, or Worsened at Study Month 18	Improved	24 (25.5%)	21 (29.6%)	3 (13.0%)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	46 (48.9%)	35 (49.3%)	11 (47.8%)
	Worsened	24 (25.5%)	15 (21.1%)	9 (39.1%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	88.7 (20.2)	87.8 (23.1)	90.8 (11.4)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	66.7, 100.0
	95% CI	83.7, 93.7	80.8, 94.7	85.5, 96.2
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	3.1 (20.4)	3.0 (20.8)	3.3 (19.9)
	Median (Q1, Q3)	0.0 (0.0, 16.7)	0.0 (0.0, 16.7)	0.0 (-8.3, 16.7)
	Min, Max	-50.0, 66.7	-50.0, 66.7	-33.3, 50.0
	95% CI	-2.0, 8.1	-3.3, 9.2	-6.0, 12.7
Percent Improved, Stable, or Worsened at Study Month 21	Improved	20 (30.8%)	14 (31.1%)	6 (30.0%)
	Stable	30 (46.2%)	21 (46.7%)	9 (45.0%)
	Worsened	15 (23.1%)	10 (22.2%)	5 (25.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	90.2 (16.2)	88.5 (17.7)	94.4 (10.9)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)	100.0 (91.7, 100.0)
	Min, Max	33.3, 100.0	33.3, 100.0	66.7, 100.0
	95% CI	85.2, 95.1	82.2, 94.9	87.5, 101.3
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	2.7 (15.2)	1.6 (14.3)	5.6 (17.9)
	Median (Q1, Q3)	0.0 (0.0, 0.0)	0.0 (0.0, 8.3)	0.0 (0.0, 0.0)
	Min, Max	-33.3, 50.0	-33.3, 33.3	-16.7, 50.0

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	-2.0, 7.3	-3.6, 6.7	-5.8, 16.9
Percent Improved, Stable, or Worsened at Study Month 24	Improved	10 (22.7%)	8 (25.0%)	2 (16.7%)
	Stable	27 (61.4%)	18 (56.3%)	9 (75.0%)
	Worsened	7 (15.9%)	6 (18.8%)	1 (8.3%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

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Table 3.1.06 EORTC QLQ-C30 Social Functioning Score and Change from Screening by Visit (QoL Analysis Set)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Screening				
Score at Screening	n	295	165	130
	Mean (STDEV)	76.7 (24.2)	76.5 (23.8)	76.9 (24.8)
	Median (Q1, Q3)	83.3 (66.7, 100.0)	83.3 (66.7, 100.0)	83.3 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	73.9, 79.4	72.8, 80.1	72.6, 81.2
Study Day 50				
Score at Study Day 50	n	288	163	125
	Mean (STDEV)	65.5 (27.9)	65.5 (29.2)	65.3 (26.2)
	Median (Q1, Q3)	66.7 (50.0, 83.3)	66.7 (50.0, 100.0)	66.7 (50.0, 83.3)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	62.2, 68.7	61.0, 70.1	60.7, 70.0
Change from Screening at Study Day 50	n	287	163	124
	Mean (STDEV)	-10.9 (26.2)	-10.7 (27.4)	-11.2 (24.6)
	Median (Q1, Q3)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)	0.0 (-33.3, 0.0)
	Min, Max	-83.3, 66.7	-83.3, 66.7	-66.7, 50.0
	95% CI	-14.0, -7.9	-15.0, -6.5	-15.5, -6.8
Percent Improved, Stable, or Worsened at Study Day 50	Improved	50 (17.4%)	32 (19.6%)	18 (14.5%)
	Stable	106 (36.9%)	59 (36.2%)	47 (37.9%)
	Worsened	131 (45.6%)	72 (44.2%)	59 (47.6%)
Study Day 100				
Score at Study Day 100	n	209	146	63
	Mean (STDEV)	71.9 (29.1)	77.5 (26.1)	58.7 (31.7)
	Median (Q1, Q3)	66.7 (50.0, 100.0)	83.3 (66.7, 100.0)	66.7 (33.3, 83.3)

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	67.9, 75.8	73.2, 81.8	50.8, 66.7
Change from Screening at Study Day 100	n	209	146	63
	Mean (STDEV)	-6.1 (31.0)	1.6 (26.6)	-23.8 (33.3)
	Median (Q1, Q3)	0.0 (-33.3, 16.7)	0.0 (0.0, 16.7)	-16.7 (-50.0, 0.0)
	Min, Max	-100.0, 66.7	-100.0, 66.7	-100.0, 50.0
	95% CI	-10.3, -1.8	-2.8, 6.0	-32.2, -15.4
Percent Improved, Stable, or Worsened at Study Day 100	Improved	56 (26.8%)	50 (34.2%)	6 (9.5%)
	Stable	77 (36.8%)	60 (41.1%)	17 (27.0%)
	Worsened	76 (36.4%)	36 (24.7%)	40 (63.5%)
Study Day 150				
Score at Study Day 150	n	166	110	56
	Mean (STDEV)	79.8 (23.0)	84.2 (19.9)	71.1 (26.1)
	Median (Q1, Q3)	83.3 (66.7, 100.0)	100.0 (66.7, 100.0)	66.7 (50.0, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	0.0, 100.0
	95% CI	76.3, 83.3	80.5, 88.0	64.1, 78.1
Change from Screening at Study Day 150	n	166	110	56
	Mean (STDEV)	1.8 (27.6)	9.1 (24.5)	-12.5 (27.9)
	Median (Q1, Q3)	0.0 (-16.7, 16.7)	0.0 (0.0, 33.3)	-8.3 (-33.3, 0.0)
	Min, Max	-100.0, 66.7	-66.7, 66.7	-100.0, 50.0
	95% CI	-2.4, 6.0	4.5, 13.7	-20.0, -5.0
Percent Improved, Stable, or Worsened at Study Day 150	Improved	58 (34.9%)	48 (43.6%)	10 (17.9%)
	Stable	63 (38.0%)	45 (40.9%)	18 (32.1%)
	Worsened	45 (27.1%)	17 (15.5%)	28 (50.0%)
Study Month 9				
Score at Study Month 9	n	128	88	40

Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Mean (STDEV)	83.5 (23.5)	87.3 (21.9)	75.0 (25.0)
	Median (Q1, Q3)	100.0 (66.7, 100.0)	100.0 (83.3, 100.0)	66.7 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	33.3, 100.0
	95% CI	79.3, 87.6	82.7, 91.9	67.0, 83.0
Change from Screening at Study Month 9	n	128	88	40
	Mean (STDEV)	6.5 (30.4)	12.5 (29.4)	-6.7 (28.7)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	8.3 (0.0, 33.3)	0.0 (-33.3, 0.0)
	Min, Max	-66.7, 100.0	-66.7, 100.0	-66.7, 50.0
	95% CI	1.2, 11.8	6.3, 18.7	-15.8, 2.5
Percent Improved, Stable, or Worsened at Study Month 9	Improved	53 (41.4%)	44 (50.0%)	9 (22.5%)
	Stable	47 (36.7%)	30 (34.1%)	17 (42.5%)
	Worsened	28 (21.9%)	14 (15.9%)	14 (35.0%)
Study Month 12				
Score at Study Month 12	n	112	79	33
	Mean (STDEV)	84.5 (25.4)	83.3 (27.6)	87.4 (19.1)
	Median (Q1, Q3)	100.0 (66.7, 100.0)	100.0 (66.7, 100.0)	100.0 (66.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	16.7, 100.0
	95% CI	79.8, 89.3	77.1, 89.5	80.6, 94.1
Change from Screening at Study Month 12	n	112	79	33
	Mean (STDEV)	7.9 (31.5)	9.7 (34.2)	3.5 (23.5)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	0.0 (0.0, 33.3)	0.0 (-16.7, 16.7)
	Min, Max	-100.0, 100.0	-100.0, 100.0	-33.3, 50.0
	95% CI	2.0, 13.8	2.0, 17.4	-4.8, 11.9
Percent Improved, Stable, or Worsened at Study Month 12	Improved	45 (40.2%)	35 (44.3%)	10 (30.3%)
	Stable	42 (37.5%)	28 (35.4%)	14 (42.4%)
	Worsened	25 (22.3%)	16 (20.3%)	9 (27.3%)

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
Study Month 15				
Score at Study Month 15	n	93	67	26
	Mean (STDEV)	86.2 (24.0)	84.8 (26.2)	89.7 (17.0)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	50.0, 100.0
	95% CI	81.3, 91.1	78.4, 91.2	82.9, 96.6
Change from Screening at Study Month 15	n	93	67	26
	Mean (STDEV)	11.1 (31.8)	13.4 (33.2)	5.1 (27.4)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	16.7 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	-100.0, 83.3	-100.0, 83.3	-50.0, 50.0
	95% CI	4.6, 17.7	5.3, 21.5	-5.9, 16.2
Percent Improved, Stable, or Worsened at Study Month 15	Improved	46 (49.5%)	36 (53.7%)	10 (38.5%)
	Stable	33 (35.5%)	23 (34.3%)	10 (38.5%)
	Worsened	14 (15.1%)	8 (11.9%)	6 (23.1%)
Study Month 18				
Score at Study Month 18	n	94	71	23
	Mean (STDEV)	87.6 (19.8)	87.3 (21.5)	88.4 (13.7)
	Median (Q1, Q3)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)	100.0 (83.3, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	66.7, 100.0
	95% CI	83.5, 91.7	82.2, 92.4	82.5, 94.3
Change from Screening at Study Month 18	n	94	71	23
	Mean (STDEV)	12.6 (27.4)	15.3 (27.7)	4.3 (25.2)
	Median (Q1, Q3)	8.3 (0.0, 33.3)	16.7 (0.0, 33.3)	0.0 (-16.7, 33.3)
	Min, Max	-50.0, 83.3	-50.0, 83.3	-33.3, 50.0
	95% CI	7.0, 18.2	8.7, 21.8	-6.6, 15.3
Percent Improved, Stable, or Worsened at Study Month 18	Improved	47 (50.0%)	37 (52.1%)	10 (43.5%)

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	Stable	28 (29.8%)	22 (31.0%)	6 (26.1%)
	Worsened	19 (20.2%)	12 (16.9%)	7 (30.4%)
Study Month 21				
Score at Study Month 21	n	65	45	20
	Mean (STDEV)	91.0 (20.0)	90.0 (22.6)	93.3 (12.6)
	Median (Q1, Q3)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (91.7, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	66.7, 100.0
	95% CI	86.1, 96.0	83.2, 96.8	87.5, 99.2
Change from Screening at Study Month 21	n	65	45	20
	Mean (STDEV)	14.6 (24.6)	17.0 (24.7)	9.2 (23.9)
	Median (Q1, Q3)	0.0 (0.0, 33.3)	16.7 (0.0, 33.3)	0.0 (0.0, 33.3)
	Min, Max	-33.3, 66.7	-33.3, 66.7	-33.3, 50.0
	95% CI	8.5, 20.7	9.6, 24.5	-2.0, 20.3
Percent Improved, Stable, or Worsened at Study Month 21	Improved	32 (49.2%)	24 (53.3%)	8 (40.0%)
	Stable	26 (40.0%)	17 (37.8%)	9 (45.0%)
	Worsened	7 (10.8%)	4 (8.9%)	3 (15.0%)
Study Month 24				
Score at Study Month 24	n	44	32	12
	Mean (STDEV)	89.8 (22.2)	85.9 (25.1)	100.0 (0.0)
	Median (Q1, Q3)	100.0 (100.0, 100.0)	100.0 (66.7, 100.0)	100.0 (100.0, 100.0)
	Min, Max	0.0, 100.0	0.0, 100.0	100.0, 100.0
	95% CI	83.0, 96.5	76.9, 95.0	nd
Change from Screening at Study Month 24	n	44	32	12
	Mean (STDEV)	15.9 (25.4)	16.1 (27.9)	15.3 (18.1)
	Median (Q1, Q3)	16.7 (0.0, 33.3)	16.7 (0.0, 33.3)	8.3 (0.0, 33.3)
	Min, Max	-33.3, 66.7	-33.3, 66.7	0.0, 50.0

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Variable	Statistic or Category	Overall (N = 296)	Axicabtagene Ciloleucel (N = 165)	Standard of Care Therapy (N = 131)
	95% CI	8.2, 23.6	6.1, 26.2	3.8, 26.8
Percent Improved, Stable, or Worsened at Study Month 24	Improved	24 (54.5%)	18 (56.3%)	6 (50.0%)
	Stable	15 (34.1%)	9 (28.1%)	6 (50.0%)
	Worsened	5 (11.4%)	5 (15.6%)	0 (0.0%)

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; Q1, first quartile; Q3, third quartile; QoL, quality of life; STDEV, standard deviation.
Data Source: ADPRO Program Name: Tables 3.X.X- Scores and CHG by Visit v6 2021.07.06.sas Output Generated: 09AUG2021

Tabelle 4-20 (Anhang): Ergebnisse der MMRM Analyse zu EORTC QLQ-C30 (gesundheitsbezogene Lebensqualität) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Table 4.1.01 EORTC QLQ-C30 Global Health Status/QoL Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	994		
	Number of Observations Not Used	1		
	Model Fit Statistics			
	-2 Res Log Likelihood	8434.5		
	AIC (Smaller is Better)	8476.5		
	AICC (Smaller is Better)	8477.4		
	BIC (Smaller is Better)	8554		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-9.6 (-14.0, -5.3)	-10.5 (-15.2, -5.9)
	Difference in Mean Change from Screening (95% CI)		0.9 (-4.1, 5.9)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-0.2 (-4.5, 4.2)	-18.3 (-23.8, -12.8)
	Difference in Mean Change from Screening (95% CI)		18.1 (12.3, 23.9)	nd
	Study Day 150 Mean Change from Screening (95% CI)		3.4 (-1.7, 8.5)	-6.4 (-12.8, 0.0)
	Difference in Mean Change from Screening (95% CI)		9.8 (2.6, 17.0)	nd
	Study Month 9 Mean Change from Screening (95% CI)		5.3 (0.1, 10.5)	0.9 (-5.9, 7.8)
	Difference in Mean Change from Screening (95% CI)		4.4 (-3.3, 12.0)	nd
	Study Month 12 Mean Change from Screening (95% CI)		4.9 (-0.4, 10.3)	6.4 (-0.9, 13.6)
	Difference in Mean Change from Screening (95% CI)		-1.5 (-9.6, 6.6)	nd
	Study Month 15 Mean Change from Screening (95% CI)		3.8 (-1.5, 9.0)	8.7 (1.5, 15.9)
	Difference in Mean Change from Screening (95% CI)		-4.9 (-13.0, 3.1)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	994		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	1		
	Model Fit Statistics			
	-2 Res Log Likelihood	8418.4		
	AIC (Smaller is Better)	8460.4		
	AICC (Smaller is Better)	8461.3		
	BIC (Smaller is Better)	8537.9		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-11.9 (-17.5, -6.3)	-12.0 (-17.7, -6.3)
	Difference in Mean Change from Screening (95% CI)		0.1 (-5.5, 5.8)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-2.5 (-8.1, 3.2)	-19.7 (-25.7, -13.7)
	Difference in Mean Change from Screening (95% CI)		17.2 (11.2, 23.3)	nd
	Study Day 150 Mean Change from Screening (95% CI)		1.1 (-5.2, 7.3)	-7.9 (-14.8, -1.0)
	Difference in Mean Change from Screening (95% CI)		8.9 (1.5, 16.4)	nd
	Study Month 9 Mean Change from Screening (95% CI)		2.8 (-3.5, 9.2)	-0.6 (-8.0, 6.7)
	Difference in Mean Change from Screening (95% CI)		3.4 (-4.4, 11.3)	nd
	Study Month 12 Mean Change from Screening (95% CI)		2.5 (-4.0, 8.9)	4.8 (-2.9, 12.5)
	Difference in Mean Change from Screening (95% CI)		-2.3 (-10.7, 6.0)	nd
	Study Month 15 Mean Change from Screening (95% CI)		1.3 (-5.1, 7.7)	7.2 (-0.5, 14.8)
	Difference in Mean Change from Screening (95% CI)		-5.8 (-14.1, 2.4)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	995		
	Number of Observations Used	994		
	Number of Observations Not Used	1		
	Model Fit Statistics			
	-2 Res Log Likelihood	8337.1		
	AIC (Smaller is Better)	8379.1		
	AICC (Smaller is Better)	8380.1		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8456.6		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-13.1 (-22.0, -4.2)	-11.9 (-20.5, -3.4)
	Difference in Mean Change from Screening (95% CI)		-1.2 (-6.9, 4.6)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-3.8 (-12.7, 5.2)	-19.5 (-28.2, -10.8)
	Difference in Mean Change from Screening (95% CI)		15.8 (9.5, 22.1)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-0.2 (-9.5, 9.1)	-7.7 (-17.1, 1.7)
	Difference in Mean Change from Screening (95% CI)		7.5 (-0.2, 15.1)	nd
	Study Month 9 Mean Change from Screening (95% CI)		1.5 (-7.9, 10.9)	-0.4 (-10.2, 9.3)
	Difference in Mean Change from Screening (95% CI)		1.9 (-6.2, 10.0)	nd
	Study Month 12 Mean Change from Screening (95% CI)		1.1 (-8.4, 10.6)	5.0 (-5.0, 15.0)
	Difference in Mean Change from Screening (95% CI)		-3.9 (-12.3, 4.6)	nd
	Study Month 15 Mean Change from Screening (95% CI)		0.0 (-9.4, 9.4)	7.3 (-2.6, 17.3)
	Difference in Mean Change from Screening (95% CI)		-7.3 (-15.6, 1.0)	nd

Data cutoff date = 18MAR2021

Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed; QoL, quality of life.

Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.

[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).

Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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Table 4.1.02 EORTC QLQ-C30 Physical Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	997		
	Number of Observations Used	996		
	Number of Observations Not Used	1		
	Model Fit Statistics			
	-2 Res Log Likelihood	8182.3		
	AIC (Smaller is Better)	8224.3		
	AICC (Smaller is Better)	8225.3		
	BIC (Smaller is Better)	8301.8		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-13.5 (-17.4, -9.6)	-8.6 (-12.8, -4.3)
	Difference in Mean Change from Screening (95% CI)		-5.0 (-9.6, -0.3)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-2.1 (-5.9, 1.6)	-15.2 (-20.0, -10.4)
	Difference in Mean Change from Screening (95% CI)		13.1 (8.0, 18.2)	nd
	Study Day 150 Mean Change from Screening (95% CI)		1.1 (-3.1, 5.3)	-4.0 (-9.3, 1.4)
	Difference in Mean Change from Screening (95% CI)		5.1 (-0.9, 11.0)	nd
	Study Month 9 Mean Change from Screening (95% CI)		2.9 (-1.4, 7.2)	-0.7 (-6.4, 4.9)
	Difference in Mean Change from Screening (95% CI)		3.6 (-2.7, 9.8)	nd
	Study Month 12 Mean Change from Screening (95% CI)		1.2 (-3.5, 5.8)	3.9 (-2.5, 10.2)
	Difference in Mean Change from Screening (95% CI)		-2.7 (-9.8, 4.5)	nd
	Study Month 15 Mean Change from Screening (95% CI)		1.8 (-2.7, 6.3)	4.6 (-1.5, 10.8)
	Difference in Mean Change from Screening (95% CI)		-2.9 (-9.7, 4.0)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	997		
	Number of Observations Used	996		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	1		
	Model Fit Statistics			
	-2 Res Log Likelihood	8169.1		
	AIC (Smaller is Better)	8211.1		
	AICC (Smaller is Better)	8212		
	BIC (Smaller is Better)	8288.6		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-13.1 (-18.1, -8.2)	-8.2 (-13.4, -3.1)
	Difference in Mean Change from Screening (95% CI)		-4.9 (-10.1, 0.3)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-1.7 (-6.6, 3.1)	-14.9 (-20.2, -9.7)
	Difference in Mean Change from Screening (95% CI)		13.2 (7.9, 18.5)	nd
	Study Day 150 Mean Change from Screening (95% CI)		1.5 (-3.8, 6.8)	-3.6 (-9.5, 2.2)
	Difference in Mean Change from Screening (95% CI)		5.1 (-1.0, 11.3)	nd
	Study Month 9 Mean Change from Screening (95% CI)		3.3 (-2.0, 8.7)	-0.4 (-6.5, 5.8)
	Difference in Mean Change from Screening (95% CI)		3.7 (-2.7, 10.1)	nd
	Study Month 12 Mean Change from Screening (95% CI)		1.6 (-4.0, 7.3)	4.2 (-2.6, 11.0)
	Difference in Mean Change from Screening (95% CI)		-2.6 (-9.9, 4.7)	nd
	Study Month 15 Mean Change from Screening (95% CI)		2.2 (-3.3, 7.7)	5.0 (-1.6, 11.6)
	Difference in Mean Change from Screening (95% CI)		-2.8 (-9.8, 4.2)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	997		
	Number of Observations Used	996		
	Number of Observations Not Used	1		
	Model Fit Statistics			
	-2 Res Log Likelihood	8081		
	AIC (Smaller is Better)	8123		
	AICC (Smaller is Better)	8124		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8200.5		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-15.6 (-23.2, -8.1)	-8.9 (-16.3, -1.5)
	Difference in Mean Change from Screening (95% CI)		-6.7 (-11.9, -1.5)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-4.3 (-11.8, 3.3)	-15.5 (-23.1, -8.0)
	Difference in Mean Change from Screening (95% CI)		11.3 (5.9, 16.7)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-1.1 (-8.9, 6.7)	-4.1 (-12.0, 3.8)
	Difference in Mean Change from Screening (95% CI)		3.1 (-3.1, 9.2)	nd
	Study Month 9 Mean Change from Screening (95% CI)		0.7 (-7.2, 8.6)	-0.8 (-8.9, 7.4)
	Difference in Mean Change from Screening (95% CI)		1.4 (-5.1, 7.9)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-1.0 (-9.1, 7.0)	3.7 (-4.9, 12.4)
	Difference in Mean Change from Screening (95% CI)		-4.8 (-12.2, 2.6)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-0.4 (-8.4, 7.5)	4.5 (-4.0, 13.0)
	Difference in Mean Change from Screening (95% CI)		-4.9 (-12.0, 2.2)	nd

Data cutoff date = 18MAR2021

Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.

Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.

[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).

Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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Table 4.1.03 EORTC QLQ-C30 Role Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	998		
	Number of Observations Used	998		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	9112.3		
	AIC (Smaller is Better)	9154.3		
	AICC (Smaller is Better)	9155.3		
	BIC (Smaller is Better)	9231.8		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-20.6 (-26.7, -14.5)	-12.0 (-18.6, -5.4)
	Difference in Mean Change from Screening (95% CI)		-8.6 (-16.0, -1.3)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-3.4 (-9.2, 2.4)	-23.2 (-30.8, -15.7)
	Difference in Mean Change from Screening (95% CI)		19.8 (11.8, 27.9)	nd
	Study Day 150 Mean Change from Screening (95% CI)		4.0 (-2.2, 10.2)	-11.1 (-19.0, -3.2)
	Difference in Mean Change from Screening (95% CI)		15.1 (6.4, 23.7)	nd
	Study Month 9 Mean Change from Screening (95% CI)		4.6 (-2.2, 11.3)	-2.0 (-11.0, 7.0)
	Difference in Mean Change from Screening (95% CI)		6.6 (-3.4, 16.6)	nd
	Study Month 12 Mean Change from Screening (95% CI)		2.4 (-4.4, 9.3)	9.6 (0.2, 19.1)
	Difference in Mean Change from Screening (95% CI)		-7.2 (-17.6, 3.3)	nd
	Study Month 15 Mean Change from Screening (95% CI)		4.1 (-2.8, 11.1)	7.1 (-2.6, 16.8)
	Difference in Mean Change from Screening (95% CI)		-3.0 (-13.7, 7.8)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	998		
	Number of Observations Used	998		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	9096.5		
	AIC (Smaller is Better)	9138.5		
	AICC (Smaller is Better)	9139.5		
	BIC (Smaller is Better)	9216		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-21.2 (-28.8, -13.5)	-12.4 (-20.4, -4.4)
	Difference in Mean Change from Screening (95% CI)		-8.8 (-17.0, -0.5)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-4.0 (-11.5, 3.5)	-23.7 (-31.9, -15.4)
	Difference in Mean Change from Screening (95% CI)		19.7 (11.4, 28.0)	nd
	Study Day 150 Mean Change from Screening (95% CI)		3.4 (-4.5, 11.2)	-11.5 (-20.2, -2.9)
	Difference in Mean Change from Screening (95% CI)		14.9 (6.0, 23.8)	nd
	Study Month 9 Mean Change from Screening (95% CI)		3.9 (-4.4, 12.3)	-2.5 (-12.1, 7.2)
	Difference in Mean Change from Screening (95% CI)		6.4 (-3.9, 16.7)	nd
	Study Month 12 Mean Change from Screening (95% CI)		1.7 (-6.7, 10.2)	9.1 (-1.1, 19.3)
	Difference in Mean Change from Screening (95% CI)		-7.3 (-18.0, 3.3)	nd
	Study Month 15 Mean Change from Screening (95% CI)		3.5 (-5.0, 12.0)	6.6 (-3.7, 17.0)
	Difference in Mean Change from Screening (95% CI)		-3.1 (-14.2, 7.9)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	998		
	Number of Observations Used	998		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8979.6		
	AIC (Smaller is Better)	9021.6		
	AICC (Smaller is Better)	9022.5		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	9099.1		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-23.2 (-34.5, -11.8)	-11.4 (-22.6, -0.3)
	Difference in Mean Change from Screening (95% CI)		-11.7 (-19.8, -3.7)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-5.9 (-17.2, 5.4)	-22.6 (-34.0, -11.3)
	Difference in Mean Change from Screening (95% CI)		16.7 (8.5, 25.0)	nd
	Study Day 150 Mean Change from Screening (95% CI)		1.4 (-10.1, 12.9)	-10.4 (-22.0, 1.2)
	Difference in Mean Change from Screening (95% CI)		11.8 (2.9, 20.7)	nd
	Study Month 9 Mean Change from Screening (95% CI)		1.8 (-10.0, 13.7)	-1.3 (-13.7, 11.1)
	Difference in Mean Change from Screening (95% CI)		3.2 (-7.1, 13.4)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-0.6 (-12.5, 11.4)	10.2 (-2.7, 23.2)
	Difference in Mean Change from Screening (95% CI)		-10.8 (-21.5, -0.1)	nd
	Study Month 15 Mean Change from Screening (95% CI)		1.3 (-10.6, 13.3)	7.7 (-5.2, 20.7)
	Difference in Mean Change from Screening (95% CI)		-6.4 (-17.3, 4.5)	nd

Data cutoff date = 18MAR2021

Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.

Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.

[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).

Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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Table 4.1.04 EORTC QLQ-C30 Emotional Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8251.5		
	AIC (Smaller is Better)	8293.5		
	AICC (Smaller is Better)	8294.4		
	BIC (Smaller is Better)	8371		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		1.7 (-2.3, 5.7)	-3.1 (-7.4, 1.2)
	Difference in Mean Change from Screening (95% CI)		4.9 (0.2, 9.5)	nd
	Study Day 100 Mean Change from Screening (95% CI)		4.9 (0.8, 9.0)	-1.2 (-6.5, 4.1)
	Difference in Mean Change from Screening (95% CI)		6.1 (0.4, 11.8)	nd
	Study Day 150 Mean Change from Screening (95% CI)		7.0 (3.0, 11.0)	2.3 (-2.8, 7.3)
	Difference in Mean Change from Screening (95% CI)		4.8 (-0.6, 10.1)	nd
	Study Month 9 Mean Change from Screening (95% CI)		9.7 (5.5, 14.0)	4.0 (-1.6, 9.6)
	Difference in Mean Change from Screening (95% CI)		5.7 (-0.4, 11.8)	nd
	Study Month 12 Mean Change from Screening (95% CI)		6.7 (2.1, 11.4)	8.9 (2.6, 15.2)
	Difference in Mean Change from Screening (95% CI)		-2.2 (-9.2, 4.8)	nd
	Study Month 15 Mean Change from Screening (95% CI)		6.4 (1.9, 10.8)	8.0 (2.0, 14.1)
	Difference in Mean Change from Screening (95% CI)		-1.7 (-8.4, 5.0)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8236.9		
	AIC (Smaller is Better)	8278.9		
	AICC (Smaller is Better)	8279.8		
	BIC (Smaller is Better)	8356.4		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		1.1 (-3.9, 6.2)	-4.6 (-9.8, 0.5)
	Difference in Mean Change from Screening (95% CI)		5.8 (0.5, 11.0)	nd
	Study Day 100 Mean Change from Screening (95% CI)		4.4 (-0.8, 9.6)	-2.0 (-7.7, 3.7)
	Difference in Mean Change from Screening (95% CI)		6.4 (0.5, 12.4)	nd
	Study Day 150 Mean Change from Screening (95% CI)		6.5 (1.4, 11.7)	1.4 (-4.1, 6.9)
	Difference in Mean Change from Screening (95% CI)		5.1 (-0.5, 10.7)	nd
	Study Month 9 Mean Change from Screening (95% CI)		9.2 (3.9, 14.6)	3.1 (-2.9, 9.2)
	Difference in Mean Change from Screening (95% CI)		6.1 (-0.2, 12.4)	nd
	Study Month 12 Mean Change from Screening (95% CI)		6.2 (0.6, 11.8)	8.0 (1.3, 14.6)
	Difference in Mean Change from Screening (95% CI)		-1.8 (-8.9, 5.4)	nd
	Study Month 15 Mean Change from Screening (95% CI)		5.8 (0.3, 11.3)	7.0 (0.5, 13.5)
	Difference in Mean Change from Screening (95% CI)		-1.2 (-8.1, 5.7)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8155.9		
	AIC (Smaller is Better)	8197.9		
	AICC (Smaller is Better)	8198.9		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8275.4		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-7.1 (-15.1, 0.8)	-12.1 (-19.7, -4.4)
	Difference in Mean Change from Screening (95% CI)		4.9 (-0.4, 10.3)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-3.8 (-11.9, 4.2)	-9.5 (-17.5, -1.5)
	Difference in Mean Change from Screening (95% CI)		5.6 (-0.5, 11.8)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-1.7 (-9.7, 6.3)	-6.3 (-14.2, 1.7)
	Difference in Mean Change from Screening (95% CI)		4.5 (-1.3, 10.4)	nd
	Study Month 9 Mean Change from Screening (95% CI)		0.9 (-7.2, 9.0)	-4.4 (-12.6, 3.9)
	Difference in Mean Change from Screening (95% CI)		5.3 (-1.0, 11.6)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-2.1 (-10.4, 6.2)	0.4 (-8.4, 9.1)
	Difference in Mean Change from Screening (95% CI)		-2.5 (-9.8, 4.8)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-2.4 (-10.7, 5.8)	-0.6 (-9.2, 8.1)
	Difference in Mean Change from Screening (95% CI)		-1.9 (-8.9, 5.2)	nd

Data cutoff date = 18MAR2021

Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.

Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.

[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).

Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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Table 4.1.05 EORTC QLQ-C30 Cognitive Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8021.6		
	AIC (Smaller is Better)	8063.6		
	AICC (Smaller is Better)	8064.6		
	BIC (Smaller is Better)	8141.1		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-4.0 (-7.6, -0.4)	-7.5 (-11.4, -3.6)
	Difference in Mean Change from Screening (95% CI)		3.5 (-0.6, 7.6)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-2.2 (-6.0, 1.6)	-7.1 (-12.0, -2.2)
	Difference in Mean Change from Screening (95% CI)		5.0 (-0.3, 10.3)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-0.7 (-4.5, 3.1)	-5.5 (-10.3, -0.7)
	Difference in Mean Change from Screening (95% CI)		4.8 (-0.4, 10.0)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-1.8 (-6.1, 2.6)	-3.9 (-9.7, 1.8)
	Difference in Mean Change from Screening (95% CI)		2.2 (-4.2, 8.6)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-3.2 (-7.7, 1.2)	-0.5 (-6.6, 5.5)
	Difference in Mean Change from Screening (95% CI)		-2.7 (-9.4, 4.1)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-1.3 (-5.6, 3.1)	-3.0 (-8.9, 3.0)
	Difference in Mean Change from Screening (95% CI)		1.7 (-4.9, 8.3)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	8007.2		
	AIC (Smaller is Better)	8049.2		
	AICC (Smaller is Better)	8050.2		
	BIC (Smaller is Better)	8126.7		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-5.6 (-10.4, -0.9)	-9.2 (-14.0, -4.4)
	Difference in Mean Change from Screening (95% CI)		3.6 (-1.1, 8.2)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-3.7 (-8.6, 1.2)	-8.4 (-13.7, -3.1)
	Difference in Mean Change from Screening (95% CI)		4.7 (-0.8, 10.1)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-2.3 (-7.2, 2.6)	-6.8 (-12.1, -1.6)
	Difference in Mean Change from Screening (95% CI)		4.5 (-0.9, 9.9)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-3.4 (-8.7, 2.0)	-5.3 (-11.4, 0.8)
	Difference in Mean Change from Screening (95% CI)		1.9 (-4.7, 8.5)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-4.8 (-10.2, 0.6)	-1.9 (-8.3, 4.6)
	Difference in Mean Change from Screening (95% CI)		-3.0 (-9.9, 4.0)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-2.9 (-8.2, 2.5)	-4.3 (-10.7, 2.0)
	Difference in Mean Change from Screening (95% CI)		1.5 (-5.3, 8.3)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	996		
	Number of Observations Not Used	0		
	Model Fit Statistics			
	-2 Res Log Likelihood	7919.5		
	AIC (Smaller is Better)	7961.5		
	AICC (Smaller is Better)	7962.5		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8039		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-8.3 (-15.6, -1.1)	-10.5 (-17.6, -3.5)
	Difference in Mean Change from Screening (95% CI)		2.2 (-2.5, 6.9)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-6.3 (-13.8, 1.1)	-9.9 (-17.3, -2.5)
	Difference in Mean Change from Screening (95% CI)		3.5 (-2.1, 9.1)	nd
	Study Day 150 Mean Change from Screening (95% CI)		-5.0 (-12.4, 2.4)	-8.2 (-15.5, -0.9)
	Difference in Mean Change from Screening (95% CI)		3.1 (-2.3, 8.6)	nd
	Study Month 9 Mean Change from Screening (95% CI)		-6.1 (-13.8, 1.6)	-6.7 (-14.7, 1.2)
	Difference in Mean Change from Screening (95% CI)		0.6 (-5.9, 7.2)	nd
	Study Month 12 Mean Change from Screening (95% CI)		-7.5 (-15.3, 0.2)	-3.3 (-11.4, 4.9)
	Difference in Mean Change from Screening (95% CI)		-4.3 (-11.2, 2.7)	nd
	Study Month 15 Mean Change from Screening (95% CI)		-5.6 (-13.3, 2.1)	-5.8 (-13.9, 2.4)
	Difference in Mean Change from Screening (95% CI)		0.1 (-6.7, 6.9)	nd

Data cutoff date = 18MAR2021

Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.

Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.

[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).

Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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Table 4.1.06 EORTC QLQ-C30 Social Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set)

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
Model 1: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	995		
	Number of Observations Not Used	1		
	Model Fit Statistics			
	-2 Res Log Likelihood	8908.4		
	AIC (Smaller is Better)	8950.4		
	AICC (Smaller is Better)	8951.4		
	BIC (Smaller is Better)	9027.9		
Model 1: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-13.0 (-18.3, -7.8)	-12.9 (-18.6, -7.3)
	Difference in Mean Change from Screening (95% CI)		-0.1 (-6.2, 6.0)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-1.1 (-6.7, 4.6)	-23.9 (-31.2, -16.7)
	Difference in Mean Change from Screening (95% CI)		22.8 (15.0, 30.7)	nd
	Study Day 150 Mean Change from Screening (95% CI)		6.2 (0.7, 11.7)	-10.7 (-17.6, -3.7)
	Difference in Mean Change from Screening (95% CI)		16.9 (9.3, 24.4)	nd
	Study Month 9 Mean Change from Screening (95% CI)		11.1 (4.8, 17.4)	-3.1 (-11.5, 5.3)
	Difference in Mean Change from Screening (95% CI)		14.2 (4.8, 23.6)	nd
	Study Month 12 Mean Change from Screening (95% CI)		5.9 (-1.1, 12.9)	10.0 (0.4, 19.5)
	Difference in Mean Change from Screening (95% CI)		-4.1 (-14.9, 6.7)	nd
	Study Month 15 Mean Change from Screening (95% CI)		8.7 (1.6, 15.7)	8.9 (-1.0, 18.8)
	Difference in Mean Change from Screening (95% CI)		-0.2 (-11.3, 10.9)	nd
Model 2: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	995		

Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	Number of Observations Not Used	1		
	Model Fit Statistics			
	-2 Res Log Likelihood	8892.6		
	AIC (Smaller is Better)	8934.6		
	AICC (Smaller is Better)	8935.6		
	BIC (Smaller is Better)	9012.1		
Model 2: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-12.0 (-18.8, -5.1)	-11.4 (-18.3, -4.4)
	Difference in Mean Change from Screening (95% CI)		-0.6 (-7.4, 6.2)	nd
	Study Day 100 Mean Change from Screening (95% CI)		-0.1 (-7.3, 7.0)	-22.9 (-30.7, -15.1)
	Difference in Mean Change from Screening (95% CI)		22.8 (14.6, 31.0)	nd
	Study Day 150 Mean Change from Screening (95% CI)		7.3 (0.1, 14.4)	-9.5 (-17.2, -1.8)
	Difference in Mean Change from Screening (95% CI)		16.8 (8.9, 24.6)	nd
	Study Month 9 Mean Change from Screening (95% CI)		12.2 (4.4, 20.0)	-1.9 (-10.9, 7.2)
	Difference in Mean Change from Screening (95% CI)		14.1 (4.4, 23.7)	nd
	Study Month 12 Mean Change from Screening (95% CI)		6.9 (-1.3, 15.2)	11.1 (1.0, 21.2)
	Difference in Mean Change from Screening (95% CI)		-4.2 (-15.2, 6.9)	nd
	Study Month 15 Mean Change from Screening (95% CI)		9.7 (1.4, 18.0)	10.1 (-0.3, 20.5)
	Difference in Mean Change from Screening (95% CI)		-0.4 (-11.8, 11.0)	nd
Model 3: Observations and fit statistics[a]	Number of Observations			
	Number of Observations Read	996		
	Number of Observations Used	995		
	Number of Observations Not Used	1		
	Model Fit Statistics			
	-2 Res Log Likelihood	8793.9		
	AIC (Smaller is Better)	8835.9		
	AICC (Smaller is Better)	8836.9		

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Variable	Statistic	Model Summary	Axicabtagene Ciloleucel	Standard of Care Therapy
	BIC (Smaller is Better)	8913.4		
Model 3: Parameter Estimates	Study Day 50 Mean Change from Screening (95% CI)		-11.0 (-21.5, -0.4)	-8.8 (-19.0, 1.4)
	Difference in Mean Change from Screening (95% CI)		-2.2 (-9.1, 4.8)	nd
	Study Day 100 Mean Change from Screening (95% CI)		0.9 (-9.9, 11.7)	-20.0 (-30.8, -9.2)
	Difference in Mean Change from Screening (95% CI)		20.9 (12.6, 29.2)	nd
	Study Day 150 Mean Change from Screening (95% CI)		8.2 (-2.5, 19.0)	-6.5 (-17.1, 4.1)
	Difference in Mean Change from Screening (95% CI)		14.8 (7.0, 22.5)	nd
	Study Month 9 Mean Change from Screening (95% CI)		13.1 (1.9, 24.3)	1.2 (-10.4, 12.8)
	Difference in Mean Change from Screening (95% CI)		11.9 (2.4, 21.4)	nd
	Study Month 12 Mean Change from Screening (95% CI)		8.0 (-3.5, 19.5)	14.0 (1.5, 26.4)
	Difference in Mean Change from Screening (95% CI)		-6.0 (-16.9, 4.9)	nd
	Study Month 15 Mean Change from Screening (95% CI)		10.9 (-0.5, 22.4)	12.8 (0.1, 25.4)
	Difference in Mean Change from Screening (95% CI)		-1.8 (-12.9, 9.3)	nd

Data cutoff date = 18MAR2021

Abbreviations: AIC, Akaike Information Criterion; AICC, AIC corrected for small sample sizes; BIC, Bayesian Information Criterion; CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; nd, not displayed.

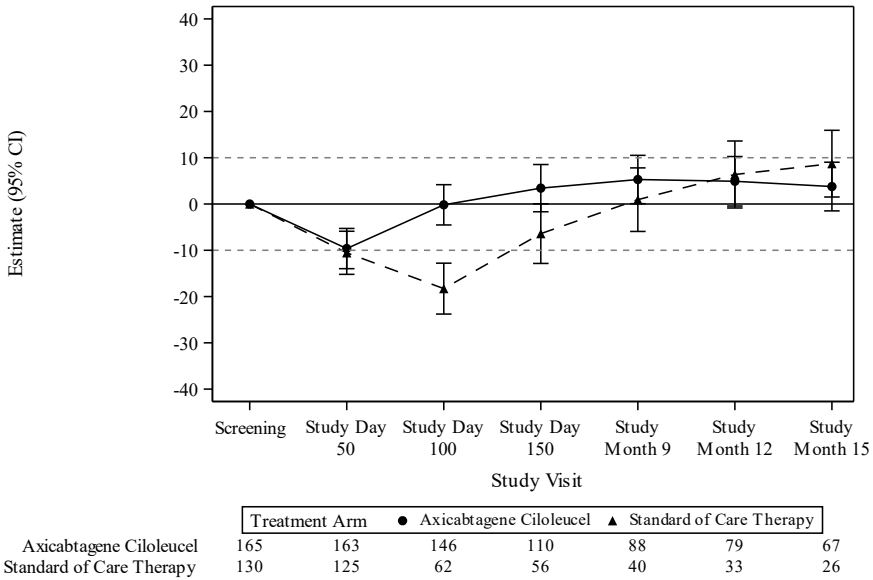
Note: Results end at Month 15 because of convergence issues for models containing more data points beyond Month 15.

[a] Model 1 included variables for treatment, time, and treatment by time interaction (primary analysis) and controlled for Response to first-line therapy (primary refractory, relapse <= 6 months of first-line therapy, relapse > 6 and <= 12 months of first-line therapy) and Age-adjusted IPI (0 to 1 vs 2 to 3) at time of screening. Model 2 includes all variables in Model 1 with additional covariates to control for patterns of missingness through day 150. Model 3 includes all variables in Model 2 with additional covariates for: Geographic region (Rest of World, United States); ECOG performance status at screening (0, 1); Age at randomization (>= 65, < 65); Sex; Race/ethnicity (Asian, Black or African American, Other, White); Disease type (diffuse large B-cell lymphoma, HGBL with or without MYC and BCL2 and/or BCL6 rearrangement, large cell transformation from follicular lymphoma, other);Molecular subgroup (Germinal center B-cell like, Non-germinal center B-cell like, Not Tested); and Double/Triple hit status (Double expressor lymphoma, HGBL-double hit, HGBL-triple hit, missing).

Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Abbildung 9 (Anhang): Verlaufskurven zu EORTC QLQ-C30 (gesundheitsbezogene Lebensqualität) - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Figure 4.1.01.1 EORTC QLQ-C30 Global Health Status/QoL Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.01. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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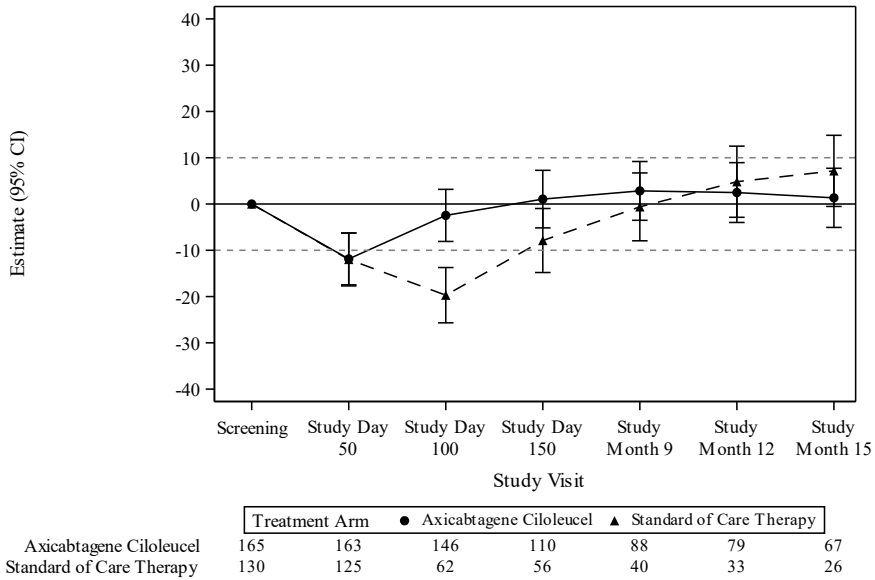
Figure 4.1.01.2 EORTC QLQ-C30 Global Health Status/QoL Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Axicabtagene Ciloleucel	165	163	146	110	88	79	67
Standard of Care Therapy	130	125	62	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.01. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
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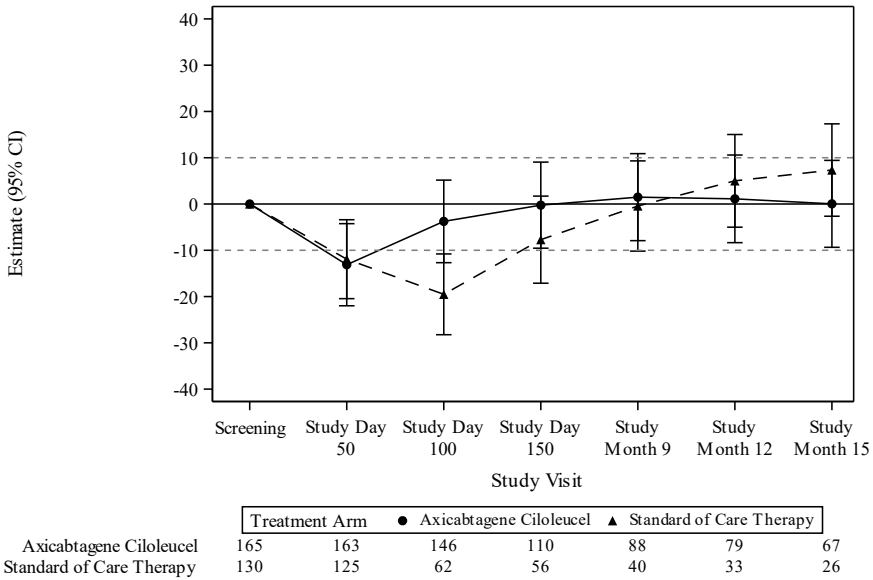
Figure 4.1.01.3 EORTC QLQ-C30 Global Health Status/QoL Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Axicabtagene Ciloleucel	165	163	146	110	88	79	67
Standard of Care Therapy	130	125	62	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.01. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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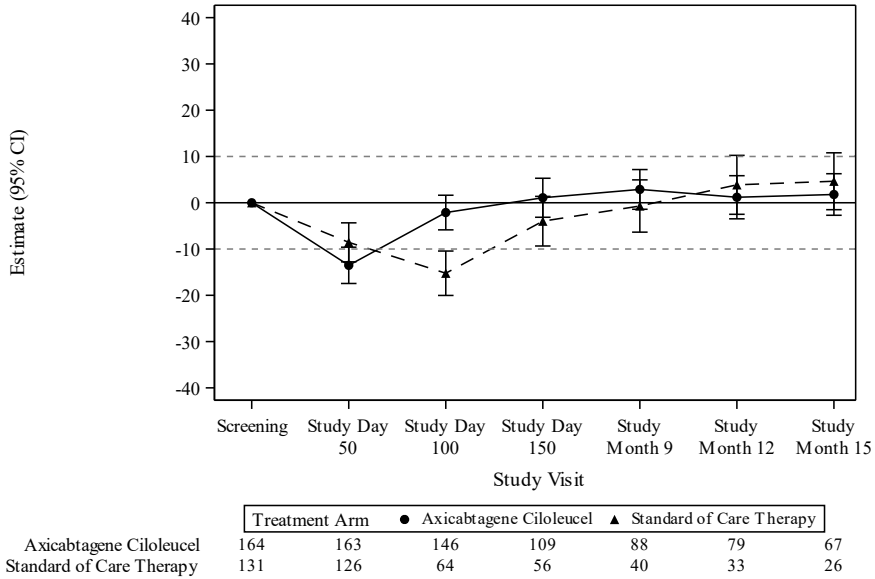
Figure 4.1.02.1 EORTC QLQ-C30 Physical Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Axicabtagene Ciloleucel	164	163	146	109	88	79	67
Standard of Care Therapy	131	126	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.02. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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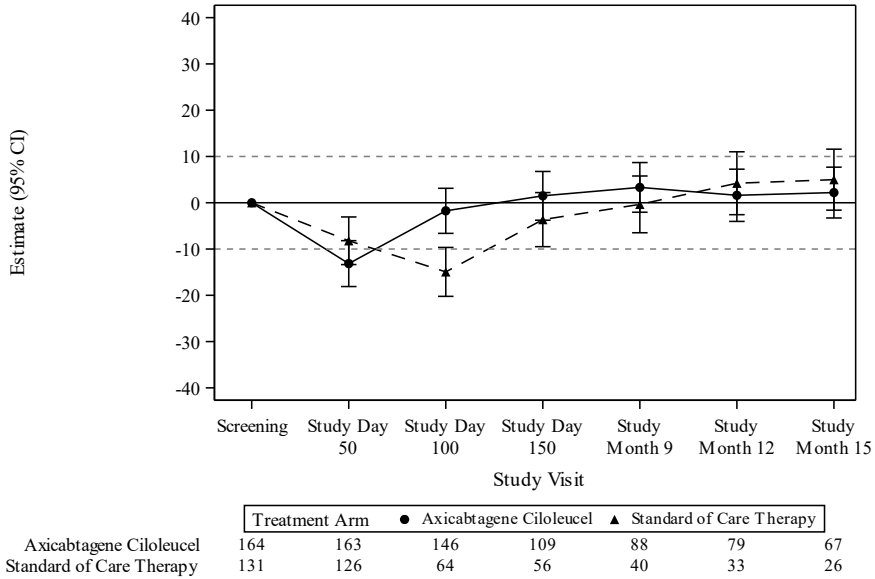
Figure 4.1.02.2 EORTC QLQ-C30 Physical Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Axicabtagene Ciloleucel	164	163	146	109	88	79	67
Standard of Care Therapy	131	126	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.02. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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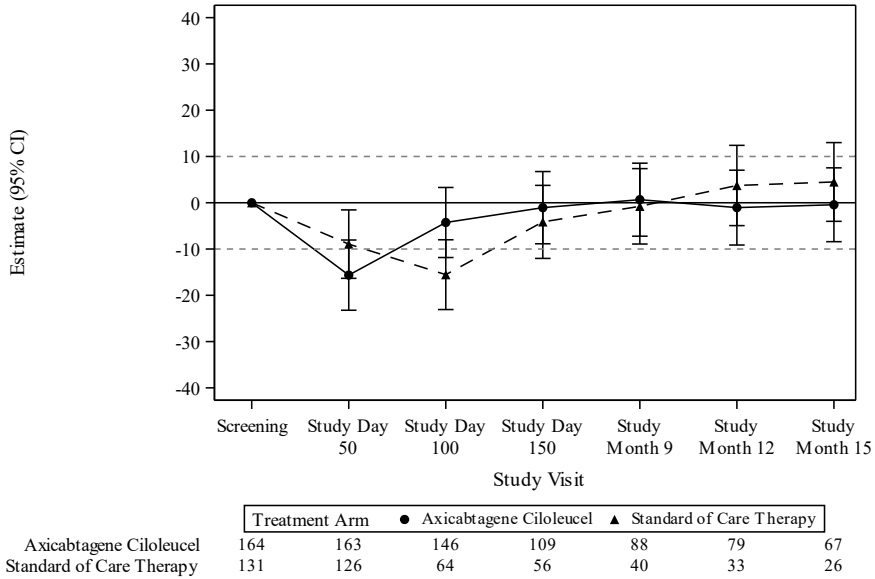
Figure 4.1.02.3 EORTC QLQ-C30 Physical Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Axicabtagene Ciloleucel	164	163	146	109	88	79	67
Standard of Care Therapy	131	126	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.02. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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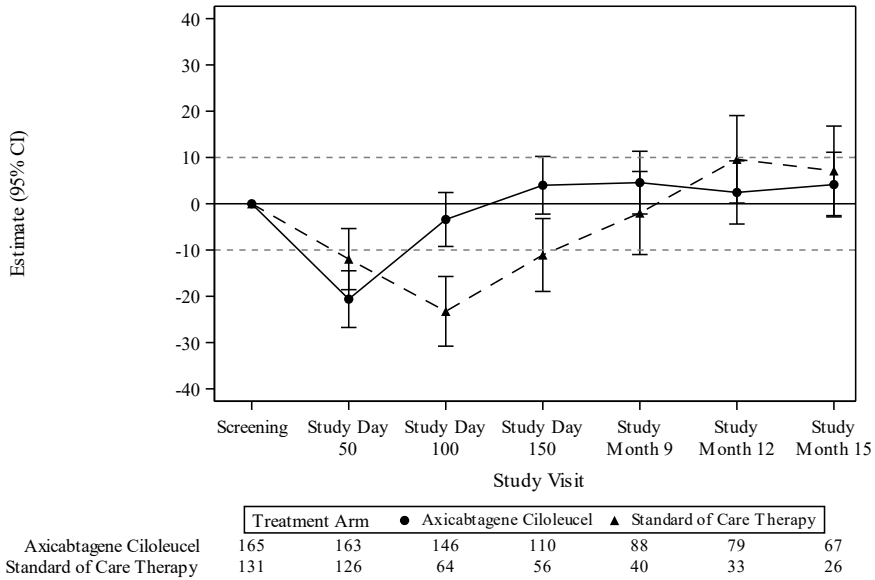
Version: 1.0 (10Aug2021)

Figure 4.1.03.1 EORTC QLQ-C30 Role Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Axicabtagene Ciloleucel	165	163	146	110	88	79	67
Standard of Care Therapy	131	126	64	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.03. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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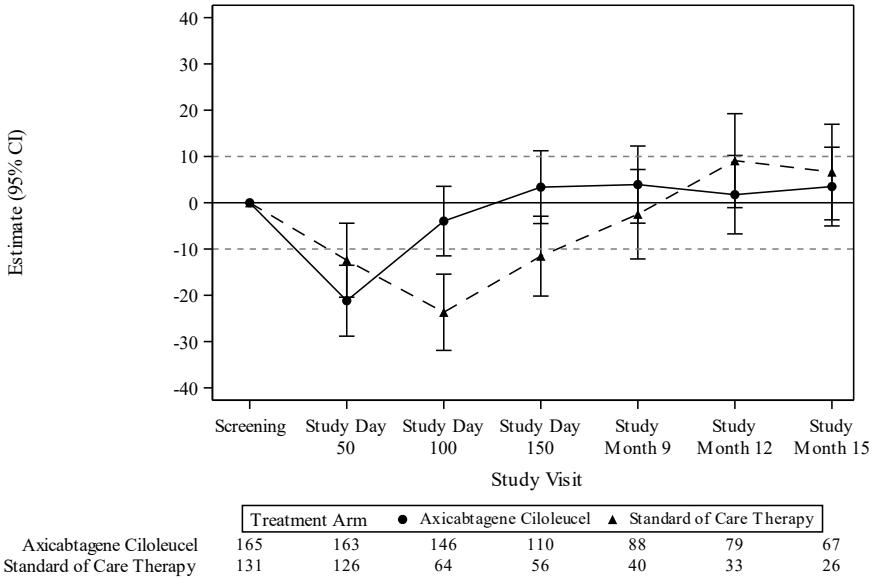
Version: 1.0 (10Aug2021)

Figure 4.1.03.2 EORTC QLQ-C30 Role Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.03. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

PRO Tables
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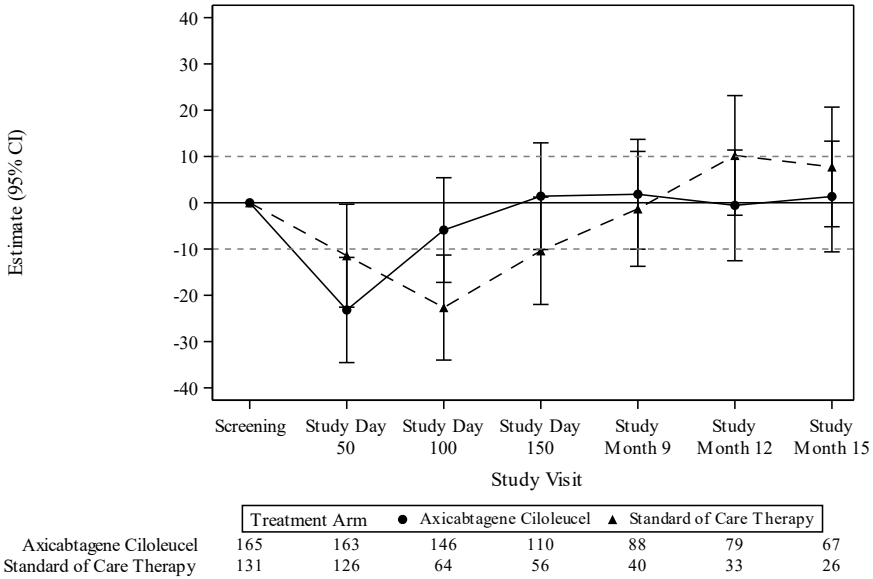
Version: 1.0 (10Aug2021)

Figure 4.1.03.3 EORTC QLQ-C30 Role Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.03. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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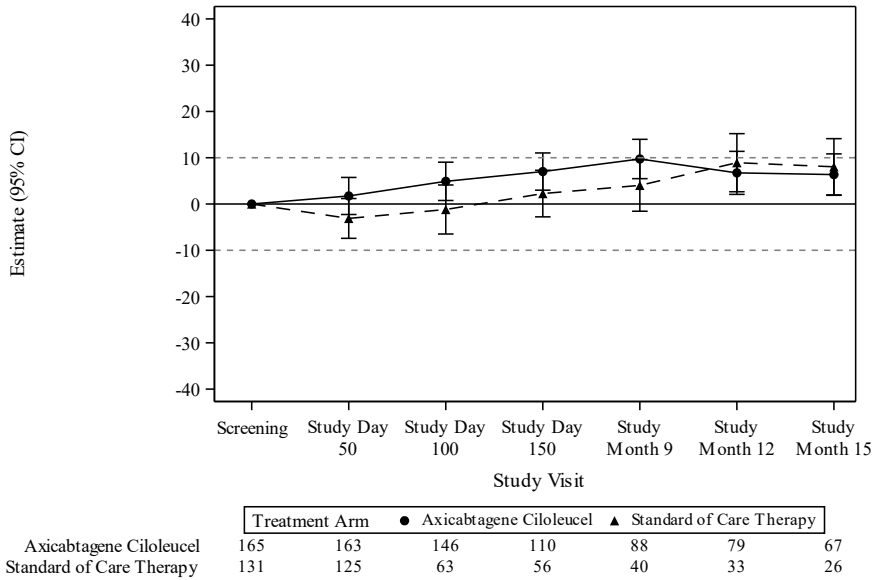
Figure 4.1.04.1 EORTC QLQ-C30 Emotional Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Axicabtagene Ciloleucel	165	163	146	110	88	79	67
Standard of Care Therapy	131	125	63	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.04. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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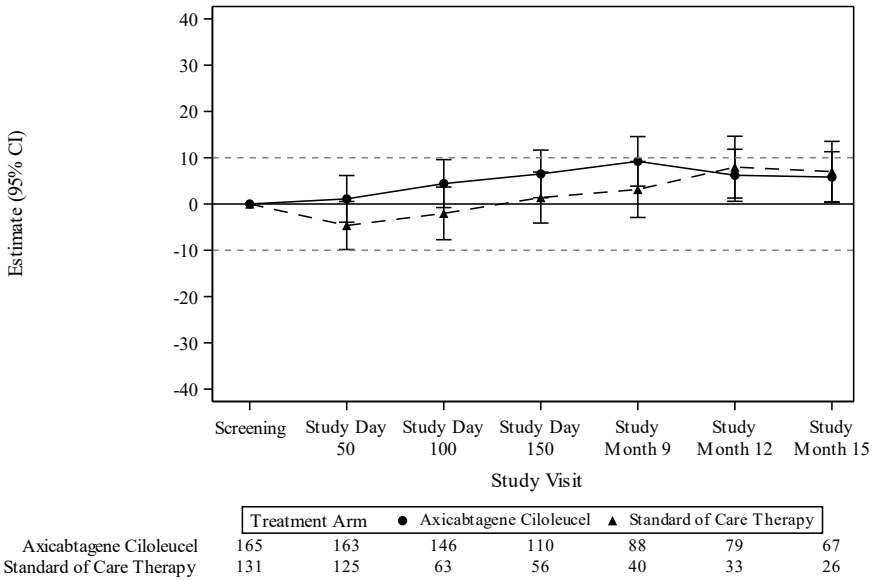
Figure 4.1.04.2 EORTC QLQ-C30 Emotional Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Axicabtagene Ciloleucel	165	163	146	110	88	79	67
Standard of Care Therapy	131	125	63	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.04. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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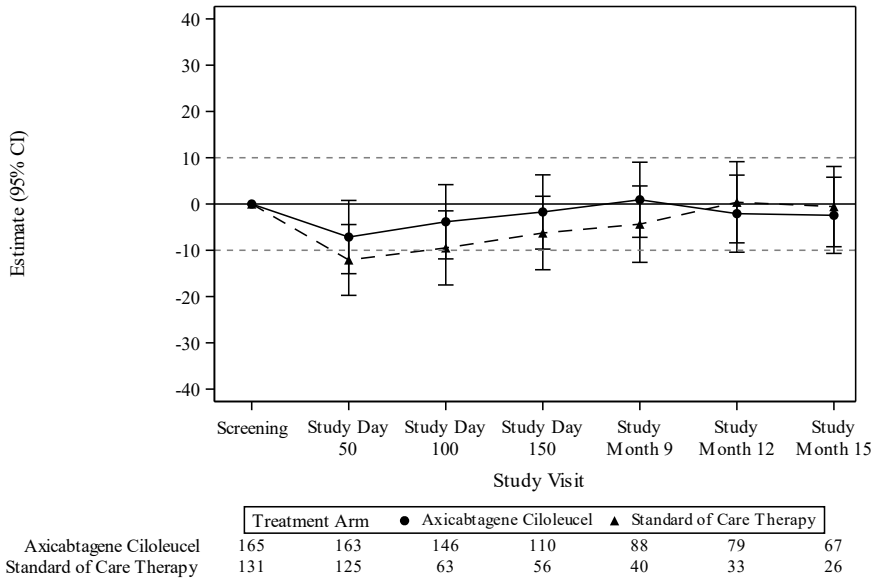
Figure 4.1.04.3 EORTC QLQ-C30 Emotional Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Axicabtagene Ciloleucel	165	163	146	110	88	79	67
Standard of Care Therapy	131	125	63	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.04. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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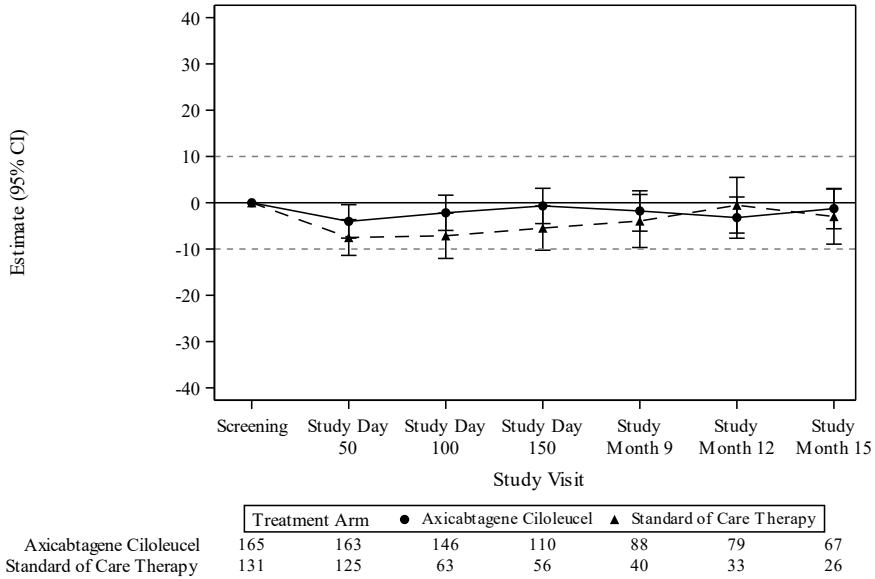
Version: 1.0 (10Aug2021)

Figure 4.1.05.1 EORTC QLQ-C30 Cognitive Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Axicabtagene Ciloleucel	165	163	146	110	88	79	67
Standard of Care Therapy	131	125	63	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.05. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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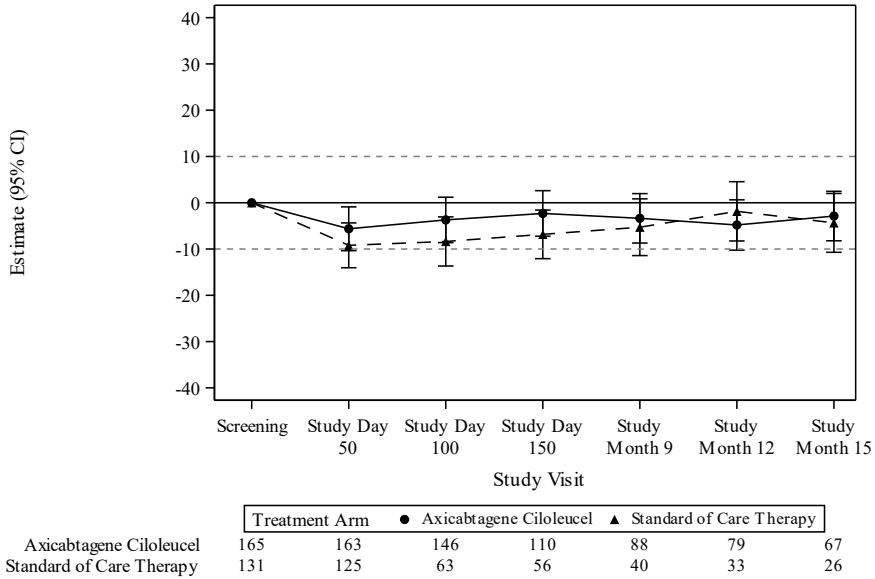
Version: 1.0 (10Aug2021)

Figure 4.1.05.2 EORTC QLQ-C30 Cognitive Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)



Axicabtagene Ciloleucel	165	163	146	110	88	79	67
Standard of Care Therapy	131	125	63	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.05. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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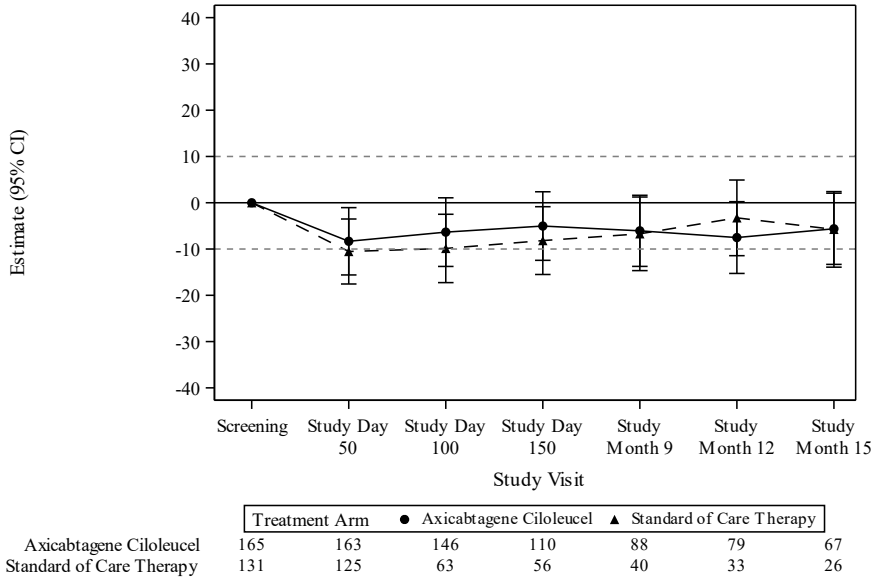
Figure 4.1.05.3 EORTC QLQ-C30 Cognitive Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.05. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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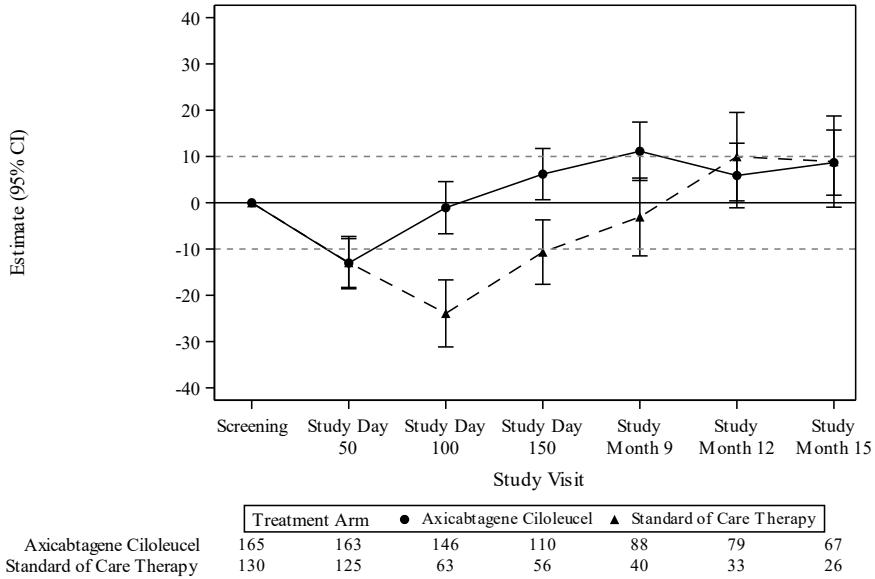
Version: 1.0 (10Aug2021)

Figure 4.1.06.1 EORTC QLQ-C30 Social Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 1)



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.06. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

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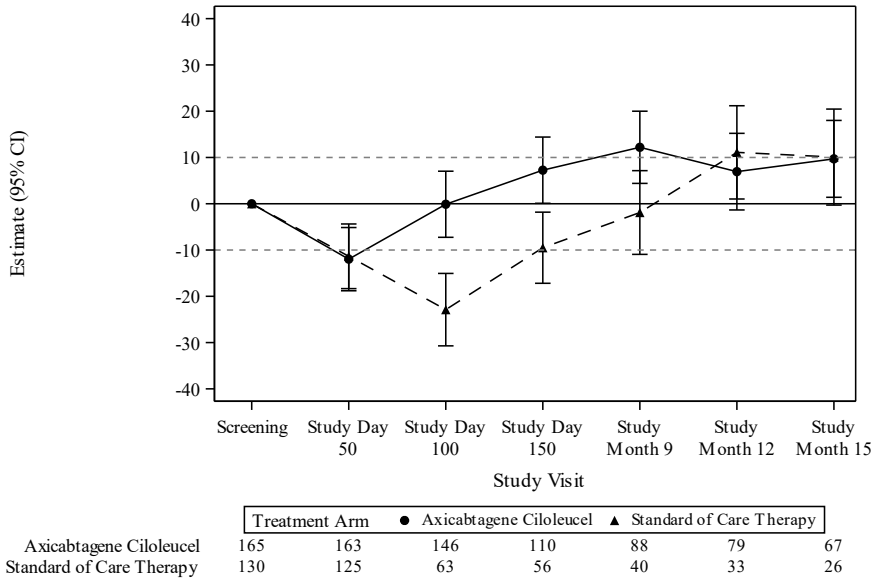
Version: 1.0 (10Aug2021)

Figure 4.1.06.2 EORTC QLQ-C30 Social Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 2)

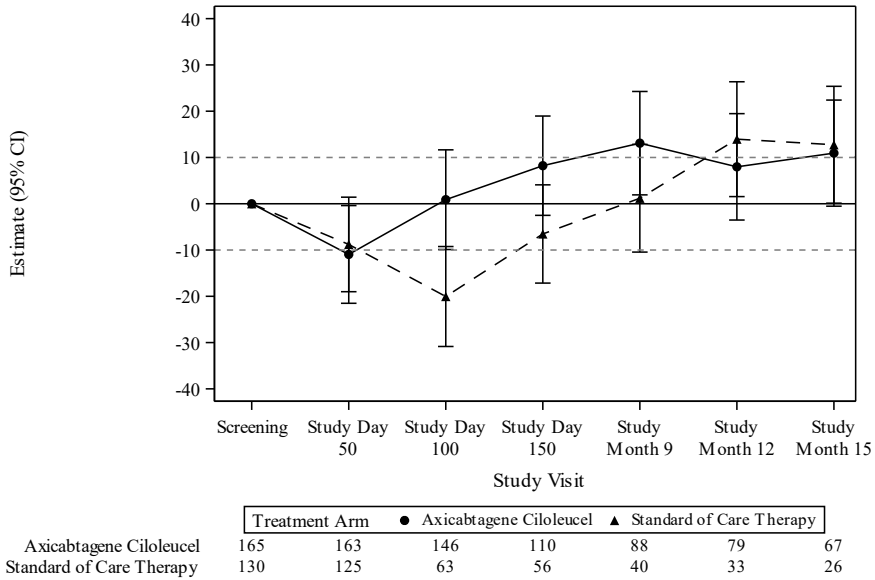


Axicabtagene Ciloleucel	165	163	146	110	88	79	67
Standard of Care Therapy	130	125	63	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.06. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

PRO Tables
Protocol KTE-C19-107
Version: 1.0 (10Aug2021)

Figure 4.1.06.3 EORTC QLQ-C30 Social Functioning Mixed Model with Repeated Measures for Change from Screening (QoL Analysis Set, Model 3)



Axicabtagene Ciloleucel	165	163	146	110	88	79	67
Standard of Care Therapy	130	125	63	56	40	33	26

Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; EORTC QLC-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; QoL, quality of life.
Note: Results populated only through Month 15 due to lack of model convergence when using time points. Figure based on Model 1 as described in Table 4.1.06. Horizontal lines represent the minimally important difference thresholds for meaningful change and are provided for clarity of interpretation.
Data Source: ADPRO Program Name: Tables 4.X.X- MMRMs v10 2021.07.09 (up to M15, used missing_pattern_D150).sas Output Generated: 09AUG2021

Anhang 4-G2.8: Ergänzende Darstellung zu unerwünschte Ereignisse - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Tabelle 4-21 (Anhang): Gesamtraten unerwünschter Ereignisse, ergänzende Darstellung - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1. Overall Summary of Treatment-emergent Adverse Events (Safety Analysis Set)

	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Any TEAE	170 (100)	168 (100)	338 (100)
Worst Grade 1	4 (2)	8 (5)	12 (4)
Worst Grade 2	11 (6)	20 (12)	31 (9)
Worst Grade 3	33 (19)	36 (21)	69 (20)
Worst Grade 4	105 (62)	97 (58)	202 (60)
Worst Grade 5	17 (10)	7 (4)	24 (7)
Worst Grade 5, excluding PD	10 (6)	2 (1)	12 (4)
Worst Grade ≥ 3	155 (91)	140 (83)	295 (87)
Any serious TEAE	95 (56)	78 (46)	173 (51)
Worst Grade 1	4 (2)	3 (2)	7 (2)
Worst Grade 2	13 (8)	7 (4)	20 (6)
Worst Grade 3	45 (26)	43 (26)	88 (26)
Worst Grade 4	17 (10)	19 (11)	36 (11)
Worst Grade 5	16 (9)	6 (4)	22 (7)
Worst Grade 5, excluding PD	9 (5)	2 (1)	11 (3)
Worst Grade ≥ 3	78 (46)	68 (40)	146 (43)
Any treatment-related TEAE	163 (96)	160 (95)	323 (96)
Worst Grade 1	10 (6)	15 (9)	25 (7)
Worst Grade 2	41 (24)	14 (8)	55 (16)
Worst Grade 3	50 (29)	35 (21)	85 (25)
Worst Grade 4	61 (36)	94 (56)	155 (46)
Worst Grade 5	1 (1)	2 (1)	3 (1)
Worst Grade 5, excluding PD	1 (1)	2 (1)	3 (1)
Worst Grade ≥ 3	112 (66)	131 (78)	243 (72)
Any serious treatment-related TEAE	63 (37)	59 (35)	122 (36)
Worst Grade 1	2 (1)	2 (1)	4 (1)
Worst Grade 2	12 (7)	6 (4)	18 (5)
Worst Grade 3	37 (22)	32 (19)	69 (20)
Worst Grade 4	11 (6)	17 (10)	28 (8)
Worst Grade 5	1 (1)	2 (1)	3 (1)
Worst Grade 5, excluding PD	1 (1)	2 (1)	3 (1)
Worst Grade ≥ 3	49 (29)	51 (30)	100 (30)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; NA, not applicable; PD, progressive disease; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Subjects were summarized at their worst CTCAE grade or Lee Grade for CRS.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.

Data Source: ADSL, ADAE Program Name: t_aesum.sas Output Generated: 20230314T16:17

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Table 14.3.1.1. Overall Summary of Treatment-emergent Adverse Events (Safety Analysis Set)

	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Any TE neurologic event	103 (61)	33 (20)	136 (40)
Worst Grade 1	43 (25)	23 (14)	66 (20)
Worst Grade 2	24 (14)	9 (5)	33 (10)
Worst Grade 3	26 (15)	1 (1)	27 (8)
Worst Grade 4	10 (6)	0 (0)	10 (3)
Worst Grade 5	0 (0)	0 (0)	0 (0)
Worst Grade 5, excluding PD	0 (0)	0 (0)	0 (0)
Worst Grade ≥ 3	36 (21)	1 (1)	37 (11)
Any serious TE neurologic event	34 (20)	1 (1)	35 (10)
Worst Grade 1	2 (1)	0 (0)	2 (1)
Worst Grade 2	6 (4)	1 (1)	7 (2)
Worst Grade 3	19 (11)	0 (0)	19 (6)
Worst Grade 4	7 (4)	0 (0)	7 (2)
Worst Grade 5	0 (0)	0 (0)	0 (0)
Worst Grade 5, excluding PD	0 (0)	0 (0)	0 (0)
Worst Grade ≥ 3	26 (15)	0 (0)	26 (8)
Any TE CRS	157 (92)	NA	157 (46)
Worst Grade 1	70 (41)	NA	70 (21)
Worst Grade 2	76 (45)	NA	76 (22)
Worst Grade 3	8 (5)	NA	8 (2)
Worst Grade 4	3 (2)	NA	3 (1)
Worst Grade 5	0 (0)	NA	0 (0)
Worst Grade 5, excluding PD	0 (0)	NA	0 (0)
Worst Grade ≥ 3	11 (6)	NA	11 (3)
Any serious TE CRS	29 (17)	NA	29 (9)
Worst Grade 1	6 (4)	NA	6 (2)
Worst Grade 2	13 (8)	NA	13 (4)
Worst Grade 3	7 (4)	NA	7 (2)
Worst Grade 4	3 (2)	NA	3 (1)
Worst Grade 5	0 (0)	NA	0 (0)
Worst Grade 5, excluding PD	0 (0)	NA	0 (0)
Worst Grade ≥ 3	10 (6)	NA	10 (3)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; NA, not applicable; PD, progressive disease; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Subjects were summarized at their worst CTCAE grade or Lee Grade for CRS.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.

Data Source: ADSL, ADAE Program Name: t_aesum.sas Output Generated: 20230314T16:17

Table 14.3.1.1. Overall Summary of Treatment-emergent Adverse Events (Safety Analysis Set)

	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Any TE hypogammaglobulinemia	19 (11)	1 (1)	20 (6)
Worst Grade 1	6 (4)	1 (1)	7 (2)
Worst Grade 2	13 (8)	0 (0)	13 (4)
Worst Grade 3	0 (0)	0 (0)	0 (0)
Worst Grade 4	0 (0)	0 (0)	0 (0)
Worst Grade 5	0 (0)	0 (0)	0 (0)
Worst Grade 5, excluding PD	0 (0)	0 (0)	0 (0)
Worst Grade ≥ 3	0 (0)	0 (0)	0 (0)
Any TE cytopenias	136 (80)	135 (80)	271 (80)
Worst Grade 1	2 (1)	4 (2)	6 (2)
Worst Grade 2	6 (4)	5 (3)	11 (3)
Worst Grade 3	23 (14)	28 (17)	51 (15)
Worst Grade 4	105 (62)	98 (58)	203 (60)
Worst Grade 5	0 (0)	0 (0)	0 (0)
Worst Grade 5, excluding PD	0 (0)	0 (0)	0 (0)
Worst Grade ≥ 3	128 (75)	126 (75)	254 (75)
Any TE infections	76 (45)	53 (32)	129 (38)
Worst Grade 1	10 (6)	10 (6)	20 (6)
Worst Grade 2	38 (22)	23 (14)	61 (18)
Worst Grade 3	18 (11)	14 (8)	32 (9)
Worst Grade 4	3 (2)	6 (4)	9 (3)
Worst Grade 5	7 (4)	0 (0)	7 (2)
Worst Grade 5, excluding PD	7 (4)	0 (0)	7 (2)
Worst Grade ≥ 3	28 (16)	20 (12)	48 (14)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; NA, not applicable; PD, progressive disease; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Subjects were summarized at their worst CTCAE grade or Lee Grade for CRS.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.

Data Source: ADSL, ADAE Program Name: t_aesum.sas Output Generated: 20230314T16:17

Tabelle 4-22 (Anhang): Aufgetretene neurologische Ereignisse nach bevorzugten Terms - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.4.1.2.1. Subject Incidence of Treatment-emergent Adverse Events of Interest – Neurologic Events by Preferred Term and Worst Grade (Safety Analysis Set)

Preferred Term Worst CTCAE Grade	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Subjects with any TE neurologic events	103 (61)	33 (20)	136 (40)
Grade 1	43 (25)	23 (14)	66 (20)
Grade 2	24 (14)	9 (5)	33 (10)
Grade 3	26 (15)	1 (1)	27 (8)
Grade 4	10 (6)	0 (0)	10 (3)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	36 (21)	1 (1)	37 (11)
Tremor	44 (26)	1 (1)	45 (13)
Grade 1	37 (22)	1 (1)	38 (11)
Grade 2	5 (3)	0 (0)	5 (1)
Grade 3	2 (1)	0 (0)	2 (1)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	2 (1)	0 (0)	2 (1)
Confusional state	40 (24)	4 (2)	44 (13)
Grade 1	19 (11)	4 (2)	23 (7)
Grade 2	12 (7)	0 (0)	12 (4)
Grade 3	8 (5)	0 (0)	8 (2)
Grade 4	1 (1)	0 (0)	1 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	9 (5)	0 (0)	9 (3)
Aphasia	36 (21)	0 (0)	36 (11)
Grade 1	15 (9)	0 (0)	15 (4)
Grade 2	9 (5)	0 (0)	9 (3)
Grade 3	12 (7)	0 (0)	12 (4)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	12 (7)	0 (0)	12 (4)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the overall column.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: Neurologic events are identified using a modified search strategy based on Topp 2015.

Data Source: ADSL, ADAE Program Name: t_teae.sas Output Generated: 20230315T15:13

Table 14.3.1.4.1.2.1. Subject Incidence of Treatment-emergent Adverse Events of Interest – Neurologic Events by Preferred Term and Worst Grade (Safety Analysis Set)

Preferred Term Worst CTCAE Grade	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Encephalopathy	29 (17)	2 (1)	31 (9)
Grade 1	3 (2)	0 (0)	3 (1)
Grade 2	6 (4)	2 (1)	8 (2)
Grade 3	15 (9)	0 (0)	15 (4)
Grade 4	5 (3)	0 (0)	5 (1)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	20 (12)	0 (0)	20 (6)
Paraesthesia	8 (5)	14 (8)	22 (7)
Grade 1	6 (4)	14 (8)	20 (6)
Grade 2	1 (1)	0 (0)	1 (0)
Grade 3	1 (1)	0 (0)	1 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	1 (1)	0 (0)	1 (0)
Somnolence	19 (11)	2 (1)	21 (6)
Grade 1	9 (5)	2 (1)	11 (3)
Grade 2	5 (3)	0 (0)	5 (1)
Grade 3	3 (2)	0 (0)	3 (1)
Grade 4	2 (1)	0 (0)	2 (1)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	5 (3)	0 (0)	5 (1)
Agitation	10 (6)	2 (1)	12 (4)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	5 (3)	2 (1)	7 (2)
Grade 3	4 (2)	0 (0)	4 (1)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	4 (2)	0 (0)	4 (1)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the overall column.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: Neurologic events are identified using a modified search strategy based on Topp 2015.

Data Source: ADSL, ADAE Program Name: t_teae.sas Output Generated: 20230315T15:13

Table 14.3.1.4.1.2.1. Subject Incidence of Treatment-emergent Adverse Events of Interest – Neurologic Events by Preferred Term and Worst Grade (Safety Analysis Set)

Preferred Term Worst CTCAE Grade	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Mental status changes	10 (6)	0 (0)	10 (3)
Grade 1	2 (1)	0 (0)	2 (1)
Grade 2	4 (2)	0 (0)	4 (1)
Grade 3	2 (1)	0 (0)	2 (1)
Grade 4	2 (1)	0 (0)	2 (1)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	4 (2)	0 (0)	4 (1)
Hypoaesthesia	8 (5)	1 (1)	9 (3)
Grade 1	5 (3)	1 (1)	6 (2)
Grade 2	1 (1)	0 (0)	1 (0)
Grade 3	2 (1)	0 (0)	2 (1)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	2 (1)	0 (0)	2 (1)
Lethargy	7 (4)	2 (1)	9 (3)
Grade 1	0 (0)	0 (0)	0 (0)
Grade 2	7 (4)	2 (1)	9 (3)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Delirium	3 (2)	5 (3)	8 (2)
Grade 1	0 (0)	1 (1)	1 (0)
Grade 2	0 (0)	3 (2)	3 (1)
Grade 3	2 (1)	1 (1)	3 (1)
Grade 4	1 (1)	0 (0)	1 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	3 (2)	1 (1)	4 (1)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the overall column.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: Neurologic events are identified using a modified search strategy based on Topp 2015.

Data Source: ADSL, ADAE Program Name: t_teae.sas Output Generated: 20230315T15:13

Table 14.3.1.4.1.2.1. Subject Incidence of Treatment-emergent Adverse Events of Interest – Neurologic Events by Preferred Term and Worst Grade (Safety Analysis Set)

Preferred Term Worst CTCAE Grade	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Depressed level of consciousness	5 (3)	2 (1)	7 (2)
Grade 1	3 (2)	2 (1)	5 (1)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	1 (1)	0 (0)	1 (0)
Grade 4	1 (1)	0 (0)	1 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	2 (1)	0 (0)	2 (1)
Cognitive disorder	4 (2)	2 (1)	6 (2)
Grade 1	2 (1)	1 (1)	3 (1)
Grade 2	2 (1)	1 (1)	3 (1)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Memory impairment	5 (3)	1 (1)	6 (2)
Grade 1	2 (1)	1 (1)	3 (1)
Grade 2	3 (2)	0 (0)	3 (1)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Ataxia	5 (3)	0 (0)	5 (1)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	2 (1)	0 (0)	2 (1)
Grade 3	2 (1)	0 (0)	2 (1)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	2 (1)	0 (0)	2 (1)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the overall column.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: Neurologic events are identified using a modified search strategy based on Topp 2015.

Data Source: ADSL, ADAE Program Name: t_teae.sas Output Generated: 20230315T15:13

Table 14.3.1.4.1.2.1. Subject Incidence of Treatment-emergent Adverse Events of Interest – Neurologic Events by Preferred Term and Worst Grade (Safety Analysis Set)

Preferred Term Worst CTCAE Grade	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Bradyphrenia	4 (2)	1 (1)	5 (1)
Grade 1	4 (2)	1 (1)	5 (1)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Seizure	5 (3)	0 (0)	5 (1)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	3 (2)	0 (0)	3 (1)
Grade 3	1 (1)	0 (0)	1 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	1 (1)	0 (0)	1 (0)
Dysarthria	4 (2)	0 (0)	4 (1)
Grade 1	2 (1)	0 (0)	2 (1)
Grade 2	2 (1)	0 (0)	2 (1)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Dysgraphia	4 (2)	0 (0)	4 (1)
Grade 1	2 (1)	0 (0)	2 (1)
Grade 2	1 (1)	0 (0)	1 (0)
Grade 3	1 (1)	0 (0)	1 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	1 (1)	0 (0)	1 (0)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the overall column.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: Neurologic events are identified using a modified search strategy based on Topp 2015.

Data Source: ADSL, ADAE Program Name: t_teae.sas Output Generated: 20230315T15:13

Table 14.3.1.4.1.2.1. Subject Incidence of Treatment-emergent Adverse Events of Interest – Neurologic Events by Preferred Term and Worst Grade (Safety Analysis Set)

Preferred Term Worst CTCAE Grade	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Taste disorder	2 (1)	2 (1)	4 (1)
Grade 1	2 (1)	2 (1)	4 (1)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Disorientation	3 (2)	0 (0)	3 (1)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	2 (1)	0 (0)	2 (1)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Hallucination	1 (1)	2 (1)	3 (1)
Grade 1	0 (0)	2 (1)	2 (1)
Grade 2	1 (1)	0 (0)	1 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Myoclonus	3 (2)	0 (0)	3 (1)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	2 (1)	0 (0)	2 (1)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the overall column.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: Neurologic events are identified using a modified search strategy based on Topp 2015.

Data Source: ADSL, ADAE Program Name: t_teae.sas Output Generated: 20230315T15:13

Table 14.3.1.4.1.2.1. Subject Incidence of Treatment-emergent Adverse Events of Interest – Neurologic Events by Preferred Term and Worst Grade (Safety Analysis Set)

Preferred Term Worst CTCAE Grade	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Akathisia	2 (1)	0 (0)	2 (1)
Grade 1	2 (1)	0 (0)	2 (1)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Hemiparesis	2 (1)	0 (0)	2 (1)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	1 (1)	0 (0)	1 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Mental impairment	2 (1)	0 (0)	2 (1)
Grade 1	2 (1)	0 (0)	2 (1)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Nystagmus	1 (1)	1 (1)	2 (1)
Grade 1	0 (0)	1 (1)	1 (0)
Grade 2	1 (1)	0 (0)	1 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the overall column.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: Neurologic events are identified using a modified search strategy based on Topp 2015.

Data Source: ADSL, ADAE Program Name: t_teae.sas Output Generated: 20230315T15:13

Table 14.3.1.4.1.2.1. Subject Incidence of Treatment-emergent Adverse Events of Interest – Neurologic Events by Preferred Term and Worst Grade (Safety Analysis Set)

Preferred Term Worst CTCAE Grade	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Slow speech	2 (1)	0 (0)	2 (1)
Grade 1	2 (1)	0 (0)	2 (1)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Altered state of consciousness	1 (1)	0 (0)	1 (0)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Amnesia	1 (1)	0 (0)	1 (0)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Anisocoria	0 (0)	1 (1)	1 (0)
Grade 1	0 (0)	1 (1)	1 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the overall column.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: Neurologic events are identified using a modified search strategy based on Topp 2015.

Data Source: ADSL, ADAE Program Name: t_teae.sas Output Generated: 20230315T15:13

Table 14.3.1.4.1.2.1. Subject Incidence of Treatment-emergent Adverse Events of Interest – Neurologic Events by Preferred Term and Worst Grade (Safety Analysis Set)

Preferred Term Worst CTCAE Grade	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Apraxia	1 (1)	0 (0)	1 (0)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Cerebellar syndrome	1 (1)	0 (0)	1 (0)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Coordination abnormal	1 (1)	0 (0)	1 (0)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Delusion	1 (1)	0 (0)	1 (0)
Grade 1	0 (0)	0 (0)	0 (0)
Grade 2	1 (1)	0 (0)	1 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the overall column.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: Neurologic events are identified using a modified search strategy based on Topp 2015.

Data Source: ADSL, ADAE Program Name: t_teae.sas Output Generated: 20230315T15:13

Table 14.3.1.4.1.2.1. Subject Incidence of Treatment-emergent Adverse Events of Interest – Neurologic Events by Preferred Term and Worst Grade (Safety Analysis Set)

Preferred Term Worst CTCAE Grade	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Disturbance in attention	1 (1)	0 (0)	1 (0)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Hallucination, visual	0 (0)	1 (1)	1 (0)
Grade 1	0 (0)	1 (1)	1 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Head discomfort	0 (0)	1 (1)	1 (0)
Grade 1	0 (0)	1 (1)	1 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Loss of consciousness	1 (1)	0 (0)	1 (0)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the overall column.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: Neurologic events are identified using a modified search strategy based on Topp 2015.

Data Source: ADSL, ADAE Program Name: t_teae.sas Output Generated: 20230315T15:13

Table 14.3.1.4.1.2.1. Subject Incidence of Treatment-emergent Adverse Events of Interest – Neurologic Events by Preferred Term and Worst Grade (Safety Analysis Set)

Preferred Term Worst CTCAE Grade	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Monoparesis	1 (1)	0 (0)	1 (0)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Muscle contractions involuntary	1 (1)	0 (0)	1 (0)
Grade 1	0 (0)	0 (0)	0 (0)
Grade 2	1 (1)	0 (0)	1 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Myelitis	1 (1)	0 (0)	1 (0)
Grade 1	0 (0)	0 (0)	0 (0)
Grade 2	1 (1)	0 (0)	1 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Neuralgia	0 (0)	1 (1)	1 (0)
Grade 1	0 (0)	0 (0)	0 (0)
Grade 2	0 (0)	1 (1)	1 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the overall column.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: Neurologic events are identified using a modified search strategy based on Topp 2015.

Data Source: ADSL, ADAE Program Name: t_teae.sas Output Generated: 20230315T15:13

Table 14.3.1.4.1.2.1. Subject Incidence of Treatment-emergent Adverse Events of Interest – Neurologic Events by Preferred Term and Worst Grade (Safety Analysis Set)

Preferred Term Worst CTCAE Grade	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Restlessness	1 (1)	0 (0)	1 (0)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Sensory disturbance	1 (1)	0 (0)	1 (0)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Sleep deficit	1 (1)	0 (0)	1 (0)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Toxic encephalopathy	1 (1)	0 (0)	1 (0)
Grade 1	0 (0)	0 (0)	0 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	1 (1)	0 (0)	1 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	1 (1)	0 (0)	1 (0)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the overall column.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: Neurologic events are identified using a modified search strategy based on Topp 2015.

Data Source: ADSL, ADAE Program Name: t_teae.sas Output Generated: 20230315T15:13

Tabelle 4-23 (Anhang): Aufgetretene schwerwiegende neurologische Ereignisse nach bevorzugten Terms - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.4.1.2.5. Subject Incidence of Serious Treatment-emergent Neurologic Events by Preferred Term and Worst Grade (Safety Analysis Set)

Preferred Term Worst CTCAE Grade	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Subjects with any serious TE neurologic events	34 (20)	1 (1)	35 (10)
Grade 1	2 (1)	0 (0)	2 (1)
Grade 2	6 (4)	1 (1)	7 (2)
Grade 3	19 (11)	0 (0)	19 (6)
Grade 4	7 (4)	0 (0)	7 (2)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	26 (15)	0 (0)	26 (8)
Encephalopathy	17 (10)	1 (1)	18 (5)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	1 (1)	1 (1)	2 (1)
Grade 3	10 (6)	0 (0)	10 (3)
Grade 4	5 (3)	0 (0)	5 (1)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	15 (9)	0 (0)	15 (4)
Aphasia	9 (5)	0 (0)	9 (3)
Grade 1	0 (0)	0 (0)	0 (0)
Grade 2	1 (1)	0 (0)	1 (0)
Grade 3	8 (5)	0 (0)	8 (2)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	8 (5)	0 (0)	8 (2)
Confusional state	6 (4)	0 (0)	6 (2)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	1 (1)	0 (0)	1 (0)
Grade 3	3 (2)	0 (0)	3 (1)
Grade 4	1 (1)	0 (0)	1 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	4 (2)	0 (0)	4 (1)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the overall column.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: Neurologic events are identified using a modified search strategy based on Topp 2015.

Data Source: ADSL, ADAE Program Name: t_teae.sas Output Generated: 20230315T15:13

Table 14.3.1.4.1.2.5. Subject Incidence of Serious Treatment-emergent Neurologic Events by Preferred Term and Worst Grade (Safety Analysis Set)

Preferred Term Worst CTCAE Grade	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Somnolence	5 (3)	0 (0)	5 (1)
Grade 1	0 (0)	0 (0)	0 (0)
Grade 2	2 (1)	0 (0)	2 (1)
Grade 3	1 (1)	0 (0)	1 (0)
Grade 4	2 (1)	0 (0)	2 (1)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	3 (2)	0 (0)	3 (1)
Tremor	5 (3)	0 (0)	5 (1)
Grade 1	2 (1)	0 (0)	2 (1)
Grade 2	2 (1)	0 (0)	2 (1)
Grade 3	1 (1)	0 (0)	1 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	1 (1)	0 (0)	1 (0)
Agitation	2 (1)	0 (0)	2 (1)
Grade 1	0 (0)	0 (0)	0 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	2 (1)	0 (0)	2 (1)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	2 (1)	0 (0)	2 (1)
Hypoaesthesia	2 (1)	0 (0)	2 (1)
Grade 1	0 (0)	0 (0)	0 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	2 (1)	0 (0)	2 (1)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	2 (1)	0 (0)	2 (1)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the overall column.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: Neurologic events are identified using a modified search strategy based on Topp 2015.

Data Source: ADSL, ADAE Program Name: t_teae.sas Output Generated: 20230315T15:13

Table 14.3.1.4.1.2.5. Subject Incidence of Serious Treatment-emergent Neurologic Events by Preferred Term and Worst Grade (Safety Analysis Set)

Preferred Term Worst CTCAE Grade	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Mental status changes	2 (1)	0 (0)	2 (1)
Grade 1	0 (0)	0 (0)	0 (0)
Grade 2	1 (1)	0 (0)	1 (0)
Grade 3	1 (1)	0 (0)	1 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	1 (1)	0 (0)	1 (0)
Ataxia	1 (1)	0 (0)	1 (0)
Grade 1	0 (0)	0 (0)	0 (0)
Grade 2	1 (1)	0 (0)	1 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Bradyphrenia	1 (1)	0 (0)	1 (0)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Cognitive disorder	1 (1)	0 (0)	1 (0)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the overall column.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: Neurologic events are identified using a modified search strategy based on Topp 2015.

Data Source: ADSL, ADAE Program Name: t_teae.sas Output Generated: 20230315T15:13

Table 14.3.1.4.1.2.5. Subject Incidence of Serious Treatment-emergent Neurologic Events by Preferred Term and Worst Grade (Safety Analysis Set)

Preferred Term Worst CTCAE Grade	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Delirium	1 (1)	0 (0)	1 (0)
Grade 1	0 (0)	0 (0)	0 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	1 (1)	0 (0)	1 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	1 (1)	0 (0)	1 (0)
Depressed level of consciousness	1 (1)	0 (0)	1 (0)
Grade 1	1 (1)	0 (0)	1 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Dysarthria	1 (1)	0 (0)	1 (0)
Grade 1	0 (0)	0 (0)	0 (0)
Grade 2	1 (1)	0 (0)	1 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Hemiparesis	1 (1)	0 (0)	1 (0)
Grade 1	0 (0)	0 (0)	0 (0)
Grade 2	1 (1)	0 (0)	1 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the overall column.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: Neurologic events are identified using a modified search strategy based on Topp 2015.

Data Source: ADSL, ADAE Program Name: t_teae.sas Output Generated: 20230315T15:13

Table 14.3.1.4.1.2.5. Subject Incidence of Serious Treatment-emergent Neurologic Events by Preferred Term and Worst Grade (Safety Analysis Set)

Preferred Term Worst CTCAE Grade	Axicabtagene Ciloleucel (N = 170) n (%)	Standard of Care (N = 168) n (%)	Overall (N = 338) n (%)
Lethargy	1 (1)	0 (0)	1 (0)
Grade 1	0 (0)	0 (0)	0 (0)
Grade 2	1 (1)	0 (0)	1 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Memory impairment	1 (1)	0 (0)	1 (0)
Grade 1	0 (0)	0 (0)	0 (0)
Grade 2	1 (1)	0 (0)	1 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)
Paraesthesia	1 (1)	0 (0)	1 (0)
Grade 1	0 (0)	0 (0)	0 (0)
Grade 2	0 (0)	0 (0)	0 (0)
Grade 3	1 (1)	0 (0)	1 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	1 (1)	0 (0)	1 (0)
Seizure	1 (1)	0 (0)	1 (0)
Grade 1	0 (0)	0 (0)	0 (0)
Grade 2	1 (1)	0 (0)	1 (0)
Grade 3	0 (0)	0 (0)	0 (0)
Grade 4	0 (0)	0 (0)	0 (0)
Grade 5	0 (0)	0 (0)	0 (0)
Grade >= 3	0 (0)	0 (0)	0 (0)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the overall column.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: Neurologic events are identified using a modified search strategy based on Topp 2015.

Data Source: ADSL, ADAE Program Name: t_teae.sas Output Generated: 20230315T15:13

Tabelle 4-24 (Anhang): Aufgetretene CRS nach bevorzugten Terms - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.4.1.1.1. Subject Incidence of Treatment-emergent Adverse Events of Interest - Cytokine Release Syndrome by Preferred Term and Worst Grade (Safety Analysis Set; Axicabtagene Ciloleucel Arm, N = 170)

Event, n (%)	Any Grade	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects with any CRS[a]	157 (92)	70 (41)	76 (45)	8 (5)	3 (2)	0 (0)
CRS symptoms by preferred term[b]						
Pyrexia	155 (99)	33 (21)	108 (69)	14 (9)	0 (0)	0 (0)
Hypotension	68 (43)	7 (4)	43 (27)	18 (11)	0 (0)	0 (0)
Sinus tachycardia	49 (31)	29 (18)	17 (11)	3 (2)	0 (0)	0 (0)
Chills	38 (24)	27 (17)	11 (7)	0 (0)	0 (0)	0 (0)
Headache	32 (20)	15 (10)	15 (10)	2 (1)	0 (0)	0 (0)
Hypoxia	31 (20)	1 (1)	17 (11)	12 (8)	1 (1)	0 (0)
Fatigue	21 (13)	7 (4)	10 (6)	4 (3)	0 (0)	0 (0)
Nausea	17 (11)	6 (4)	9 (6)	2 (1)	0 (0)	0 (0)
Tachycardia	15 (10)	10 (6)	4 (3)	1 (1)	0 (0)	0 (0)
Diarrhoea	14 (9)	9 (6)	4 (3)	1 (1)	0 (0)	0 (0)
Malaise	13 (8)	8 (5)	5 (3)	0 (0)	0 (0)	0 (0)
Vomiting	11 (7)	9 (6)	2 (1)	0 (0)	0 (0)	0 (0)
Decreased appetite	9 (6)	3 (2)	3 (2)	3 (2)	0 (0)	0 (0)
Myalgia	9 (6)	7 (4)	2 (1)	0 (0)	0 (0)	0 (0)
Hypertransaminasaemia	8 (5)	7 (4)	0 (0)	1 (1)	0 (0)	0 (0)
Aspartate aminotransferase increased	7 (4)	2 (1)	4 (3)	1 (1)	0 (0)	0 (0)
Alanine aminotransferase increased	6 (4)	3 (2)	3 (2)	0 (0)	0 (0)	0 (0)
Atrial fibrillation	6 (4)	1 (1)	1 (1)	4 (3)	0 (0)	0 (0)
Tachypnoea	5 (3)	2 (1)	2 (1)	1 (1)	0 (0)	0 (0)
Blood creatinine increased	4 (3)	2 (1)	2 (1)	0 (0)	0 (0)	0 (0)
C-reactive protein increased	4 (3)	3 (2)	0 (0)	1 (1)	0 (0)	0 (0)
Pulmonary oedema	4 (3)	3 (2)	0 (0)	1 (1)	0 (0)	0 (0)
Acute kidney injury	3 (2)	2 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Asthenia	3 (2)	1 (1)	2 (1)	0 (0)	0 (0)	0 (0)
Blood alkaline phosphatase increased	3 (2)	3 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Dyspnoea	3 (2)	1 (1)	0 (0)	2 (1)	0 (0)	0 (0)
Arthralgia	2 (1)	2 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Blood bilirubin increased	2 (1)	0 (0)	2 (1)	0 (0)	0 (0)	0 (0)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the Any Grade column.
a. Overall CRS is graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014). Percentages are calculated using the total number of subjects in the axicabtagene ciloleucel arm of the analysis set as the denominator.
b: Individual CRS symptoms are coded using MedDRA version 25.1 and graded per CTCAE version 4.03. Percentages are calculated using the number of subjects with any TE CRS of any grade.

Data Source: ADSL, ADAE Program Name: t_kcrs.sas Output Generated: 20230314T16:17

Table 14.3.1.4.1.1.1. Subject Incidence of Treatment-emergent Adverse Events of Interest - Cytokine Release Syndrome by Preferred Term and Worst Grade (Safety Analysis Set; Axicabtagene Ciloleucel Arm, N = 170)

Event, n (%)	Any Grade	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Capillary leak syndrome	2 (1)	0 (0)	2 (1)	0 (0)	0 (0)	0 (0)
Hypertension	2 (1)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Hypophosphataemia	2 (1)	0 (0)	2 (1)	0 (0)	0 (0)	0 (0)
Influenza like illness	2 (1)	2 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Orthostatic hypotension	2 (1)	0 (0)	2 (1)	0 (0)	0 (0)	0 (0)
Rash	2 (1)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Sinus bradycardia	2 (1)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Apnoea	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Back pain	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Blood fibrinogen decreased	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Bone pain	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Cardiac failure	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Cardiomyopathy	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Cough	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Distributive shock	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Dyspnoea exertional	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Extrasystoles	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Heart rate increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hypomagnesaemia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hyponatraemia	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Hypothermia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Neck pain	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Non-cardiac chest pain	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Pleural effusion	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Rash macular	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory failure	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Serum ferritin increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Supraventricular tachycardia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Tremor	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Troponin I increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the Any Grade column.
a. Overall CRS is graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014). Percentages are calculated using the total number of subjects in the axicabtagene ciloleucel arm of the analysis set as the denominator.
b: Individual CRS symptoms are coded using MedDRA version 25.1 and graded per CTCAE version 4.03. Percentages are calculated using the number of subjects with any TE CRS of any grade.

Data Source: ADSL, ADAE Program Name: t_kcrs.sas Output Generated: 20230314T16:17

Table 14.3.1.4.1.1.1. Subject Incidence of Treatment-emergent Adverse Events of Interest - Cytokine Release Syndrome by Preferred Term and Worst Grade (Safety Analysis Set; Axicabtagene Ciloleucel Arm, N = 170)

Event, n (%)	Any Grade	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Urinary incontinence	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Vertigo	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Vision blurred	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the Any Grade column.
a. Overall CRS is graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014). Percentages are calculated using the total number of subjects in the axicabtagene ciloleucel arm of the analysis set as the denominator.
b: Individual CRS symptoms are coded using MedDRA version 25.1 and graded per CTCAE version 4.03. Percentages are calculated using the number of subjects with any TE CRS of any grade.

Data Source: ADSL, ADAE Program Name: t_kcrs.sas Output Generated: 20230314T16:17

Tabelle 4-25 (Anhang): Aufgetretene schwerwiegende CRS nach bevorzugten Terms - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

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Table 14.3.1.4.1.1.2. Subject Incidence of Treatment-emergent Adverse Events of Interest – Serious Symptoms of Cytokine Release Syndrome by Preferred Term and Worst Grade (Safety Analysis Set; Axicabtagene Ciloleucel Arm, N = 170)

MedDRA Preferred Term, n (%)	Any Grade	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Pyrexia	20 (12)	4 (2)	16 (9)	0 (0)	0 (0)	0 (0)
Hypotension	15 (9)	1 (1)	7 (4)	7 (4)	0 (0)	0 (0)
Atrial fibrillation	3 (2)	0 (0)	0 (0)	3 (2)	0 (0)	0 (0)
Hypoxia	3 (2)	1 (1)	1 (1)	0 (0)	1 (1)	0 (0)
Dyspnoea	2 (1)	0 (0)	0 (0)	2 (1)	0 (0)	0 (0)
Headache	2 (1)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
Sinus tachycardia	2 (1)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Tachycardia	2 (1)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Tachypnoea	2 (1)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Acute kidney injury	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Aspartate aminotransferase increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Blood fibrinogen decreased	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Cardiac failure	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Cardiomyopathy	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Fatigue	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Malaise	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Nausea	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Respiratory failure	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Troponin I increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Vomiting	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; MedDRA, Medical Dictionary for Regulatory Activities; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: Preferred terms are sorted in descending order of frequency count in the Any Grade column.
Note: Individual CRS symptoms are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Percentages are calculated using the total number of subjects in the axicabtagene ciloleucel arm of the analysis set as the denominator.

Data Source: ADSL, ADAE Program Name: t_kcrs.sas Output Generated: 20230314T16:17

Anhang 4-G3: Ergänzende Darstellung der Subgruppenanalyse in der RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Anhang 4-G3.1: Ergänzende Subgruppenanalysen zu Symptomatik anhand EQ-5D VAS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-26 (Anhang): Ergebnisse der Subgruppenanalyse für Symptomatik anhand EQ-5D VAS - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Version: 1.0 (15July2022)

Table 2 EQ-5D-5L VAS Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	18/119	8/89	1.43 (0.62, 3.28)	0.5840
	Relapse <= 12 Months of First Line therapy	9/46	4/42	2.19 (0.69, 6.93)	
Age	<65 Years	21/119	10/89	1.47 (0.70, 3.09)	0.6079
	≥65 Years	6/46	2/42	2.41 (0.47, 12.30)	
Second line age adjusted IPI score per IXRS	0 - 1	17/96	9/75	1.28 (0.57, 2.88)	0.3381
	2 - 3	10/69	3/56	2.65 (0.74, 9.44)	
Sex	Male	19/101	9/95	1.87 (0.86, 4.09)	0.6313
	Female	8/64	3/36	1.40 (0.37, 5.27)	
Geographic region	North America	23/128	9/94	1.74 (0.81, 3.73)	0.4971
	Europe	3/31	3/34	0.91 (0.18, 4.47)	
ECOG - performance status	0	17/89	8/81	1.83 (0.80, 4.19)	0.7255
	1	10/76	4/50	1.46 (0.46, 4.67)	
Central laboratory disease type	Diffuse large B-cell lymphoma	16/117	10/94	1.15 (0.52, 2.54)	0.6478
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	6/28	2/17	1.78 (0.38, 8.34)	

Data cutoff date = 18MAR2021

Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy; VAS, visual analog scale.

Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.

Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.

For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.

Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

Anhang 4-G3.2: Ergänzende Subgruppenanalysen zu Symptomatik anhand EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-27 (Anhang): Ergebnisse der Subgruppenanalyse für Symptomatik anhand EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Version: 1.0 (15July2022)

Table 1.7 EORTC QLQ-C30 Fatigue Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	26/119	13/89	1.37 (0.71, 2.67)	0.2488
	Relapse <= 12 Months of First Line therapy	14/46	5/42	2.73 (1.00, 7.44)	
Age	<65 Years	31/119	14/89	1.60 (0.85, 3.02)	0.7864
	≥65 Years	9/46	4/42	2.01 (0.62, 6.47)	
Second line age adjusted IPI score per IXRS	0 - 1	25/96	13/75	1.41 (0.73, 2.75)	0.3861
	2 - 3	15/69	5/56	2.43 (0.87, 6.73)	
Sex	Male	25/101	15/95	1.55 (0.82, 2.93)	0.4255
	Female	15/64	3/36	2.55 (0.75, 8.68)	
Geographic region	North America	34/128	15/94	1.60 (0.87, 2.93)	0.7101
	Europe	6/31	3/34	2.04 (0.52, 7.95)	
ECOG - performance status	0	20/89	10/81	1.76 (0.83, 3.75)	0.8121
	1	20/76	8/50	1.57 (0.70, 3.55)	
Central laboratory disease type	Diffuse large B-cell lymphoma	25/117	14/94	1.35 (0.70, 2.58)	0.2328
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	11/28	2/17	3.66 (0.79, 16.99)	

Data cutoff date = 18MAR2021

Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.

Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.

Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.

For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.

Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

Version: 1.0 (15July2022)

Table 1.8 EORTC QLQ-C30 Nausea and Vomiting Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	11/119	3/89	2.65 (0.74, 9.46)	0.9650
	Relapse <= 12 Months of First Line therapy	3/46	1/42	2.77 (0.30, 25.76)	
Age	<65 Years	11/119	3/89	2.66 (0.74, 9.50)	0.9955
	≥65 Years	3/46	1/42	2.54 (0.26, 25.03)	
Second line age adjusted IPI score per IXRS	0 - 1	7/96	3/75	1.73 (0.45, 6.72)	0.3553
	2 - 3	7/69	1/56	5.69 (0.69, 46.72)	
Sex	Male	9/101	3/95	2.69 (0.73, 9.87)	0.9955
	Female	5/64	1/36	2.77 (0.32, 23.85)	
Geographic region	North America	12/128	3/94	2.88 (0.81, 10.23)	0.5153
	Europe	1/31	1/34	1.00 (0.07, 14.34)	
ECOG - performance status	0	6/89	2/81	2.61 (0.53, 12.84)	0.9537
	1	8/76	2/50	2.54 (0.54, 11.97)	
Central laboratory disease type	Diffuse large B-cell lymphoma	8/117	3/94	2.03 (0.54, 7.55)	NE[a]
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/28	0/17	NE[a]	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
[a] Due to 0 events in one arm, the hazard ratio is not interpretable, and hence HR and p-values have been labeled NE.
Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

Version: 1.0 (15July2022)

Table 1.9 EORTC QLQ-C30 Pain Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	28/119	20/89	0.95 (0.54, 1.69)	0.8035
	Relapse <= 12 Months of First Line therapy	12/46	12/42	0.85 (0.38, 1.86)	
Age	<65 Years	32/119	23/89	0.96 (0.56, 1.64)	0.6134
	≥65 Years	8/46	9/42	0.73 (0.29, 1.85)	
Second line age adjusted IPI score per IXRS	0 - 1	20/96	20/75	0.69 (0.37, 1.28)	0.1766
	2 - 3	20/69	12/56	1.32 (0.65, 2.70)	
Sex	Male	26/101	19/95	1.25 (0.69, 2.26)	0.0558
	Female	14/64	13/36	0.48 (0.23, 1.01)	
Geographic region	North America	33/128	25/94	0.88 (0.53, 1.48)	0.5024
	Europe	4/31	7/34	0.56 (0.17, 1.84)	
ECOG - performance status	0	19/89	18/81	0.89 (0.47, 1.70)	0.9486
	1	21/76	14/50	0.88 (0.45, 1.73)	
Central laboratory disease type	Diffuse large B-cell lymphoma	28/117	25/94	0.82 (0.48, 1.40)	0.4001
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/28	3/17	1.54 (0.41, 5.83)	

Data cutoff date = 18MAR2021

Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.

Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.

Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.

For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.

Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

Version: 1.0 (15July2022)

Table 1.10 EORTC QLQ-C30 Dyspnea Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	24/119	9/89	1.89 (0.87, 4.08)	0.1640
	Relapse <= 12 Months of First Line therapy	9/46	1/42	8.83 (1.16, 67.42)+	
Age	<65 Years	26/119	10/89	1.92 (0.92, 4.00)	NE[a]
	≥65 Years	7/46	0/42	NE[a]	
Second line age adjusted IPI score per IXRS	0 - 1	19/96	7/75	2.00 (0.84, 4.79)	0.3948
	2 - 3	14/69	3/56	3.92 (1.12, 13.71)+	
Sex	Male	20/101	5/95	3.78 (1.41, 10.19)+	0.1728
	Female	13/64	5/36	1.36 (0.49, 3.81)	
Geographic region	North America	30/128	8/94	2.76 (1.26, 6.04)+	0.5645
	Europe	3/31	2/34	1.61 (0.27, 9.51)	
ECOG - performance status	0	16/89	4/81	3.68 (1.22, 11.09)+	0.3182
	1	17/76	6/50	1.78 (0.70, 4.54)	
Central laboratory disease type	Diffuse large B-cell lymphoma	21/117	7/94	2.37 (1.00, 5.61)	0.8703
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/28	2/17	2.74 (0.63, 11.92)	

Data cutoff date = 18MAR2021

Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.

Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.

Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.

For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.

[a] Due to 0 events in one arm, the hazard ratio is not interpretable, and hence HR and p-values have been labeled NE.

+ 95% CI does not include 1.

Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

Version: 1.0 (15July2022)

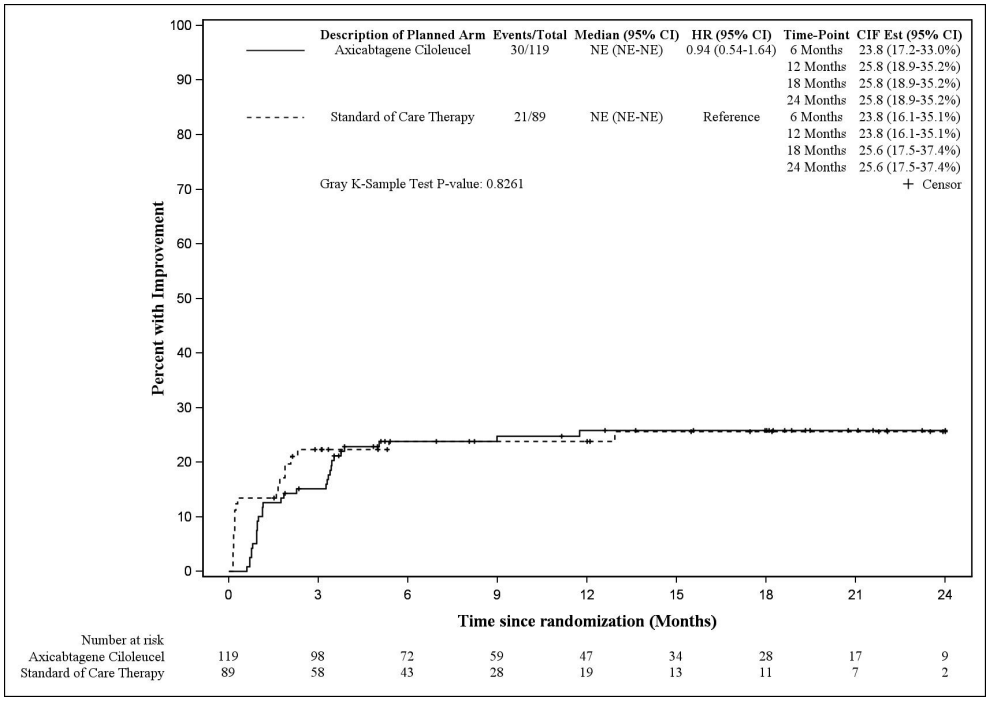
Table 1.11 EORTC QLQ-C30 Insomnia Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	30/119	21/89	0.94 (0.54, 1.64)	0.0472*
	Relapse <= 12 Months of First Line therapy	15/46	5/42	2.96 (1.09, 8.06)+	
Age	<65 Years	35/119	17/89	1.45 (0.81, 2.60)	0.4667
	≥65 Years	10/46	9/42	0.93 (0.38, 2.29)	
Second line age adjusted IPI score per IXRS	0 - 1	24/96	18/75	0.94 (0.51, 1.72)	0.1086
	2 - 3	21/69	8/56	2.16 (0.95, 4.92)	
Sex	Male	20/101	18/95	0.93 (0.50, 1.75)	0.1885
	Female	25/64	8/36	1.83 (0.83, 4.05)	
Geographic region	North America	37/128	19/94	1.33 (0.76, 2.32)	0.6719
	Europe	7/31	7/34	1.07 (0.38, 2.97)	
ECOG - performance status	0	23/89	18/81	1.05 (0.57, 1.94)	0.3062
	1	22/76	8/50	1.83 (0.81, 4.11)	
Central laboratory disease type	Diffuse large B-cell lymphoma	30/117	20/94	1.13 (0.64, 1.99)	0.1190
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	10/28	1/17	6.16 (0.75, 50.49)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
* Statistically significant (p-value <0.05)
+ 95% CI does not include 1.Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

Version: 1.0 (15July2022)

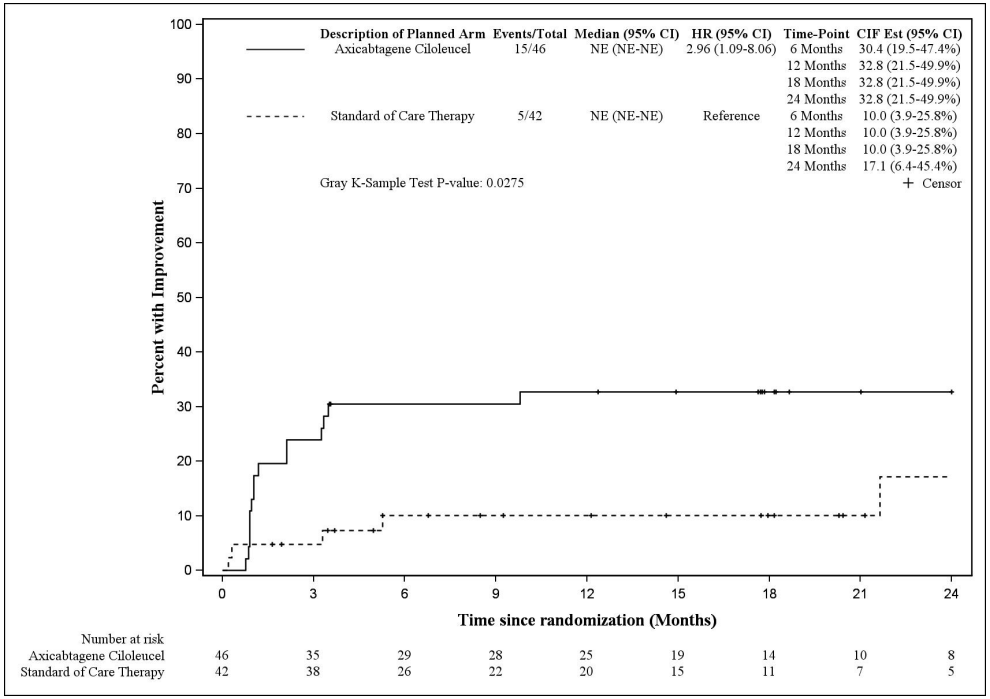
Figure 1.11.1 EORTC QLQ-C30 Insomnia Time Until Definitive Improvement for Primary Refractory



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CIF, cumulative incidence function; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HR, hazard ratio; NE, not estimable.
Note: this figure plots the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk; an event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points; + on the curve represents censor.
Data Source: ADTUDI Program Name: Create figures by subgroup.sas Output Generated: 13JUL2022

Version: 1.0 (15July2022)

Figure 1.11.2 EORTC QLQ-C30 Insomnia Time Until Definitive Improvement for Relapse less than 12 Months of First Line therapy



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CIF, cumulative incidence function; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HR, hazard ratio; NE, not estimable.
Note: this figure plots the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk; an event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points; + on the curve represents censor.
Data Source: ADTUDI Program Name: Create figures by subgroup.sas Output Generated: 13JUL2022

Table 1.12 EORTC QLQ-C30 Appetite Loss Time Until Definitive Improvement by Subgroup

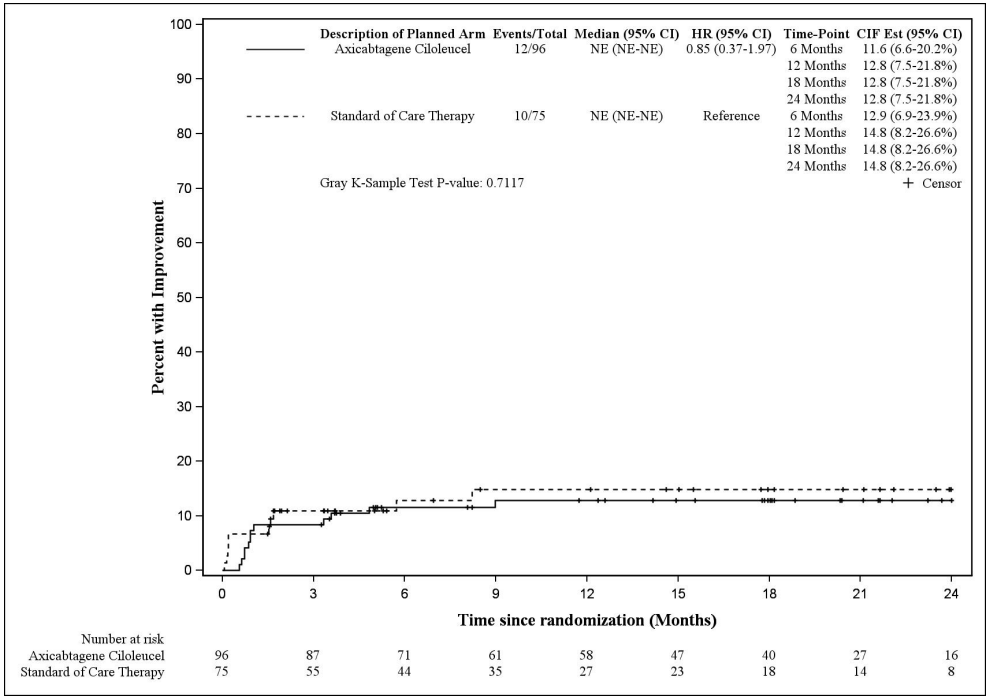
Version: 1.0 (15July2022)

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	20/119	11/89	1.23 (0.59, 2.57)	0.1906
	Relapse <= 12 Months of First Line therapy	6/46	1/42	5.61 (0.67, 47.37)	
Age	<65 Years	21/119	8/89	1.92 (0.85, 4.34)	0.4266
	≥65 Years	5/46	4/42	1.09 (0.30, 3.95)	
Second line age adjusted IPI score per IXRS	0 - 1	12/96	10/75	0.85 (0.37, 1.97)	0.0237*
	2 - 3	14/69	2/56	5.96 (1.37, 25.94)+	
Sex	Male	17/101	7/95	2.18 (0.91, 5.23)	0.2417
	Female	9/64	5/36	0.98 (0.33, 2.92)	
Geographic region	North America	25/128	10/94	1.76 (0.84, 3.68)	0.3371
	Europe	1/31	2/34	0.54 (0.05, 5.98)	
ECOG - performance status	0	13/89	5/81	2.31 (0.82, 6.47)	0.3272
	1	13/76	7/50	1.15 (0.46, 2.87)	
Central laboratory disease type	Diffuse large B-cell lymphoma	16/117	8/94	1.53 (0.66, 3.57)	0.5996
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	5/28	1/17	2.97 (0.34, 25.94)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
* Statistically significant (p-value <0.05)
+ 95% CI does not include 1.
Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

Version: 1.0 (15July2022)

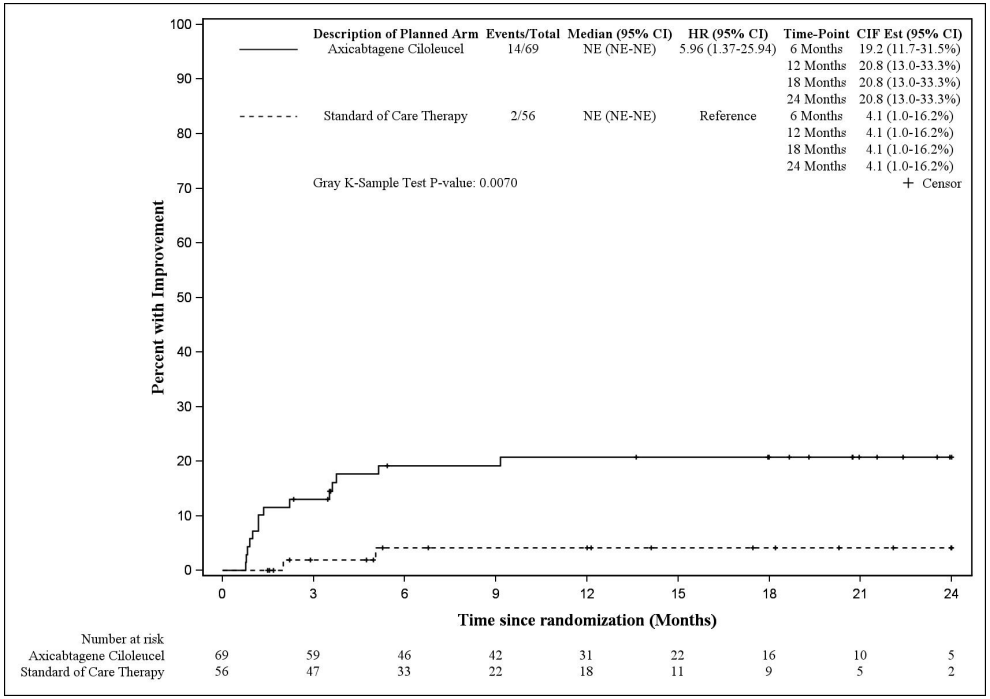
Figure 1.12.1 EORTC QLQ-C30 Appetite Loss Time Until Definitive Improvement for IPI 0-1



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CIF, cumulative incidence function; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HR, hazard ratio; NE, not estimable.
Note: this figure plots the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk; an event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points; + on the curve represents censor.
Data Source: ADTUDI Program Name: Create figures by subgroup.sas Output Generated: 13JUL2022

Version: 1.0 (15July2022)

Figure 1.12.2 EORTC QLQ-C30 Appetite Loss Time Until Definitive Improvement for IPI 2-3



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CIF, cumulative incidence function; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HR, hazard ratio; NE, not estimable.
Note: this figure plots the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk; an event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points; + on the curve represents censor.
Data Source: ADTUDI Program Name: Create figures by subgroup.sas Output Generated: 13JUL2022

Version: 1.0 (15July2022)

Table 1.13 EORTC QLQ-C30 Constipation Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	15/119	10/89	1.03 (0.47, 2.27)	0.6132
	Relapse <= 12 Months of First Line therapy	5/46	6/42	0.71 (0.22, 2.28)	
Age	<65 Years	14/119	10/89	0.96 (0.43, 2.15)	0.8561
	≥65 Years	6/46	6/42	0.83 (0.27, 2.56)	
Second line age adjusted IPI score per IXRS	0 - 1	8/96	10/75	0.56 (0.22, 1.41)	0.1307
	2 - 3	12/69	6/56	1.56 (0.59, 4.14)	
Sex	Male	12/101	10/95	1.03 (0.45, 2.36)	0.5532
	Female	8/64	6/36	0.70 (0.25, 2.00)	
Geographic region	North America	18/128	14/94	0.86 (0.43, 1.72)	0.6842
	Europe	1/31	2/34	0.54 (0.05, 5.80)	
ECOG - performance status	0	8/89	5/81	1.39 (0.46, 4.22)	0.2682
	1	12/76	11/50	0.63 (0.28, 1.40)	
Central laboratory disease type	Diffuse large B-cell lymphoma	11/117	13/94	0.62 (0.28, 1.37)	0.9035
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/28	2/17	0.50 (0.08, 3.29)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

Version: 1.0 (15July2022)

Table 1.14 EORTC QLQ-C30 Diarrhea Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	14/119	8/89	1.24 (0.52, 2.98)	0.3848
	Relapse <= 12 Months of First Line therapy	6/46	2/42	2.81 (0.58, 13.77)	
Age	<65 Years	14/119	8/89	1.27 (0.53, 3.04)	0.4226
	≥65 Years	6/46	2/42	2.69 (0.54, 13.44)	
Second line age adjusted IPI score per IXRS	0 - 1	11/96	8/75	1.03 (0.41, 2.57)	0.1557
	2 - 3	9/69	2/56	3.69 (0.80, 17.00)	
Sex	Male	11/101	7/95	1.44 (0.56, 3.72)	0.8586
	Female	9/64	3/36	1.66 (0.45, 6.20)	
Geographic region	North America	17/128	7/94	1.75 (0.72, 4.23)	0.5830
	Europe	3/31	3/34	1.07 (0.22, 5.22)	
ECOG - performance status	0	10/89	5/81	1.83 (0.62, 5.36)	0.6322
	1	10/76	5/50	1.24 (0.42, 3.64)	
Central laboratory disease type	Diffuse large B-cell lymphoma	14/117	7/94	1.56 (0.63, 3.88)	0.8316
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/28	1/17	1.14 (0.11, 11.68)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

Anhang 4-G3.3: Ergänzende Subgruppenanalysen zu gesundheitsbezogene Lebensqualität anhand EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 18. März 2021)

Tabelle 4-28 (Anhang): Ergebnisse der Subgruppenanalyse für gesundheitsbezogene Lebensqualität anhand EORTC QLQ-C30 - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Version: 1.0 (15July2022)

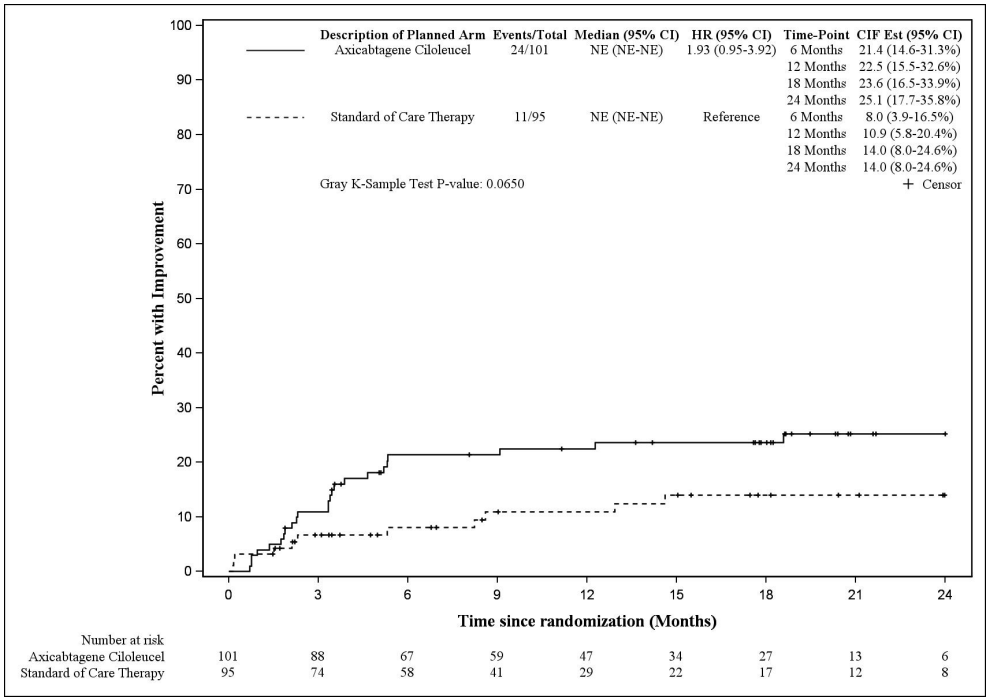
Table 1.1 EORTC QLQ-C30 Global Health Status/QoL Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	24/119	15/89	1.05 (0.56, 2.00)	0.3391
	Relapse <= 12 Months of First Line therapy	7/46	3/42	2.04 (0.53, 7.81)	
Age	<65 Years	22/119	15/89	0.98 (0.51, 1.87)	0.1928
	≥65 Years	9/46	3/42	2.59 (0.70, 9.55)	
Second line age adjusted IPI score per IXRS	0 - 1	19/96	10/75	1.30 (0.61, 2.77)	0.8388
	2 - 3	12/69	8/56	1.16 (0.48, 2.81)	
Sex	Male	24/101	11/95	1.93 (0.95, 3.92)	0.0274*
	Female	7/64	7/36	0.46 (0.16, 1.31)	
Geographic region	North America	25/128	14/94	1.19 (0.62, 2.27)	0.9689
	Europe	5/31	4/34	1.26 (0.35, 4.57)	
ECOG - performance status	0	16/89	8/81	1.71 (0.74, 3.98)	0.2406
	1	15/76	10/50	0.85 (0.38, 1.87)	
Central laboratory disease type	Diffuse large B-cell lymphoma	16/117	14/94	0.77 (0.38, 1.58)	0.0797
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	9/28	1/17	5.65 (0.68, 46.71)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; QoL, quality of life; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
* Statistically significant (p-value <0.05)
Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

Version: 1.0 (15July2022)

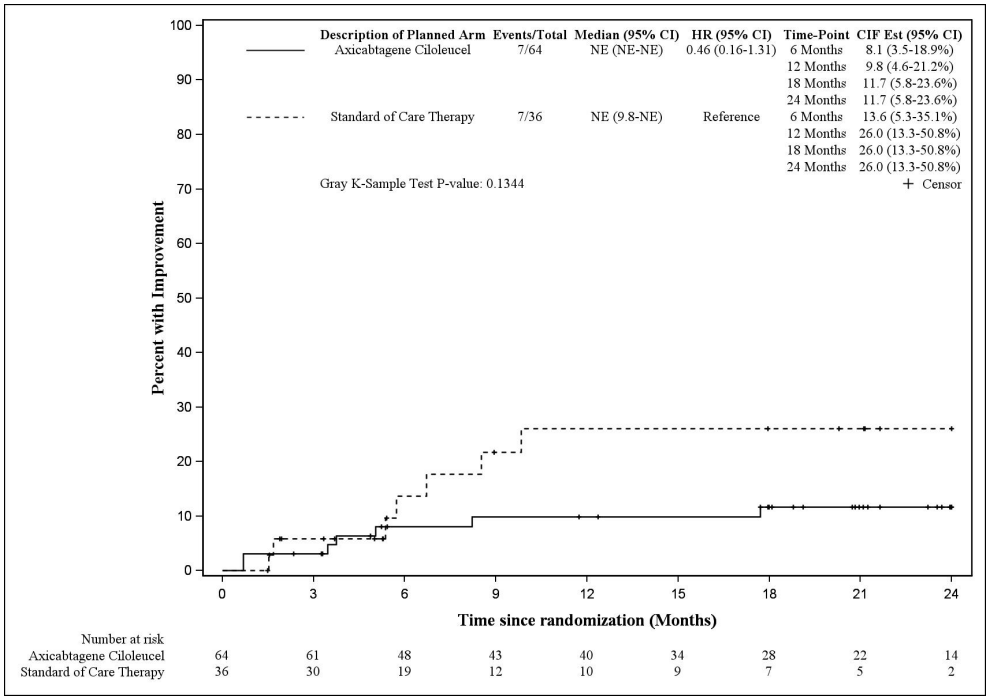
Figure 1.1.1 EORTC QLQ-C30 Global Health Status/QoL Time Until Definitive Improvement for Male Subgroup



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CIF, cumulative incidence function; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HR, hazard ratio; NE, not estimable; QoL, quality of life.
Note: this figure plots the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk; an event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points; + on the curve represents censor.
Data Source: ADTUDI Program Name: Create figures by subgroup.sas Output Generated: 13JUL2022

Version: 1.0 (15July2022)

Figure 1.1.2 EORTC QLQ-C30 Global Health Status/QoL Time Until Definitive Improvement for Female Subgroup



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CIF, cumulative incidence function; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HR, hazard ratio; NE, not estimable; QoL, quality of life.
Note: this figure plots the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk; an event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points; + on the curve represents censor.
Data Source: ADTUDI Program Name: Create figures by subgroup.sas Output Generated: 13JUL2022

Version: 1.0 (15July2022)

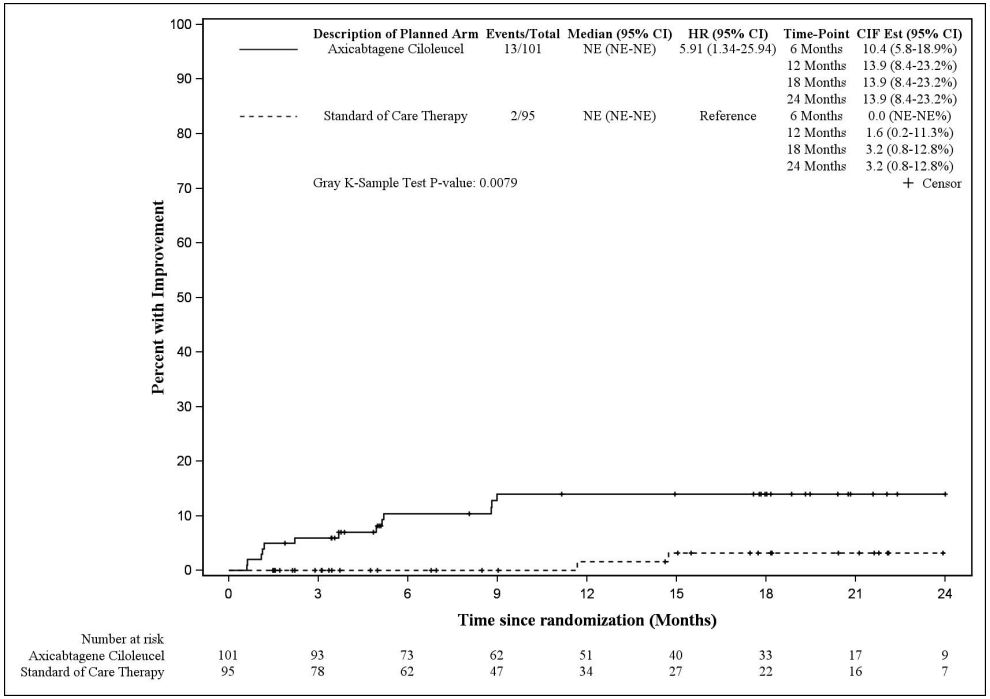
Table 1.2 EORTC QLQ-C30 Physical Functioning Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	13/119	5/89	1.72 (0.61, 4.83)	0.7738
	Relapse <= 12 Months of First Line therapy	5/46	2/42	2.30 (0.45, 11.58)	
Age	<65 Years	12/119	7/89	1.21 (0.47, 3.07)	NE[a]
	≥65 Years	6/46	0/42	NE[a]	
Second line age adjusted IPI score per IXRS	0 - 1	10/96	6/75	1.14 (0.41, 3.19)	0.1430
	2 - 3	8/69	1/56	6.40 (0.80, 50.98)	
Sex	Male	13/101	2/95	5.91 (1.34, 25.94)[+]	0.0113[*]
	Female	5/64	5/36	0.50 (0.15, 1.74)	
Geographic region	North America	14/128	4/94	2.40 (0.79, 7.26)	0.5615
	Europe	4/31	3/34	1.33 (0.30, 5.92)	
ECOG - performance status	0	10/89	5/81	1.66 (0.57, 4.86)	0.7104
	1	8/76	2/50	2.49 (0.54, 11.61)	
Central laboratory disease type	Diffuse large B-cell lymphoma	11/117	4/94	2.02 (0.64, 6.37)	0.4193
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	5/28	3/17	0.98 (0.25, 3.92)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
[a] Due to 0 events in one arm, the hazard ratio is not interpretable, and hence HR and p-values have been labeled NE.
[*] Statistically significant (p-value <0.05)
[+] 95% CI does not include 1.
Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

Version: 1.0 (15July2022)

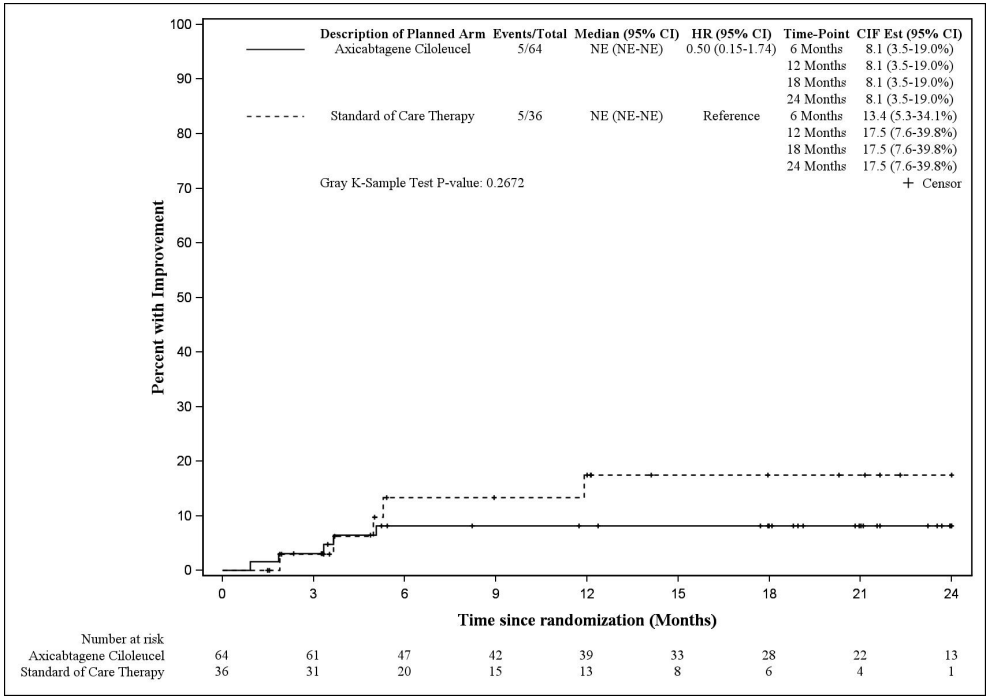
Figure 1.2.1 EORTC QLQ-C30 Physical Functioning Time Until Definitive Improvement for Male



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CIF, cumulative incidence function; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HR, hazard ratio; NE, not estimable.
Note: this figure plots the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk; an event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points; + on the curve represents censor.
Data Source: ADTUDI Program Name: Create figures by subgroup.sas Output Generated: 13JUL2022

Version: 1.0 (15July2022)

Figure 1.2.2 EORTC QLQ-C30 Physical Functioning Time Until Definitive Improvement for Female



Data cutoff date = 18MAR2021
Abbreviations: CI, confidence interval; CIF, cumulative incidence function; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HR, hazard ratio; NE, not estimable.
Note: this figure plots the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk; an event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points; + on the curve represents censor.
Data Source: ADTUDI Program Name: Create figures by subgroup.sas Output Generated: 13JUL2022

Version: 1.0 (15July2022)

Table 1.3 EORTC QLQ-C30 Role Functioning Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	22/119	9/89	1.64 (0.75, 3.55)	0.7183
	Relapse <= 12 Months of First Line therapy	7/46	3/42	2.19 (0.58, 8.36)	
Age	<65 Years	24/119	12/89	1.39 (0.70, 2.79)	NE[a]
	≥65 Years	5/46	0/42	NE[a]	
Second line age adjusted IPI score per IXRS	0 - 1	15/96	7/75	1.52 (0.62, 3.74)	0.5556
	2 - 3	14/69	5/56	2.23 (0.81, 6.18)	
Sex	Male	19/101	7/95	2.46 (1.03, 5.84)[+]	0.2049
	Female	10/64	5/36	1.00 (0.34, 2.91)	
Geographic region	North America	25/128	10/94	1.74 (0.83, 3.63)	0.8854
	Europe	4/31	2/34	1.81 (0.35, 9.45)	
ECOG - performance status	0	12/89	6/81	1.72 (0.65, 4.56)	0.9952
	1	17/76	6/50	1.70 (0.67, 4.31)	
Central laboratory disease type	Diffuse large B-cell lymphoma	19/117	10/94	1.39 (0.65, 2.99)	0.6171
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	7/28	2/17	2.16 (0.48, 9.86)	

Data cutoff date = 18MAR2021

Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.

Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.

Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.

For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.

[a] Due to 0 events in one arm, the hazard ratio is not interpretable, and hence HR and p-values have been labeled NE.

[+] 95% CI does not include 1.Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

Version: 1.0 (15July2022)

Table 1.4 EORTC QLQ-C30 Emotional Functioning Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	17/119	9/89	1.30 (0.58, 2.91)	0.9600
	Relapse <= 12 Months of First Line therapy	9/46	6/42	1.36 (0.49, 3.79)	
Age	<65 Years	21/119	12/89	1.23 (0.61, 2.50)	0.8426
	≥65 Years	5/46	3/42	1.41 (0.33, 6.04)	
Second line age adjusted IPI score per IXRS	0 - 1	16/96	12/75	0.94 (0.45, 1.99)	0.1725
	2 - 3	10/69	3/56	2.69 (0.75, 9.67)	
Sex	Male	20/101	12/95	1.53 (0.75, 3.11)	0.6067
	Female	6/64	3/36	1.03 (0.27, 4.04)	
Geographic region	North America	19/128	12/94	1.08 (0.52, 2.22)	0.5523
	Europe	5/31	3/34	1.75 (0.43, 7.23)	
ECOG - performance status	0	13/89	9/81	1.27 (0.54, 2.96)	0.9340
	1	13/76	6/50	1.29 (0.49, 3.37)	
Central laboratory disease type	Diffuse large B-cell lymphoma	14/117	10/94	1.05 (0.47, 2.38)	0.9273
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	6/28	3/17	1.13 (0.29, 4.43)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

Version: 1.0 (15July2022)

Table 1.5 EORTC QLQ-C30 Cognitive Functioning Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	16/119	16/89	0.67 (0.34, 1.34)	0.4743
	Relapse <= 12 Months of First Line therapy	6/46	5/42	1.10 (0.34, 3.61)	
Age	<65 Years	16/119	15/89	0.75 (0.37, 1.51)	0.8622
	≥65 Years	6/46	6/42	0.85 (0.28, 2.63)	
Second line age adjusted IPI score per IXRS	0 - 1	13/96	14/75	0.66 (0.31, 1.42)	0.5026
	2 - 3	9/69	7/56	1.01 (0.38, 2.69)	
Sex	Male	14/101	12/95	1.05 (0.48, 2.27)	0.1529
	Female	8/64	9/36	0.44 (0.17, 1.12)	
Geographic region	North America	19/128	15/94	0.87 (0.44, 1.71)	0.4927
	Europe	3/31	6/34	0.51 (0.13, 2.04)	
ECOG - performance status	0	9/89	11/81	0.71 (0.29, 1.73)	0.9183
	1	13/76	10/50	0.77 (0.34, 1.74)	
Central laboratory disease type	Diffuse large B-cell lymphoma	13/117	13/94	0.75 (0.35, 1.61)	0.9336
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	5/28	4/17	0.73 (0.20, 2.65)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

Version: 1.0 (15July2022)

Table 1.6 EORTC QLQ-C30 Social Functioning Time Until Definitive Improvement by Subgroup

Subgroup	Subgroup level	Axi-cel (Event/N)	SOCT (Event/N)	HR (95% CI)	P-value for Interaction (subgroup*treatment)
Response to first line therapy per IXRS	Primary Refractory	32/119	17/89	1.34 (0.75, 2.41)	0.8474
	Relapse <= 12 Months of First Line therapy	7/46	4/42	1.57 (0.46, 5.35)	
Age	<65 Years	30/119	18/89	1.21 (0.68, 2.17)	0.3020
	≥65 Years	9/46	3/42	2.60 (0.70, 9.66)	
Second line age adjusted IPI score per IXRS	0 - 1	25/96	17/75	1.07 (0.58, 1.98)	0.1231
	2 - 3	14/69	4/56	2.85 (0.94, 8.67)	
Sex	Male	25/101	16/95	1.45 (0.77, 2.71)	0.9954
	Female	14/64	5/36	1.47 (0.52, 4.12)	
Geographic region	North America	32/128	16/94	1.43 (0.78, 2.61)	0.6178
	Europe	5/31	5/34	0.95 (0.29, 3.16)	
ECOG - performance status	0	16/89	13/81	1.03 (0.50, 2.13)	0.2658
	1	23/76	8/50	1.92 (0.86, 4.29)	
Central laboratory disease type	Diffuse large B-cell lymphoma	24/117	15/94	1.21 (0.64, 2.31)	0.8134
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	7/28	3/17	1.43 (0.38, 5.40)	

Data cutoff date = 18MAR2021
Abbreviations: Axi-cel, Axicabtagene ciloleucel; BCL2, B-cell lymphoma 2; BCL6, B-cell lymphoma 6; CI, confidence interval; CIF, cumulative incidence function; ECOG, Eastern Cooperative Oncology Group; EORTC QLC-C30 European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HGBL, high grade B-cell lymphoma; HR, hazard ratio; IPI, international prognostic index; IXRS, interactive voice/web response system; MYC, MYC gene; NE, not estimable; SOCT, standard of care therapy.
Note: Results were based on the cumulative incidence of improvement (greater than the minimally important difference) in scores from screening with no further decline, controlling for death as a competing risk. An event was defined as the first time reaching the threshold for improvement and no deterioration below the threshold at later time points.
Results should be interpreted with caution because of the low event count in each subgroup, and HR is not estimable if any treatment group with zero events. The P-value for the interaction term was from a competing risk survival model with treatment, subgroup, and interaction of treatment and subgroup as covariates.
For the subgroup by region, patients in Australia and Israel were not included; For the subgroup by central laboratory disease type, patients with other disease type were not included.
Data Source: ADBASE, ADSL, ADTUDI Program Name: Competing Risk Survival Analysis.sas Output Generated: 13JUL2022

Anhang 4-G3.4: Ergänzende Subgruppenanalysen zu unerwünschte Ereignisse - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Anhang 4-G3.4.1: Subgruppenanalyse der Gesamtraten UE sowie UESI - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Tabelle 4-29 (Anhang): Subgruppenanalysen für UE (Gesamtraten sowie UESI)- RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.11.1. Overall Summary of TEAEs by Response to First-line Therapy Per IXRS (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Any TEAE	Primary refractory	123/123 (100)	123/123 (100)	0 (NE, NE), NE	NE
	Relapse ≤ 12 months of first-line therapy	47/47 (100)	45/45 (100)	0 (NE, NE), NE	
Grade ≥ 3 TEAE	Primary refractory	112/123 (91)	99/123 (80)	10.57 (1.21, 19.88), 0.0165	0.2981
	Relapse ≤ 12 months of first-line therapy	43/47 (91)	41/45 (91)	0.38 (-13.73, 14.81), 0.9524	
Grade 5 TEAE	Primary refractory	11/123 (9)	3/123 (2)	6.50 (-0.06, 13.59), 0.0277	0.3068
	Relapse ≤ 12 months of first-line therapy	6/47 (13)	4/45 (9)	3.88 (-11.32, 18.81), 0.5564	
Serious TEAE	Primary refractory	68/123 (55)	48/123 (39)	16.26 (3.21, 28.58), 0.0108	0.0366
	Relapse ≤ 12 months of first-line therapy	27/47 (57)	30/45 (67)	-9.22 (-29.14, 11.81), 0.3621	
Any treatment-related TEAE	Primary refractory	118/123 (96)	115/123 (93)	2.44 (-4.17, 9.25), 0.3946	0.9909
	Relapse ≤ 12 months of first-line therapy	45/47 (96)	45/45 (100)	-4.26 (-15.73, 6.15), 0.1670	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.1. Overall Summary of TEAEs by Response to First-line Therapy Per IXRS (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Grade ≥ 3 treatment-related TEAE	Primary refractory	82/123 (67)	91/123 (74)	-7.32 (-19.02, 4.65), 0.2188	0.0631
	Relapse ≤ 12 months of first-line therapy	30/47 (64)	40/45 (89)	-25.06 (-41.91, -6.07), 0.0049	
Serious treatment-related TEAE	Primary refractory	45/123 (37)	34/123 (28)	8.94 (-3.28, 20.82), 0.1295	0.0274
	Relapse ≤ 12 months of first-line therapy	18/47 (38)	25/45 (56)	-17.26 (-37.01, 4.49), 0.1005	
Any TE neurologic event	Primary refractory	71/123 (58)	19/123 (15)	42.28 (30.13, 52.70), <.0001	0.3912
	Relapse ≤ 12 months of first-line therapy	32/47 (68)	14/45 (31)	36.97 (15.03, 54.57), 0.0005	
Grade ≥ 3 TE neurologic event	Primary refractory	26/123 (21)	1/123 (1)	20.33 (12.42, 28.83), <.0001	0.9903
	Relapse ≤ 12 months of first-line therapy	10/47 (21)	0	21.28 (7.22, 36.07), 0.0012	
Serious TE neurologic event	Primary refractory	23/123 (19)	1/123 (1)	17.89 (10.31, 26.17), <.0001	0.9903
	Relapse ≤ 12 months of first-line therapy	11/47 (23)	0	23.40 (8.96, 38.37), 0.0006	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.1. Overall Summary of TEAEs by Response to First-line Therapy Per IXRS (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Any TE CRS	Primary refractory	112/123 (91)	NA	NA	NA
	Relapse ≤ 12 months of first-line therapy	45/47 (96)	NA	NA	
Grade ≥ 3 TE CRS	Primary refractory	8/123 (7)	NA	NA	NA
	Relapse ≤ 12 months of first-line therapy	3/47 (6)	NA	NA	
Serious TE CRS	Primary refractory	21/123 (17)	NA	NA	NA
	Relapse ≤ 12 months of first-line therapy	8/47 (17)	NA	NA	
Any TE hypogammaglobulinemia	Primary refractory	14/123 (11)	0	11.38 (5.28, 18.68), 0.0001	0.9911
	Relapse ≤ 12 months of first-line therapy	5/47 (11)	1/45 (2)	8.42 (-4.45, 21.84), 0.1062	
Grade ≥ 3 TE hypogammaglobulinemia	Primary refractory	0	0	NE	NE
	Relapse ≤ 12 months of first-line therapy	0	0	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.1. Overall Summary of TEAEs by Response to First-line Therapy Per IXRS (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Serious TE hypogammaglobulinemia	Primary refractory	0	0	NE	NE
	Relapse ≤ 12 months of first-line therapy	0	0	NE	
Any TE cytopenias	Primary refractory	101/123 (82)	93/123 (76)	6.50 (-4.31, 17.15), 0.2107	0.0094
	Relapse ≤ 12 months of first-line therapy	35/47 (74)	42/45 (93)	-18.87 (-34.75, -2.03), 0.0155	
Grade ≥ 3 TE cytopenias	Primary refractory	98/123 (80)	88/123 (72)	8.13 (-3.19, 19.20), 0.1380	0.0083
	Relapse ≤ 12 months of first-line therapy	30/47 (64)	38/45 (84)	-20.61 (-38.19, -1.06), 0.0260	
Serious TE cytopenias	Primary refractory	10/123 (8)	22/123 (18)	-9.76 (-18.82, -0.70), 0.0236	0.3657
	Relapse ≤ 12 months of first-line therapy	2/47 (4)	9/45 (20)	-15.74 (-31.20, -0.58), 0.0211	
Any TE infections	Primary refractory	53/123 (43)	30/123 (24)	18.70 (6.31, 30.34), 0.0021	0.0627
	Relapse ≤ 12 months of first-line therapy	23/47 (49)	23/45 (51)	-2.17 (-23.09, 19.00), 0.8374	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.1. Overall Summary of TEAEs by Response to First-line Therapy Per IXRS (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Grade ≥ 3 TE infections	Primary refractory	19/123 (15)	12/123 (10)	5.69 (-3.32, 14.71), 0.1673	0.5029
	Relapse ≤ 12 months of first-line therapy	9/47 (19)	8/45 (18)	1.37 (-16.22, 18.65), 0.8681	
Serious TE infections	Primary refractory	23/123 (19)	9/123 (7)	11.38 (2.37, 20.42), 0.0084	0.0643
	Relapse ≤ 12 months of first-line therapy	8/47 (17)	9/45 (20)	-2.98 (-20.46, 14.44), 0.7180	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.2. Overall Summary of TEAEs by Age (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Any TEAE	Age < 65	121/121 (100)	113/113 (100)	0 (NE, NE), NE	NE
	Age ≥ 65	49/49 (100)	55/55 (100)	0 (NE, NE), NE	
Grade ≥ 3 TEAE	Age < 65	109/121 (90)	95/113 (84)	6.01 (-3.27, 15.48), 0.1374	0.4431
	Age ≥ 65	46/49 (94)	45/55 (82)	12.06 (-2.54, 25.99), 0.0713	
Grade 5 TEAE	Age < 65	13/121 (11)	5/113 (4)	6.32 (-1.36, 14.09), 0.0780	0.8548
	Age ≥ 65	4/49 (8)	2/55 (4)	4.53 (-6.87, 17.21), 0.4892	
Serious TEAE	Age < 65	64/121 (53)	52/113 (46)	6.87 (-6.46, 19.88), 0.3041	0.4969
	Age ≥ 65	31/49 (63)	26/55 (47)	15.99 (-4.40, 34.63), 0.1802	
Any treatment-related TEAE	Age < 65	115/121 (95)	109/113 (96)	-1.42 (-7.86, 5.09), 0.5328	0.1605
	Age ≥ 65	48/49 (98)	51/55 (93)	5.23 (-6.09, 16.55), 0.1925	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.2. Overall Summary of TEAEs by Age (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Grade ≥ 3 treatment-related TEAE	Age < 65	74/121 (61)	88/113 (78)	-16.72 (-28.40, -4.29), 0.0090	0.2207
	Age ≥ 65	38/49 (78)	43/55 (78)	-0.63 (-18.04, 16.32), 0.8992	
Serious treatment-related TEAE	Age < 65	41/121 (34)	36/113 (32)	2.03 (-10.54, 14.42), 0.6887	0.9735
	Age ≥ 65	22/49 (45)	23/55 (42)	3.08 (-16.72, 22.67), 0.8055	
Any TE neurologic event	Age < 65	70/121 (58)	19/113 (17)	41.04 (28.45, 51.78), <.0001	0.7575
	Age ≥ 65	33/49 (67)	14/55 (25)	41.89 (21.50, 57.98), 0.0001	
Grade ≥ 3 TE neurologic event	Age < 65	23/121 (19)	0	19.01 (11.46, 27.37), <.0001	0.9895
	Age ≥ 65	13/49 (27)	1/55 (2)	24.71 (10.29, 39.62), 0.0003	
Serious TE neurologic event	Age < 65	22/121 (18)	1/113 (1)	17.30 (9.54, 25.61), <.0001	0.9895
	Age ≥ 65	12/49 (24)	0	24.49 (11.07, 39.18), 0.0003	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.2. Overall Summary of TEAEs by Age (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Any TE CRS	Age < 65	109/121 (90)	NA	NA	NA
	Age ≥ 65	48/49 (98)	NA	NA	
Grade ≥ 3 TE CRS	Age < 65	7/121 (6)	NA	NA	NA
	Age ≥ 65	4/49 (8)	NA	NA	
Serious TE CRS	Age < 65	17/121 (14)	NA	NA	NA
	Age ≥ 65	12/49 (24)	NA	NA	
Any TE hypogammaglobulinemia	Age < 65	9/121 (7)	0	7.44 (1.87, 14.04), 0.0046	0.9937
	Age ≥ 65	10/49 (20)	1/55 (2)	18.59 (5.25, 33.05), 0.0023	
Grade ≥ 3 TE hypogammaglobulinemia	Age < 65	0	0	NE	NE
	Age ≥ 65	0	0	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.2. Overall Summary of TEAEs by Age (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Serious TE hypogammaglobulinemia	Age < 65	0	0	NE	NE
	Age ≥ 65	0	0	NE	
Any TE cytopenias	Age < 65	95/121 (79)	90/113 (80)	-1.13 (-12.06, 9.97), 0.6613	0.5001
	Age ≥ 65	41/49 (84)	45/55 (82)	1.86 (-14.50, 17.55), 0.5781	
Grade ≥ 3 TE cytopenias	Age < 65	87/121 (72)	84/113 (74)	-2.44 (-14.20, 9.52), 0.5605	0.1992
	Age ≥ 65	41/49 (84)	42/55 (76)	7.31 (-9.78, 23.44), 0.2443	
Serious TE cytopenias	Age < 65	6/121 (5)	20/113 (18)	-12.74 (-21.78, -4.06), 0.0017	0.1218
	Age ≥ 65	6/49 (12)	11/55 (20)	-7.76 (-22.93, 8.31), 0.7268	
Any TE infections	Age < 65	46/121 (38)	32/113 (28)	9.70 (-2.98, 21.89), 0.1588	0.2088
	Age ≥ 65	30/49 (61)	21/55 (38)	23.04 (2.46, 41.22), 0.0072	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.2. Overall Summary of TEAEs by Age (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Grade ≥ 3 TE infections	Age < 65	14/121 (12)	11/113 (10)	1.84 (-7.01, 10.51), 0.7539	0.5793
	Age ≥ 65	14/49 (29)	9/55 (16)	12.21 (-5.13, 29.20), 0.4194	
Serious TE infections	Age < 65	20/121 (17)	9/113 (8)	8.56 (-0.61, 17.60), 0.0899	0.6035
	Age ≥ 65	11/49 (22)	9/55 (16)	6.09 (-10.39, 22.76), 0.5873	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.3. Overall Summary of TEAEs by Second-line Age-adjusted IPI Score Per IXRS (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Any TEAE	Second-line age-adjusted IPI score 0 - 1	97/97 (100)	93/93 (100)	0 (NE, NE), NE	NE
	Second-line age-adjusted IPI score 2 - 3	73/73 (100)	75/75 (100)	0 (NE, NE), NE	
Grade ≥ 3 TEAE	Second-line age-adjusted IPI score 0 - 1	85/97 (88)	77/93 (83)	4.83 (-6.12, 15.86), 0.3489	0.1668
	Second-line age-adjusted IPI score 2 - 3	70/73 (96)	63/75 (84)	11.89 (1.02, 22.99), 0.0186	
Grade 5 TEAE	Second-line age-adjusted IPI score 0 - 1	11/97 (11)	1/93 (1)	10.26 (2.56, 18.77), 0.0041	0.0452
	Second-line age-adjusted IPI score 2 - 3	6/73 (8)	6/75 (8)	0.22 (-10.18, 10.76), 0.9821	
Serious TEAE	Second-line age-adjusted IPI score 0 - 1	53/97 (55)	42/93 (45)	9.48 (-5.39, 23.80), 0.1851	0.9719
	Second-line age-adjusted IPI score 2 - 3	42/73 (58)	36/75 (48)	9.53 (-7.35, 25.71), 0.2621	
Any treatment-related TEAE	Second-line age-adjusted IPI score 0 - 1	94/97 (97)	88/93 (95)	2.28 (-4.89, 9.93), 0.4273	0.3854
	Second-line age-adjusted IPI score 2 - 3	69/73 (95)	72/75 (96)	-1.48 (-10.65, 7.36), 0.6549	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.3. Overall Summary of TEAEs by Second-line Age-adjusted IPI Score Per IXRS (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Grade ≥ 3 treatment-related TEAE	Second-line age-adjusted IPI score 0 - 1	59/97 (61)	72/93 (77)	-16.59 (-29.62, -2.68), 0.0146	0.3774
	Second-line age-adjusted IPI score 2 - 3	53/73 (73)	59/75 (79)	-6.06 (-20.56, 8.67), 0.3708	
Serious treatment-related TEAE	Second-line age-adjusted IPI score 0 - 1	34/97 (35)	32/93 (34)	0.64 (-13.45, 14.64), 0.9052	0.8046
	Second-line age-adjusted IPI score 2 - 3	29/73 (40)	27/75 (36)	3.73 (-12.57, 19.80), 0.6613	
Any TE neurologic event	Second-line age-adjusted IPI score 0 - 1	51/97 (53)	22/93 (24)	28.92 (14.43, 41.80), <.0001	0.0074
	Second-line age-adjusted IPI score 2 - 3	52/73 (71)	11/75 (15)	56.57 (40.66, 68.39), <.0001	
Grade ≥ 3 TE neurologic event	Second-line age-adjusted IPI score 0 - 1	16/97 (16)	1/93 (1)	15.42 (6.84, 24.69), 0.0002	0.9916
	Second-line age-adjusted IPI score 2 - 3	20/73 (27)	0	27.40 (16.14, 39.29), <.0001	
Serious TE neurologic event	Second-line age-adjusted IPI score 0 - 1	16/97 (16)	1/93 (1)	15.42 (6.84, 24.69), 0.0002	0.9917
	Second-line age-adjusted IPI score 2 - 3	18/73 (25)	0	24.66 (13.79, 36.38), <.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.3. Overall Summary of TEAEs by Second-line Age-adjusted IPI Score Per IXRS (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Any TE CRS	Second-line age-adjusted IPI score 0 - 1	89/97 (92)	NA	NA	NA
	Second-line age-adjusted IPI score 2 - 3	68/73 (93)	NA	NA	
Grade ≥ 3 TE CRS	Second-line age-adjusted IPI score 0 - 1	6/97 (6)	NA	NA	NA
	Second-line age-adjusted IPI score 2 - 3	5/73 (7)	NA	NA	
Serious TE CRS	Second-line age-adjusted IPI score 0 - 1	16/97 (16)	NA	NA	NA
	Second-line age-adjusted IPI score 2 - 3	13/73 (18)	NA	NA	
Any TE hypogammaglobulinemia	Second-line age-adjusted IPI score 0 - 1	12/97 (12)	1/93 (1)	11.30 (3.41, 19.98), 0.0020	0.9901
	Second-line age-adjusted IPI score 2 - 3	7/73 (10)	0	9.59 (1.52, 19.33), 0.0073	
Grade ≥ 3 TE hypogammaglobulinemia	Second-line age-adjusted IPI score 0 - 1	0	0	NE	NE
	Second-line age-adjusted IPI score 2 - 3	0	0	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.3. Overall Summary of TEAEs by Second-line Age-adjusted IPI Score Per IXRS (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Serious TE hypogammaglobulinemia	Second-line age-adjusted IPI score 0 - 1	0	0	NE	NE
	Second-line age-adjusted IPI score 2 - 3	0	0	NE	
Any TE cytopenias	Second-line age-adjusted IPI score 0 - 1	77/97 (79)	75/93 (81)	-1.26 (-13.30, 10.92), 0.7722	0.8060
	Second-line age-adjusted IPI score 2 - 3	59/73 (81)	60/75 (80)	0.82 (-12.98, 14.50), 0.9357	
Grade ≥ 3 TE cytopenias	Second-line age-adjusted IPI score 0 - 1	71/97 (73)	71/93 (76)	-3.15 (-16.01, 9.93), 0.5895	0.4099
	Second-line age-adjusted IPI score 2 - 3	57/73 (78)	55/75 (73)	4.75 (-10.01, 19.19), 0.5262	
Serious TE cytopenias	Second-line age-adjusted IPI score 0 - 1	8/97 (8)	17/93 (18)	-10.03 (-20.63, 0.45), 0.0415	0.5133
	Second-line age-adjusted IPI score 2 - 3	4/73 (5)	14/75 (19)	-13.19 (-24.80, -1.56), 0.0112	
Any TE infections	Second-line age-adjusted IPI score 0 - 1	48/97 (49)	29/93 (31)	18.30 (3.60, 31.95), 0.0103	0.2695
	Second-line age-adjusted IPI score 2 - 3	28/73 (38)	24/75 (32)	6.36 (-9.79, 22.12), 0.4390	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.3. Overall Summary of TEAEs by Second-line Age-adjusted IPI Score Per IXRS (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Grade ≥ 3 TE infections	Second-line age-adjusted IPI score 0 - 1	14/97 (14)	9/93 (10)	4.76 (-5.55, 14.94), 0.3082	0.8283
	Second-line age-adjusted IPI score 2 - 3	14/73 (19)	11/75 (15)	4.51 (-8.64, 17.63), 0.4630	
Serious TE infections	Second-line age-adjusted IPI score 0 - 1	21/97 (22)	9/93 (10)	11.97 (0.77, 22.88), 0.0239	0.2203
	Second-line age-adjusted IPI score 2 - 3	10/73 (14)	9/75 (12)	1.70 (-10.31, 13.82), 0.7589	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.4. Overall Summary of TEAEs by Sex (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Any TEAE	Male	106/106 (100)	120/120 (100)	0 (NE, NE), NE	NE
	Female	64/64 (100)	48/48 (100)	0 (NE, NE), NE	
Grade ≥ 3 TEAE	Male	93/106 (88)	96/120 (80)	7.74 (-2.70, 17.75), 0.1075	0.6378
	Female	62/64 (97)	44/48 (92)	5.21 (-5.15, 18.01), 0.2242	
Grade 5 TEAE	Male	13/106 (12)	6/120 (5)	7.26 (-0.76, 15.93), 0.0589	0.8375
	Female	4/64 (6)	1/48 (2)	4.17 (-7.05, 14.13), 0.2821	
Serious TEAE	Male	56/106 (53)	51/120 (43)	10.33 (-3.29, 23.46), 0.1113	0.6671
	Female	39/64 (61)	27/48 (56)	4.69 (-14.41, 23.69), 0.4746	
Any treatment-related TEAE	Male	101/106 (95)	114/120 (95)	0.28 (-6.83, 6.99), 0.9119	0.8339
	Female	62/64 (97)	46/48 (96)	1.04 (-8.30, 12.59), 0.7771	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.4. Overall Summary of TEAEs by Sex (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Grade ≥ 3 treatment-related TEAE	Male	66/106 (62)	89/120 (74)	-11.90 (-24.30, 0.84), 0.0643	0.4188
	Female	46/64 (72)	42/48 (88)	-15.63 (-30.39, 1.24), 0.0486	
Serious treatment-related TEAE	Male	35/106 (33)	36/120 (30)	3.02 (-9.57, 15.65), 0.5813	0.5892
	Female	28/64 (44)	23/48 (48)	-4.17 (-23.27, 15.18), 0.9703	
Any TE neurologic event	Male	61/106 (58)	20/120 (17)	40.88 (28.00, 52.03), <.0001	0.8218
	Female	42/64 (66)	13/48 (27)	38.54 (18.68, 54.43), <.0001	
Grade ≥ 3 TE neurologic event	Male	21/106 (20)	1/120 (1)	18.98 (10.82, 28.11), <.0001	0.9892
	Female	15/64 (23)	0	23.44 (10.32, 35.98), 0.0002	
Serious TE neurologic event	Male	20/106 (19)	0	18.87 (11.14, 27.88), <.0001	0.9895
	Female	14/64 (22)	1/48 (2)	19.79 (6.05, 32.36), 0.0016	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.4. Overall Summary of TEAEs by Sex (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Any TE CRS	Male	97/106 (92)	NA	NA	NA
	Female	60/64 (94)	NA	NA	
Grade ≥ 3 TE CRS	Male	5/106 (5)	NA	NA	NA
	Female	6/64 (9)	NA	NA	
Serious TE CRS	Male	12/106 (11)	NA	NA	NA
	Female	17/64 (27)	NA	NA	
Any TE hypogammaglobulinemia	Male	11/106 (10)	0	10.38 (4.19, 18.19), 0.0002	0.9912
	Female	8/64 (13)	1/48 (2)	10.42 (-1.87, 21.79), 0.0605	
Grade ≥ 3 TE hypogammaglobulinemia	Male	0	0	NE	NE
	Female	0	0	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.4. Overall Summary of TEAEs by Sex (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Serious TE hypogammaglobulinemia	Male	0	0	NE	NE
	Female	0	0	NE	
Any TE cytopenias	Male	80/106 (75)	92/120 (77)	-1.19 (-13.00, 10.42), 0.8162	0.8234
	Female	56/64 (88)	43/48 (90)	-2.08 (-15.04, 12.51), 0.7205	
Grade ≥ 3 TE cytopenias	Male	73/106 (69)	85/120 (71)	-1.97 (-14.49, 10.46), 0.8172	0.9401
	Female	55/64 (86)	41/48 (85)	0.52 (-13.48, 16.01), 0.9630	
Serious TE cytopenias	Male	5/106 (5)	21/120 (18)	-12.78 (-21.54, -3.89), 0.0031	0.4745
	Female	7/64 (11)	10/48 (21)	-9.90 (-25.68, 4.82), 0.2093	
Any TE infections	Male	43/106 (41)	36/120 (30)	10.57 (-2.48, 23.27), 0.1279	0.5741
	Female	33/64 (52)	17/48 (35)	16.15 (-3.66, 34.11), 0.1042	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.4. Overall Summary of TEAEs by Sex (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Grade ≥ 3 TE infections	Male	17/106 (16)	13/120 (11)	5.20 (-4.35, 15.08), 0.2812	0.8068
	Female	11/64 (17)	7/48 (15)	2.60 (-13.29, 16.97), 0.7414	
Serious TE infections	Male	20/106 (19)	12/120 (10)	8.87 (-0.94, 18.94), 0.0747	0.6731
	Female	11/64 (17)	6/48 (13)	4.69 (-10.90, 18.66), 0.6434	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.5. Overall Summary of TEAEs by Geographic Region (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Any TEAE	North America	132/132 (100)	120/120 (100)	0 (NE, NE), NE	NE
	Europe	32/32 (100)	44/44 (100)	0 (NE, NE), NE	
Grade ≥ 3 TEAE	North America	121/132 (92)	101/120 (84)	7.50 (-1.16, 16.44), 0.0683	0.6406
	Europe	28/32 (88)	37/44 (84)	3.41 (-16.09, 20.40), 0.6125	
Grade 5 TEAE	North America	12/132 (9)	4/120 (3)	5.76 (-1.09, 12.72), 0.0566	0.6982
	Europe	4/32 (13)	3/44 (7)	5.68 (-9.71, 23.83), 0.3193	
Serious TEAE	North America	76/132 (58)	55/120 (46)	11.74 (-1.14, 24.13), 0.0567	0.3664
	Europe	16/32 (50)	22/44 (50)	0.00 (-23.38, 23.38), 0.9186	
Any treatment-related TEAE	North America	127/132 (96)	115/120 (96)	0.38 (-5.51, 6.62), 0.8828	0.9826
	Europe	30/32 (94)	41/44 (93)	0.57 (-16.17, 14.45), 0.9030	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.5. Overall Summary of TEAEs by Geographic Region (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Grade ≥ 3 treatment-related TEAE	North America	88/132 (67)	93/120 (78)	-10.83 (-22.02, 0.87), 0.0548	0.8571
	Europe	22/32 (69)	36/44 (82)	-13.07 (-34.20, 7.83), 0.2008	
Serious treatment-related TEAE	North America	51/132 (39)	42/120 (35)	3.64 (-8.78, 15.82), 0.5325	0.4053
	Europe	10/32 (31)	17/44 (39)	-7.39 (-28.87, 16.06), 0.3756	
Any TE neurologic event	North America	86/132 (65)	23/120 (19)	45.98 (33.78, 56.18), <.0001	0.1084
	Europe	14/32 (44)	9/44 (20)	23.30 (0.49, 44.27), 0.0704	
Grade ≥ 3 TE neurologic event	North America	31/132 (23)	1/120 (1)	22.65 (14.60, 31.01), <.0001	0.9906
	Europe	5/32 (16)	0	15.63 (1.67, 33.55), 0.0205	
Serious TE neurologic event	North America	27/132 (20)	0	20.45 (13.04, 28.54), <.0001	0.9890
	Europe	6/32 (19)	1/44 (2)	16.48 (0.83, 34.90), 0.0338	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.5. Overall Summary of TEAEs by Geographic Region (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Any TE CRS	North America	124/132 (94)	NA	NA	NA
	Europe	28/32 (88)	NA	NA	
Grade ≥ 3 TE CRS	North America	10/132 (8)	NA	NA	NA
	Europe	1/32 (3)	NA	NA	
Serious TE CRS	North America	25/132 (19)	NA	NA	NA
	Europe	3/32 (9)	NA	NA	
Any TE hypogammaglobulinemia	North America	15/132 (11)	1/120 (1)	10.53 (4.13, 17.56), 0.0007	0.9922
	Europe	4/32 (13)	0	12.50 (-0.57, 29.93), 0.0309	
Grade ≥ 3 TE hypogammaglobulinemia	North America	0	0	NE	NE
	Europe	0	0	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.5. Overall Summary of TEAEs by Geographic Region (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Serious TE hypogammaglobulinemia	North America	0	0	NE	NE
	Europe	0	0	NE	
Any TE cytopenias	North America	106/132 (80)	95/120 (79)	1.14 (-9.28, 11.72), 0.8498	0.2151
	Europe	24/32 (75)	38/44 (86)	-11.36 (-31.74, 7.96), 0.1371	
Grade ≥ 3 TE cytopenias	North America	100/132 (76)	90/120 (75)	0.76 (-10.32, 11.97), 0.9380	0.4350
	Europe	22/32 (69)	34/44 (77)	-8.52 (-30.25, 12.70), 0.3695	
Serious TE cytopenias	North America	11/132 (8)	26/120 (22)	-13.33 (-22.81, -3.99), 0.0025	0.9890
	Europe	0	5/44 (11)	-11.36 (-25.35, 3.75), 0.0501	
Any TE infections	North America	56/132 (42)	36/120 (30)	12.42 (-0.04, 24.29), 0.0325	0.7954
	Europe	16/32 (50)	17/44 (39)	11.36 (-12.44, 33.91), 0.4557	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.5. Overall Summary of TEAEs by Geographic Region (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Grade ≥ 3 TE infections	North America	19/132 (14)	12/120 (10)	4.39 (-4.51, 13.07), 0.2960	0.9049
	Europe	7/32 (22)	8/44 (18)	3.69 (-15.52, 24.54), 0.7541	
Serious TE infections	North America	22/132 (17)	11/120 (9)	7.50 (-1.54, 16.31), 0.0751	0.8339
	Europe	8/32 (25)	7/44 (16)	9.09 (-10.50, 29.78), 0.4035	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.6. Overall Summary of TEAEs by ECOG Performance (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Any TEAE	ECOG = 0	92/92 (100)	94/94 (100)	0 (NE, NE), NE	NE
	ECOG = 1	78/78 (100)	74/74 (100)	0 (NE, NE), NE	
Grade ≥ 3 TEAE	ECOG = 0	84/92 (91)	73/94 (78)	13.64 (2.41, 24.64), 0.0081	0.1250
	ECOG = 1	71/78 (91)	67/74 (91)	0.49 (-10.11, 11.33), 0.8282	
Grade 5 TEAE	ECOG = 0	12/92 (13)	3/94 (3)	9.85 (1.11, 19.17), 0.0119	0.1236
	ECOG = 1	5/78 (6)	4/74 (5)	1.00 (-8.47, 10.31), 0.9299	
Serious TEAE	ECOG = 0	46/92 (50)	39/94 (41)	8.51 (-6.45, 22.98), 0.1987	0.9733
	ECOG = 1	49/78 (63)	39/74 (53)	10.12 (-6.38, 25.94), 0.1906	
Any treatment-related TEAE	ECOG = 0	88/92 (96)	89/94 (95)	0.97 (-6.82, 8.78), 0.6497	0.8176
	ECOG = 1	75/78 (96)	71/74 (96)	0.21 (-8.10, 8.82), 0.8040	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.6. Overall Summary of TEAEs by ECOG Performance (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Grade ≥ 3 treatment-related TEAE	ECOG = 0	59/92 (64)	71/94 (76)	-11.40 (-24.81, 2.53), 0.1111	0.7372
	ECOG = 1	53/78 (68)	60/74 (81)	-13.13 (-27.17, 1.73), 0.0978	
Serious treatment-related TEAE	ECOG = 0	29/92 (32)	32/94 (34)	-2.52 (-16.46, 11.58), 0.8344	0.4085
	ECOG = 1	34/78 (44)	27/74 (36)	7.10 (-9.25, 22.91), 0.2659	
Any TE neurologic event	ECOG = 0	48/92 (52)	21/94 (22)	29.83 (15.26, 42.79), <.0001	0.0298
	ECOG = 1	55/78 (71)	12/74 (16)	54.30 (38.48, 66.23), <.0001	
Grade ≥ 3 TE neurologic event	ECOG = 0	13/92 (14)	1/94 (1)	13.07 (4.82, 22.31), 0.0009	0.9915
	ECOG = 1	23/78 (29)	0	29.49 (18.16, 41.04), <.0001	
Serious TE neurologic event	ECOG = 0	13/92 (14)	0	14.13 (6.31, 23.31), 0.0002	0.9918
	ECOG = 1	21/78 (27)	1/74 (1)	25.57 (14.09, 37.08), <.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.6. Overall Summary of TEAEs by ECOG Performance (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Any TE CRS	ECOG = 0	84/92 (91)	NA	NA	NA
	ECOG = 1	73/78 (94)	NA	NA	
Grade ≥ 3 TE CRS	ECOG = 0	5/92 (5)	NA	NA	NA
	ECOG = 1	6/78 (8)	NA	NA	
Serious TE CRS	ECOG = 0	14/92 (15)	NA	NA	NA
	ECOG = 1	15/78 (19)	NA	NA	
Any TE hypogammaglobulinemia	ECOG = 0	10/92 (11)	1/94 (1)	9.81 (2.16, 18.51), 0.0036	0.9934
	ECOG = 1	9/78 (12)	0	11.54 (3.08, 21.26), 0.0018	
Grade ≥ 3 TE hypogammaglobulinemia	ECOG = 0	0	0	NE	NE
	ECOG = 1	0	0	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.6. Overall Summary of TEAEs by ECOG Performance (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Serious TE hypogammaglobulinemia	ECOG = 0	0	0	NE	NE
	ECOG = 1	0	0	NE	
Any TE cytopenias	ECOG = 0	77/92 (84)	73/94 (78)	6.04 (-6.17, 18.00), 0.1897	0.0528
	ECOG = 1	59/78 (76)	62/74 (84)	-8.14 (-21.52, 5.72), 0.1683	
Grade ≥ 3 TE cytopenias	ECOG = 0	72/92 (78)	68/94 (72)	5.92 (-7.24, 18.79), 0.2710	0.1351
	ECOG = 1	56/78 (72)	58/74 (78)	-6.58 (-20.82, 8.14), 0.3422	
Serious TE cytopenias	ECOG = 0	5/92 (5)	15/94 (16)	-10.52 (-20.45, -0.72), 0.0265	0.9584
	ECOG = 1	7/78 (9)	16/74 (22)	-12.65 (-25.08, -0.19), 0.0359	
Any TE infections	ECOG = 0	37/92 (40)	35/94 (37)	2.98 (-11.57, 17.39), 0.4808	0.0521
	ECOG = 1	39/78 (50)	18/74 (24)	25.68 (9.38, 40.17), 0.0011	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.6. Overall Summary of TEAEs by ECOG Performance (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Grade ≥ 3 TE infections	ECOG = 0	11/92 (12)	12/94 (13)	-0.81 (-11.26, 9.71), 0.9052	0.1416
	ECOG = 1	17/78 (22)	8/74 (11)	10.98 (-1.90, 23.43), 0.0501	
Serious TE infections	ECOG = 0	14/92 (15)	13/94 (14)	1.39 (-9.64, 12.47), 0.6902	0.0797
	ECOG = 1	17/78 (22)	5/74 (7)	15.04 (2.86, 26.89), 0.0065	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.7. Overall Summary of TEAEs by Central Lab Disease Type (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Any TEAE	DLBCL NOS/without further classification possible	121/121 (100)	119/119 (100)	0 (NE, NE), NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	29/29 (100)	25/25 (100)	0 (NE, NE), NE	
Grade ≥ 3 TEAE	DLBCL NOS/without further classification possible	108/121 (89)	101/119 (85)	4.38 (-4.83, 13.64), 0.3331	0.9877
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	29/29 (100)	17/25 (68)	32.00 (10.16, 53.55), 0.0018	
Grade 5 TEAE	DLBCL NOS/without further classification possible	13/121 (11)	4/119 (3)	7.38 (0.14, 14.99), 0.0279	0.6536
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/29 (14)	2/25 (8)	5.79 (-15.81, 25.70), 0.6890	
Serious TEAE	DLBCL NOS/without further classification possible	65/121 (54)	57/119 (48)	5.82 (-7.32, 18.69), 0.3887	0.0486
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	20/29 (69)	9/25 (36)	32.97 (3.74, 55.89), 0.0136	
Any treatment-related TEAE	DLBCL NOS/without further classification possible	115/121 (95)	114/119 (96)	-0.76 (-7.29, 5.75), 0.7374	0.9926
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	29/29 (100)	23/25 (92)	8.00 (-7.99, 27.50), 0.2089	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.7. Overall Summary of TEAEs by Central Lab Disease Type (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Grade ≥ 3 treatment-related TEAE	DLBCL NOS/without further classification possible	76/121 (63)	94/119 (79)	-16.18 (-27.65, -4.09), 0.0054	0.0191
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	23/29 (79)	16/25 (64)	15.31 (-10.80, 39.82), 0.2125	
Serious treatment-related TEAE	DLBCL NOS/without further classification possible	44/121 (36)	41/119 (34)	1.91 (-10.65, 14.38), 0.7731	0.1809
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	14/29 (48)	7/25 (28)	20.28 (-8.09, 44.43), 0.1084	
Any TE neurologic event	DLBCL NOS/without further classification possible	68/121 (56)	22/119 (18)	37.71 (25.19, 48.62), <.0001	0.0606
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	24/29 (83)	4/25 (16)	66.76 (38.34, 81.93), <.0001	
Grade ≥ 3 TE neurologic event	DLBCL NOS/without further classification possible	24/121 (20)	1/119 (1)	18.99 (11.14, 27.47), <.0001	0.9925
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/29 (28)	0	27.59 (5.80, 47.49), 0.0048	
Serious TE neurologic event	DLBCL NOS/without further classification possible	22/121 (18)	1/119 (1)	17.34 (9.72, 25.65), <.0001	0.9923
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/29 (28)	0	27.59 (5.80, 47.49), 0.0057	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.7. Overall Summary of TEAEs by Central Lab Disease Type (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Any TE CRS	DLBCL NOS/without further classification possible	109/121 (90)	NA	NA	NA
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	29/29 (100)	NA	NA	
Grade ≥ 3 TE CRS	DLBCL NOS/without further classification possible	7/121 (6)	NA	NA	NA
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/29 (10)	NA	NA	
Serious TE CRS	DLBCL NOS/without further classification possible	20/121 (17)	NA	NA	NA
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	6/29 (21)	NA	NA	
Any TE hypogammaglobulinemia	DLBCL NOS/without further classification possible	15/121 (12)	1/119 (1)	11.56 (4.83, 19.13), 0.0005	0.9934
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/29 (14)	0	13.79 (-5.20, 32.57), 0.0316	
Grade ≥ 3 TE hypogammaglobulinemia	DLBCL NOS/without further classification possible	0	0	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0	0	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.7. Overall Summary of TEAEs by Central Lab Disease Type (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Serious TE hypogammaglobulinemia	DLBCL NOS/without further classification possible	0	0	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0	0	NE	
Any TE cytopenias	DLBCL NOS/without further classification possible	96/121 (79)	96/119 (81)	-1.33 (-12.01, 9.41), 0.7429	0.0892
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	25/29 (86)	16/25 (64)	22.21 (-3.32, 45.52), 0.0842	
Grade ≥ 3 TE cytopenias	DLBCL NOS/without further classification possible	89/121 (74)	91/119 (76)	-2.92 (-14.32, 8.61), 0.5384	0.0231
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	24/29 (83)	13/25 (52)	30.76 (3.24, 53.67), 0.0460	
Serious TE cytopenias	DLBCL NOS/without further classification possible	8/121 (7)	21/119 (18)	-11.04 (-20.04, -2.15), 0.0099	0.6655
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/29 (10)	4/25 (16)	-5.66 (-27.92, 15.44), 0.6587	
Any TE infections	DLBCL NOS/without further classification possible	54/121 (45)	38/119 (32)	12.70 (-0.18, 25.01), 0.0559	0.1249
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	15/29 (52)	5/25 (20)	31.72 (3.30, 53.90), 0.0444	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Table 14.3.1.1.11.7. Overall Summary of TEAEs by Central Lab Disease Type (Safety Analysis Set)

	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	P-value for Interaction
Grade ≥ 3 TE infections	DLBCL NOS/without further classification possible	19/121 (16)	14/119 (12)	3.94 (-5.52, 13.34), 0.3294	0.9874
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	5/29 (17)	3/25 (12)	5.24 (-17.74, 26.42), 1.0000	
Serious TE infections	DLBCL NOS/without further classification possible	23/121 (19)	12/119 (10)	8.92 (-0.68, 18.43), 0.0482	0.9093
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	5/29 (17)	2/25 (8)	9.24 (-13.01, 29.59), 0.7023	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; RD, risk difference; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Adverse events are graded per CTCAE version 4.03 and CRS events are graded according to a modified grading system proposed by Lee and colleagues (Lee et al, 2014).
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For axicabtagene ciloleucel arm, treatment-related TEAEs include TEAEs that are related to axicabtagene ciloleucel; for standard of care therapy arm, treatment-related TEAEs include TEAEs that are related to salvage chemotherapy, total body irradiation (given as part of conditioning for ASCT), high-dose therapy, and ASCT.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_aesum_sg.sas Output Generated: 20230419T14:56

Anhang 4-G3.4.2: Subgruppenanalyse häufiger UE nach SOC und PT - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7, Datenschnitt: 25. Januar 2023)

Tabelle 4-30 (Anhang): Subgruppenanalysen für häufige UE nach SOC und PT (jeglicher Grad)- RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.12.1. Subject Incidence of TEAEs by SOC and Preferred Term by Response to First-line Therapy Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders					
Neutropenia	Primary refractory	59/123 (48)	19/123 (15)	32.52 (20.54, 43.28), <.0001	0.0713
	Relapse ≤ 12 months of first line therapy	16/47 (34)	10/45 (22)	11.82 (-8.07, 30.43), 0.2118	
Anaemia	Primary refractory	51/123 (41)	60/123 (49)	-7.32 (-19.93, 5.62), 0.2661	0.1124
	Relapse ≤ 12 months of first line therapy	20/47 (43)	31/45 (69)	-26.34 (-45.08, -4.50), 0.0117	
Thrombocytopenia	Primary refractory	13/123 (11)	28/123 (23)	-12.20 (-21.95, -2.28), 0.0090	0.5283
	Relapse ≤ 12 months of first line therapy	9/47 (19)	13/45 (29)	-9.74 (-28.03, 9.17), 0.2792	
Febrile neutropenia	Primary refractory	5/123 (4)	34/123 (28)	-23.58 (-32.85, -14.20), <.0001	0.6032
	Relapse ≤ 12 months of first line therapy	1/47 (2)	12/45 (27)	-24.54 (-40.21, -8.85), 0.0008	
Cardiac disorders	Primary refractory	60/123 (49)	26/123 (21)	27.64 (15.24, 38.93), <.0001	0.9522
	Relapse ≤ 12 months of first line therapy	24/47 (51)	10/45 (22)	28.84 (7.58, 46.86), 0.0046	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:02

Table 14.3.1.1.12.1. Subject Incidence of TEAEs by SOC and Preferred Term by Response to First-line Therapy Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Sinus tachycardia	Primary refractory	43/123 (35)	14/123 (11)	23.58 (12.58, 33.93), <.0001	0.5582
	Relapse ≤ 12 months of first line therapy	15/47 (32)	3/45 (7)	25.25 (7.54, 41.36), 0.0025	
Ear and labyrinth disorders	Primary refractory	4/123 (3)	13/123 (11)	-7.32 (-14.80, -0.25), 0.0256	0.9902
	Relapse ≤ 12 months of first line therapy	0	5/45 (11)	-11.11 (-24.85, 0.59), 0.0192	
Tinnitus	Primary refractory	0	7/123 (6)	NE	NE
	Relapse ≤ 12 months of first line therapy	0	4/45 (9)	NE	
Gastrointestinal disorders					
Nausea	Primary refractory	45/123 (37)	79/123 (64)	-27.64 (-39.42, -14.62), <.0001	0.5305
	Relapse ≤ 12 months of first line therapy	24/47 (51)	37/45 (82)	-31.16 (-48.63, -10.34), 0.0018	
Constipation	Primary refractory	24/123 (20)	43/123 (35)	-15.45 (-26.63, -3.74), 0.0064	0.7329
	Relapse ≤ 12 months of first line therapy	10/47 (21)	15/45 (33)	-12.06 (-30.73, 7.57), 0.1945	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:02

Table 14.3.1.1.12.1. Subject Incidence of TEAEs by SOC and Preferred Term by Response to First-line Therapy Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Vomiting	Primary refractory	22/123 (18)	36/123 (29)	-11.38 (-22.25, -0.18), 0.0334	0.6902
	Relapse ≤ 12 months of first line therapy	11/47 (23)	19/45 (42)	-18.82 (-37.64, 1.83), 0.0568	
Dyspepsia	Primary refractory	4/123 (3)	8/123 (7)	NE	NE
	Relapse ≤ 12 months of first line therapy	1/47 (2)	6/45 (13)	NE	
Stomatitis	Primary refractory	4/123 (3)	16/123 (13)	-9.76 (-17.62, -2.31), 0.0056	0.2276
	Relapse ≤ 12 months of first line therapy	1/47 (2)	13/45 (29)	-26.76 (-42.52, -10.72), 0.0003	
General disorders and administration site conditions	Primary refractory	114/123 (93)	83/123 (67)	25.20 (14.89, 35.05), <.0001	0.6236
	Relapse ≤ 12 months of first line therapy	46/47 (98)	42/45 (93)	4.54 (-7.14, 17.34), 0.2680	
Pyrexia	Primary refractory	112/123 (91)	24/123 (20)	71.54 (60.76, 79.17), <.0001	0.7104
	Relapse ≤ 12 months of first line therapy	46/47 (98)	19/45 (42)	55.65 (36.84, 70.02), <.0001	
Chills	Primary refractory	33/123 (27)	8/123 (7)	20.33 (10.60, 29.85), <.0001	0.3388
	Relapse ≤ 12 months of first line therapy	14/47 (30)	6/45 (13)	16.45 (-2.10, 33.61), 0.0581	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:02

Table 14.3.1.1.12.1. Subject Incidence of TEAEs by SOC and Preferred Term by Response to First-line Therapy Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Mucosal inflammation	Primary refractory	0	13/123 (11)	-10.57 (-17.72, -4.62), 0.0001	0.9918
	Relapse ≤ 12 months of first line therapy	1/47 (2)	3/45 (7)	-4.54 (-17.34, 7.14), 0.2873	
Hepatobiliary disorders	Primary refractory	11/123 (9)	0	8.94 (3.32, 15.79), 0.0008	0.9903
	Relapse ≤ 12 months of first line therapy	4/47 (9)	3/45 (7)	1.84 (-12.05, 15.53), 0.7447	
Hypertransaminasaemia	Primary refractory	7/123 (6)	0	NE	NE
	Relapse ≤ 12 months of first line therapy	4/47 (9)	1/45 (2)	NE	
Immune system disorders	Primary refractory	15/123 (12)	2/123 (2)	10.57 (3.71, 18.11), 0.0012	0.8403
	Relapse ≤ 12 months of first line therapy	6/47 (13)	1/45 (2)	10.54 (-2.76, 24.38), 0.0587	
Hypogammaglobulinaemia	Primary refractory	14/123 (11)	0	11.38 (5.28, 18.68), 0.0001	0.9911
	Relapse ≤ 12 months of first line therapy	5/47 (11)	1/45 (2)	8.42 (-4.45, 21.84), 0.1062	
Infections and infestations	Primary refractory	56/123 (46)	32/123 (26)	19.51 (6.96, 31.26), 0.0015	0.1198
	Relapse ≤ 12 months of first line therapy	25/47 (53)	23/45 (51)	2.08 (-19.06, 23.00), 0.8430	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:02

Table 14.3.1.1.12.1. Subject Incidence of TEAEs by SOC and Preferred Term by Response to First-line Therapy Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Oral candidiasis	Primary refractory	8/123 (7)	4/123 (3)	NE	NE
	Relapse ≤ 12 months of first line therapy	6/47 (13)	1/45 (2)	NE	
Injury, poisoning and procedural complications	Primary refractory	8/123 (7)	19/123 (15)	-8.94 (-17.54, -0.46), 0.0258	0.8066
	Relapse ≤ 12 months of first line therapy	8/47 (17)	14/45 (31)	-14.09 (-32.12, 4.91), 0.1086	
Infusion related reaction	Primary refractory	0	8/123 (7)	NE	NE
	Relapse ≤ 12 months of first line therapy	1/47 (2)	5/45 (11)	NE	
Investigations					
Alanine aminotransferase increased	Primary refractory	24/123 (20)	11/123 (9)	10.57 (1.21, 19.88), 0.0166	0.4372
	Relapse ≤ 12 months of first line therapy	7/47 (15)	5/45 (11)	3.78 (-12.22, 19.43), 0.5926	
Platelet count decreased	Primary refractory	21/123 (17)	42/123 (34)	-17.07 (-28.00, -5.60), 0.0023	0.4062
	Relapse ≤ 12 months of first line therapy	9/47 (19)	22/45 (49)	-29.74 (-47.61, -8.86), 0.0028	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:02

Table 14.3.1.1.12.1. Subject Incidence of TEAEs by SOC and Preferred Term by Response to First-line Therapy Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
C-reactive protein increased	Primary refractory	9/123 (7)	2/123 (2)	NE	NE
	Relapse ≤ 12 months of first line therapy	6/47 (13)	2/45 (4)	NE	
Serum ferritin increased	Primary refractory	11/123 (9)	0	8.94 (3.32, 15.79), 0.0008	1.0000
	Relapse ≤ 12 months of first line therapy	4/47 (9)	0	8.51 (-2.85, 21.27), 0.0470	
Weight increased	Primary refractory	1/123 (1)	9/123 (7)	NE	NE
	Relapse ≤ 12 months of first line therapy	0	3/45 (7)	NE	
Metabolism and nutrition disorders	Primary refractory	81/123 (66)	59/123 (48)	17.89 (4.93, 30.05), 0.0041	0.0365
	Relapse ≤ 12 months of first line therapy	32/47 (68)	34/45 (76)	-7.47 (-26.38, 12.31), 0.4296	
Hypophosphataemia	Primary refractory	28/123 (23)	17/123 (14)	8.94 (-1.35, 19.07), 0.0569	0.7435
	Relapse ≤ 12 months of first line therapy	17/47 (36)	12/45 (27)	9.50 (-10.83, 28.73), 0.3323	
Hyponatraemia	Primary refractory	15/123 (12)	2/123 (2)	10.57 (3.71, 18.11), 0.0010	0.0260
	Relapse ≤ 12 months of first line therapy	6/47 (13)	6/45 (13)	-0.57 (-16.57, 15.17), 0.9351	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:02

Table 14.3.1.1.12.1. Subject Incidence of TEAEs by SOC and Preferred Term by Response to First-line Therapy Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Hypomagnesaemia	Primary refractory	14/123 (11)	19/123 (15)	-4.07 (-13.29, 5.17), 0.3458	0.1872
	Relapse ≤ 12 months of first line therapy	6/47 (13)	15/45 (33)	-20.57 (-37.97, -1.78), 0.0201	
Nervous system disorders	Primary refractory	90/123 (73)	61/123 (50)	23.58 (10.86, 35.29), 0.0001	0.8486
	Relapse ≤ 12 months of first line therapy	38/47 (81)	26/45 (58)	23.07 (2.70, 41.29), 0.0170	
Headache	Primary refractory	53/123 (43)	29/123 (24)	19.51 (7.16, 31.09), 0.0012	0.2062
	Relapse ≤ 12 months of first line therapy	17/47 (36)	14/45 (31)	5.06 (-15.38, 24.85), 0.5938	
Tremor	Primary refractory	30/123 (24)	0	24.39 (16.36, 33.11), <.0001	0.9880
	Relapse ≤ 12 months of first line therapy	14/47 (30)	1/45 (2)	27.57 (11.28, 43.00), 0.0004	
Aphasia	Primary refractory	23/123 (19)	0	18.70 (11.40, 26.95), <.0001	0.9998
	Relapse ≤ 12 months of first line therapy	13/47 (28)	0	27.66 (12.50, 42.87), 0.0001	
Dizziness	Primary refractory	28/123 (23)	14/123 (11)	11.38 (1.36, 21.23), 0.0182	0.2787
	Relapse ≤ 12 months of first line therapy	8/47 (17)	7/45 (16)	1.47 (-15.55, 18.16), 0.8535	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:02

Table 14.3.1.1.12.1. Subject Incidence of TEAEs by SOC and Preferred Term by Response to First-line Therapy Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Encephalopathy	Primary refractory	22/123 (18)	2/123 (2)	16.26 (8.55, 24.53), <.0001	0.9906
	Relapse ≤ 12 months of first line therapy	7/47 (15)	0	14.89 (2.11, 28.92), 0.0069	
Somnolence	Primary refractory	12/123 (10)	2/123 (2)	8.13 (1.69, 15.27), 0.0060	0.9913
	Relapse ≤ 12 months of first line therapy	7/47 (15)	0	14.89 (2.11, 28.92), 0.0077	
Dysgeusia	Primary refractory	3/123 (2)	10/123 (8)	-5.69 (-12.62, 0.73), 0.0469	0.8535
	Relapse ≤ 12 months of first line therapy	1/47 (2)	4/45 (9)	-6.76 (-20.15, 5.41), 0.1537	
Peripheral sensory neuropathy	Primary refractory	0	10/123 (8)	-8.13 (-14.81, -2.67), 0.0014	0.9977
	Relapse ≤ 12 months of first line therapy	0	0	NE	
Psychiatric disorders	Primary refractory	49/123 (40)	24/123 (20)	20.33 (8.36, 31.55), 0.0005	0.2977
	Relapse ≤ 12 months of first line therapy	22/47 (47)	16/45 (36)	11.25 (-10.09, 31.25), 0.2779	
Confusional state	Primary refractory	27/123 (22)	2/123 (2)	20.33 (12.09, 28.97), <.0001	0.4939
	Relapse ≤ 12 months of first line therapy	13/47 (28)	2/45 (4)	23.22 (6.60, 38.86), 0.0028	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:02

Table 14.3.1.1.12.1. Subject Incidence of TEAEs by SOC and Preferred Term by Response to First-line Therapy Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Agitation	Primary refractory	6/123 (5)	2/123 (2)	NE	NE
	Relapse ≤ 12 months of first line therapy	4/47 (9)	0	NE	
Mental status changes	Primary refractory	5/123 (4)	0	NE	NE
	Relapse ≤ 12 months of first line therapy	5/47 (11)	0	NE	
Respiratory, thoracic and mediastinal disorders	Primary refractory	66/123 (54)	47/123 (38)	15.45 (2.42, 27.78), 0.0142	0.4426
	Relapse ≤ 12 months of first line therapy	29/47 (62)	25/45 (56)	6.15 (-14.94, 26.60), 0.5552	
Cough	Primary refractory	31/123 (25)	11/123 (9)	16.26 (6.32, 25.98), 0.0007	0.2674
	Relapse ≤ 12 months of first line therapy	11/47 (23)	7/45 (16)	7.85 (-10.13, 25.09), 0.3462	
Hypoxia	Primary refractory	28/123 (23)	9/123 (7)	15.45 (5.99, 24.82), 0.0006	0.5720
	Relapse ≤ 12 months of first line therapy	9/47 (19)	4/45 (9)	10.26 (-6.04, 26.03), 0.1516	
Pleural effusion	Primary refractory	9/123 (7)	1/123 (1)	NE	NE
	Relapse ≤ 12 months of first line therapy	2/47 (4)	2/45 (4)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:02

Table 14.3.1.1.12.1. Subject Incidence of TEAEs by SOC and Preferred Term by Response to First-line Therapy Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Hiccups	Primary refractory	4/123 (3)	15/123 (12)	-8.94 (-16.69, -1.62), 0.0083	0.6675
	Relapse ≤ 12 months of first line therapy	1/47 (2)	6/45 (13)	-11.21 (-25.50, 1.94), 0.0433	
Vascular disorders	Primary refractory	64/123 (52)	41/123 (33)	18.70 (5.76, 30.81), 0.0031	0.3409
	Relapse ≤ 12 months of first line therapy	30/47 (64)	15/45 (33)	30.50 (8.53, 48.88), 0.0036	
Hypotension	Primary refractory	50/123 (41)	19/123 (15)	25.20 (13.50, 36.04), <.0001	0.2676
	Relapse ≤ 12 months of first line therapy	25/47 (53)	6/45 (13)	39.86 (19.26, 56.27), <.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:02

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Table 14.3.1.1.12.2. Subject Incidence of TEAEs by SOC and Preferred Term by Age (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders					
Neutropenia	Age < 65	53/121 (44)	16/113 (14)	29.64 (17.59, 40.50), <.0001	0.4838
	Age ≥ 65	22/49 (45)	13/55 (24)	21.26 (1.71, 39.08), 0.0164	
Anaemia	Age < 65	49/121 (40)	59/113 (52)	-11.72 (-24.54, 1.64), 0.0542	0.8019
	Age ≥ 65	22/49 (45)	32/55 (58)	-13.28 (-32.29, 7.08), 0.3604	
Thrombocytopenia	Age < 65	12/121 (10)	30/113 (27)	-16.63 (-26.93, -6.18), 0.0002	0.0158
	Age ≥ 65	10/49 (20)	11/55 (20)	0.41 (-16.10, 17.42), 0.9401	
Febrile neutropenia	Age < 65	5/121 (4)	34/113 (30)	-25.96 (-35.77, -16.05), <.0001	0.8632
	Age ≥ 65	1/49 (2)	12/55 (22)	-19.78 (-33.46, -5.79), 0.0065	
Cardiac disorders	Age < 65	58/121 (48)	25/113 (22)	25.81 (13.03, 37.42), <.0001	0.4417
	Age ≥ 65	26/49 (53)	11/55 (20)	33.06 (13.23, 49.91), 0.0006	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:02

Table 14.3.1.1.12.2. Subject Incidence of TEAEs by SOC and Preferred Term by Age (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Sinus tachycardia	Age < 65	40/121 (33)	13/113 (12)	21.55 (10.36, 32.03), <.0001	0.3713
	Age ≥ 65	18/49 (37)	4/55 (7)	29.46 (12.37, 45.26), 0.0006	
Ear and labyrinth disorders	Age < 65	3/121 (2)	14/113 (12)	-9.91 (-17.97, -2.60), 0.0135	0.9540
	Age ≥ 65	1/49 (2)	4/55 (7)	-5.23 (-16.55, 6.09), 0.4395	
Tinnitus	Age < 65	0	10/113 (9)	-8.85 (-16.06, -3.10), 0.0027	0.9997
	Age ≥ 65	0	1/55 (2)	-1.82 (-10.99, 7.40), 0.5351	
Gastrointestinal disorders					
Nausea	Age < 65	46/121 (38)	79/113 (70)	-31.89 (-43.65, -18.62), <.0001	0.1524
	Age ≥ 65	23/49 (47)	37/55 (67)	-20.33 (-38.69, -0.01), 0.0824	
Constipation	Age < 65	25/121 (21)	37/113 (33)	-12.08 (-23.70, -0.15), 0.0277	0.7531
	Age ≥ 65	9/49 (18)	21/55 (38)	-19.81 (-36.62, -0.97), 0.0863	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:02

Table 14.3.1.1.12.2. Subject Incidence of TEAEs by SOC and Preferred Term by Age (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Vomiting	Age < 65	28/121 (23)	37/113 (33)	-9.60 (-21.43, 2.47), 0.0742	0.1753
	Age ≥ 65	5/49 (10)	18/55 (33)	-22.52 (-38.00, -5.19), 0.0046	
Dyspepsia	Age < 65	5/121 (4)	8/113 (7)	NE	NE
	Age ≥ 65	0	6/55 (11)	NE	
Stomatitis	Age < 65	4/121 (3)	21/113 (19)	-15.28 (-24.21, -6.83), 0.0005	0.6912
	Age ≥ 65	1/49 (2)	8/55 (15)	-12.50 (-25.32, 0.22), 0.0244	
General disorders and administration site conditions	Age < 65	113/121 (93)	83/113 (73)	19.94 (9.95, 29.86), 0.0002	0.4386
	Age ≥ 65	47/49 (96)	42/55 (76)	19.55 (4.66, 33.66), 0.0042	
Pyrexia	Age < 65	111/121 (92)	29/113 (26)	66.07 (54.62, 74.62), <.0001	0.1876
	Age ≥ 65	47/49 (96)	14/55 (25)	70.46 (52.77, 81.37), <.0001	
Chills	Age < 65	29/121 (24)	10/113 (9)	15.12 (5.01, 24.88), 0.0017	0.2275
	Age ≥ 65	18/49 (37)	4/55 (7)	29.46 (12.37, 45.26), 0.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:02

Table 14.3.1.1.12.2. Subject Incidence of TEAEs by SOC and Preferred Term by Age (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Mucosal inflammation	Age < 65	1/121 (1)	12/113 (11)	-9.79 (-17.39, -3.33), 0.0002	0.9936
	Age ≥ 65	0	4/55 (7)	-7.27 (-18.43, 3.03), 0.0945	
Hepatobiliary disorders	Age < 65	7/121 (6)	3/113 (3)	NE	NE
	Age ≥ 65	8/49 (16)	0	NE	
Hypertransaminasaemia	Age < 65	3/121 (2)	1/113 (1)	NE	NE
	Age ≥ 65	8/49 (16)	0	NE	
Immune system disorders	Age < 65	11/121 (9)	1/113 (1)	8.21 (1.90, 15.21), 0.0036	0.6406
	Age ≥ 65	10/49 (20)	2/55 (4)	16.77 (2.87, 31.44), 0.0110	
Hypogammaglobulinaemia	Age < 65	9/121 (7)	0	7.44 (1.87, 14.04), 0.0046	0.9937
	Age ≥ 65	10/49 (20)	1/55 (2)	18.59 (5.25, 33.05), 0.0023	
Infections and infestations	Age < 65	49/121 (40)	34/113 (30)	10.41 (-2.45, 22.74), 0.1396	0.1270
	Age ≥ 65	32/49 (65)	21/55 (38)	27.12 (6.52, 44.87), 0.0030	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:02

Table 14.3.1.1.12.2. Subject Incidence of TEAEs by SOC and Preferred Term by Age (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Oral candidiasis	Age < 65	5/121 (4)	2/113 (2)	NE	NE
	Age ≥ 65	9/49 (18)	3/55 (5)	NE	
Injury, poisoning and procedural complications	Age < 65	10/121 (8)	23/113 (20)	-12.09 (-21.78, -2.51), 0.0191	0.7812
	Age ≥ 65	6/49 (12)	10/55 (18)	-5.94 (-20.93, 9.87), 0.0840	
Infusion related reaction	Age < 65	1/121 (1)	11/113 (10)	-8.91 (-16.34, -2.61), 0.0029	0.9935
	Age ≥ 65	0	2/55 (4)	-3.64 (-13.61, 5.90), 0.1977	
Investigations					
Alanine aminotransferase increased	Age < 65	21/121 (17)	12/113 (11)	6.74 (-2.94, 16.21), 0.1274	0.4371
	Age ≥ 65	10/49 (20)	4/55 (7)	13.14 (-1.64, 28.31), 0.0481	
Platelet count decreased	Age < 65	18/121 (15)	38/113 (34)	-18.75 (-29.84, -7.20), 0.0004	0.7428
	Age ≥ 65	12/49 (24)	26/55 (47)	-22.78 (-40.23, -2.89), 0.0223	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:02

Table 14.3.1.1.12.2. Subject Incidence of TEAEs by SOC and Preferred Term by Age (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
C-reactive protein increased	Age < 65	10/121 (8)	3/113 (3)	5.61 (-1.18, 12.67), 0.0615	0.5117
	Age ≥ 65	5/49 (10)	1/55 (2)	8.39 (-2.79, 21.31), 0.0328	
Serum ferritin increased	Age < 65	11/121 (9)	0	9.09 (3.19, 16.04), 0.0016	1.0000
	Age ≥ 65	4/49 (8)	0	8.16 (-1.66, 20.48), 0.0087	
Weight increased	Age < 65	1/121 (1)	9/113 (8)	NE	NE
	Age ≥ 65	0	3/55 (5)	NE	
Metabolism and nutrition disorders	Age < 65	74/121 (61)	58/113 (51)	9.83 (-3.44, 22.67), 0.0835	0.4849
	Age ≥ 65	39/49 (80)	35/55 (64)	15.96 (-2.90, 33.08), 0.0319	
Hypophosphataemia	Age < 65	25/121 (21)	21/113 (19)	2.08 (-8.81, 12.76), 0.5467	0.0524
	Age ≥ 65	20/49 (41)	8/55 (15)	26.27 (7.76, 43.03), 0.0045	
Hyponatraemia	Age < 65	13/121 (11)	7/113 (6)	4.55 (-3.54, 12.59), 0.1086	0.2108
	Age ≥ 65	8/49 (16)	1/55 (2)	14.51 (1.98, 28.49), 0.0112	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:02

Table 14.3.1.1.12.2. Subject Incidence of TEAEs by SOC and Preferred Term by Age (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Hypomagnesaemia	Age < 65	13/121 (11)	21/113 (19)	-7.84 (-17.67, 1.88), 0.0952	0.9647
	Age ≥ 65	7/49 (14)	13/55 (24)	-9.35 (-25.15, 7.50), 0.2903	
Nervous system disorders	Age < 65	90/121 (74)	60/113 (53)	21.28 (8.37, 33.33), 0.0015	0.4612
	Age ≥ 65	38/49 (78)	27/55 (49)	28.46 (8.49, 45.43), 0.0040	
Headache	Age < 65	56/121 (46)	29/113 (26)	20.62 (7.71, 32.57), 0.0023	0.2225
	Age ≥ 65	14/49 (29)	14/55 (25)	3.12 (-14.89, 21.27), 0.7141	
Tremor	Age < 65	32/121 (26)	0	26.45 (17.98, 35.38), <.0001	0.9882
	Age ≥ 65	12/49 (24)	1/55 (2)	22.67 (8.59, 37.46), 0.0010	
Aphasia	Age < 65	26/121 (21)	0	21.49 (13.61, 30.07), <.0001	1.0000
	Age ≥ 65	10/49 (20)	0	20.41 (7.76, 34.76), 0.0005	
Dizziness	Age < 65	28/121 (23)	15/113 (13)	9.87 (-0.74, 20.12), 0.0581	0.8296
	Age ≥ 65	8/49 (16)	6/55 (11)	5.42 (-9.32, 20.70), 0.3534	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:02

Table 14.3.1.1.12.2. Subject Incidence of TEAEs by SOC and Preferred Term by Age (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Encephalopathy	Age < 65	17/121 (14)	1/113 (1)	13.16 (6.02, 20.98), <.0001	0.7458
	Age ≥ 65	12/49 (24)	1/55 (2)	22.67 (8.59, 37.46), 0.0053	
Somnolence	Age < 65	14/121 (12)	0	11.57 (5.21, 18.97), 0.0003	0.9907
	Age ≥ 65	5/49 (10)	2/55 (4)	6.57 (-5.27, 19.72), 0.2142	
Dysgeusia	Age < 65	3/121 (2)	9/113 (8)	NE	NE
	Age ≥ 65	1/49 (2)	5/55 (9)	NE	
Peripheral sensory neuropathy	Age < 65	0	8/113 (7)	NE	NE
	Age ≥ 65	0	2/55 (4)	NE	
Psychiatric disorders	Age < 65	46/121 (38)	27/113 (24)	14.12 (1.64, 25.95), 0.0331	0.3014
	Age ≥ 65	25/49 (51)	13/55 (24)	27.38 (7.44, 44.86), 0.0142	
Confusional state	Age < 65	21/121 (17)	2/113 (2)	15.59 (7.66, 23.90), <.0001	0.8884
	Age ≥ 65	19/49 (39)	2/55 (4)	35.14 (18.57, 50.42), <.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:02

Table 14.3.1.1.12.2. Subject Incidence of TEAEs by SOC and Preferred Term by Age (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Agitation	Age < 65	7/121 (6)	1/113 (1)	NE	NE
	Age ≥ 65	3/49 (6)	1/55 (2)	NE	
Mental status changes	Age < 65	6/121 (5)	0	NE	NE
	Age ≥ 65	4/49 (8)	0	NE	
Respiratory, thoracic and mediastinal disorders	Age < 65	62/121 (51)	46/113 (41)	10.53 (-2.81, 23.37), 0.1109	0.3831
	Age ≥ 65	33/49 (67)	26/55 (47)	20.07 (-0.31, 38.27), 0.0351	
Cough	Age < 65	24/121 (20)	9/113 (8)	11.87 (2.32, 21.22), 0.0108	0.9714
	Age ≥ 65	18/49 (37)	9/55 (16)	20.37 (2.07, 37.46), 0.0382	
Hypoxia	Age < 65	22/121 (18)	7/113 (6)	11.99 (2.93, 20.95), 0.0092	0.8362
	Age ≥ 65	15/49 (31)	6/55 (11)	19.70 (2.77, 35.98), 0.0229	
Pleural effusion	Age < 65	7/121 (6)	2/113 (2)	NE	NE
	Age ≥ 65	4/49 (8)	1/55 (2)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:02

Table 14.3.1.1.12.2. Subject Incidence of TEAEs by SOC and Preferred Term by Age (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Hiccups	Age < 65	5/121 (4)	16/113 (14)	-10.03 (-18.55, -2.02), 0.0083	0.9895
	Age ≥ 65	0	5/55 (9)	-9.09 (-20.71, 1.61), 0.0485	
Vascular disorders	Age < 65	68/121 (56)	40/113 (35)	20.80 (7.42, 33.19), 0.0043	0.5181
	Age ≥ 65	26/49 (53)	16/55 (29)	23.97 (3.72, 41.94), 0.0193	
Hypotension	Age < 65	52/121 (43)	17/113 (15)	27.93 (15.83, 38.90), <.0001	0.4495
	Age ≥ 65	23/49 (47)	8/55 (15)	32.39 (13.39, 48.90), 0.0002	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:02

Table 14.3.1.1.12.3. Subject Incidence of TEAEs by SOC and Preferred Term by Second-line Age-adjusted IPI Score Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders					
Neutropenia	Second-line age-adjusted IPI score 0 - 1	45/97 (46)	19/93 (20)	25.96 (11.84, 38.69), 0.0002	0.5457
	Second-line age-adjusted IPI score 2 - 3	30/73 (41)	10/75 (13)	27.76 (12.57, 41.48), 0.0002	
Anaemia	Second-line age-adjusted IPI score 0 - 1	36/97 (37)	51/93 (55)	-17.73 (-31.63, -2.82), 0.0110	0.2609
	Second-line age-adjusted IPI score 2 - 3	35/73 (48)	40/75 (53)	-5.39 (-21.78, 11.40), 0.4836	
Thrombocytopenia	Second-line age-adjusted IPI score 0 - 1	13/97 (13)	28/93 (30)	-16.71 (-28.71, -4.23), 0.0054	0.3138
	Second-line age-adjusted IPI score 2 - 3	9/73 (12)	13/75 (17)	-5.00 (-17.50, 7.68), 0.3607	
Febrile neutropenia	Second-line age-adjusted IPI score 0 - 1	4/97 (4)	27/93 (29)	-24.91 (-35.75, -13.92), <.0001	0.8000
	Second-line age-adjusted IPI score 2 - 3	2/73 (3)	19/75 (25)	-22.59 (-34.40, -10.73), <.0001	
Cardiac disorders	Second-line age-adjusted IPI score 0 - 1	45/97 (46)	26/93 (28)	18.43 (3.93, 31.89), 0.0099	0.0174
	Second-line age-adjusted IPI score 2 - 3	39/73 (53)	10/75 (13)	40.09 (24.30, 53.37), <.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.3. Subject Incidence of TEAEs by SOC and Preferred Term by Second-line Age-adjusted IPI Score Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Sinus tachycardia	Second-line age-adjusted IPI score 0 - 1	31/97 (32)	8/93 (9)	23.36 (11.31, 34.66), <.0001	0.8204
	Second-line age-adjusted IPI score 2 - 3	27/73 (37)	9/75 (12)	24.99 (10.25, 38.55), 0.0004	
Ear and labyrinth disorders	Second-line age-adjusted IPI score 0 - 1	2/97 (2)	7/93 (8)	-5.47 (-13.52, 1.77), 0.0744	0.7075
	Second-line age-adjusted IPI score 2 - 3	2/73 (3)	11/75 (15)	-11.93 (-22.65, -1.67), 0.0115	
Tinnitus	Second-line age-adjusted IPI score 0 - 1	0	4/93 (4)	NE	NE
	Second-line age-adjusted IPI score 2 - 3	0	7/75 (9)	NE	
Gastrointestinal disorders					
Nausea	Second-line age-adjusted IPI score 0 - 1	42/97 (43)	66/93 (71)	-27.67 (-40.86, -12.88), 0.0001	0.8529
	Second-line age-adjusted IPI score 2 - 3	27/73 (37)	50/75 (67)	-29.68 (-44.52, -12.65), 0.0002	
Constipation	Second-line age-adjusted IPI score 0 - 1	19/97 (20)	38/93 (41)	-21.27 (-34.11, -7.49), 0.0013	0.1682
	Second-line age-adjusted IPI score 2 - 3	15/73 (21)	20/75 (27)	-6.12 (-20.40, 8.55), 0.3914	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.3. Subject Incidence of TEAEs by SOC and Preferred Term by Second-line Age-adjusted IPI Score Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Vomiting	Second-line age-adjusted IPI score 0 - 1	22/97 (23)	33/93 (35)	-12.80 (-25.92, 0.84), 0.0526	0.6710
	Second-line age-adjusted IPI score 2 - 3	11/73 (15)	22/75 (29)	-14.26 (-27.96, 0.17), 0.0373	
Dyspepsia	Second-line age-adjusted IPI score 0 - 1	2/97 (2)	7/93 (8)	NE	NE
	Second-line age-adjusted IPI score 2 - 3	3/73 (4)	7/75 (9)	NE	
Stomatitis	Second-line age-adjusted IPI score 0 - 1	2/97 (2)	13/93 (14)	-11.92 (-21.18, -3.47), 0.0028	0.8822
	Second-line age-adjusted IPI score 2 - 3	3/73 (4)	16/75 (21)	-17.22 (-28.90, -5.54), 0.0015	
General disorders and administration site conditions	Second-line age-adjusted IPI score 0 - 1	92/97 (95)	75/93 (81)	14.20 (4.15, 24.50), 0.0020	0.5707
	Second-line age-adjusted IPI score 2 - 3	68/73 (93)	50/75 (67)	26.48 (12.82, 39.17), <.0001	
Pyrexia	Second-line age-adjusted IPI score 0 - 1	91/97 (94)	28/93 (30)	63.71 (50.89, 73.28), <.0001	0.7716
	Second-line age-adjusted IPI score 2 - 3	67/73 (92)	15/75 (20)	71.78 (57.18, 81.14), <.0001	
Chills	Second-line age-adjusted IPI score 0 - 1	26/97 (27)	6/93 (6)	20.35 (9.13, 31.16), 0.0002	0.4673
	Second-line age-adjusted IPI score 2 - 3	21/73 (29)	8/75 (11)	18.10 (4.32, 31.31), 0.0064	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.3. Subject Incidence of TEAEs by SOC and Preferred Term by Second-line Age-adjusted IPI Score Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Mucosal inflammation	Second-line age-adjusted IPI score 0 - 1	1/97 (1)	15/93 (16)	-15.10 (-24.55, -6.63), 0.0002	0.9941
	Second-line age-adjusted IPI score 2 - 3	0	1/75 (1)	-1.33 (-8.21, 5.02), 0.3302	
Hepatobiliary disorders	Second-line age-adjusted IPI score 0 - 1	8/97 (8)	1/93 (1)	NE	NE
	Second-line age-adjusted IPI score 2 - 3	7/73 (10)	2/75 (3)	NE	
Hypertransaminasaemia	Second-line age-adjusted IPI score 0 - 1	5/97 (5)	0	NE	NE
	Second-line age-adjusted IPI score 2 - 3	6/73 (8)	1/75 (1)	NE	
Immune system disorders	Second-line age-adjusted IPI score 0 - 1	12/97 (12)	1/93 (1)	11.30 (3.41, 19.98), 0.0020	0.4743
	Second-line age-adjusted IPI score 2 - 3	9/73 (12)	2/75 (3)	9.66 (-0.07, 20.18), 0.0280	
Hypogammaglobulinaemia	Second-line age-adjusted IPI score 0 - 1	12/97 (12)	1/93 (1)	11.30 (3.41, 19.98), 0.0020	0.9901
	Second-line age-adjusted IPI score 2 - 3	7/73 (10)	0	9.59 (1.52, 19.33), 0.0073	
Infections and infestations	Second-line age-adjusted IPI score 0 - 1	50/97 (52)	30/93 (32)	19.29 (4.50, 32.96), 0.0072	0.3476
	Second-line age-adjusted IPI score 2 - 3	31/73 (42)	25/75 (33)	9.13 (-7.31, 24.97), 0.2646	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.3. Subject Incidence of TEAEs by SOC and Preferred Term by Second-line Age-adjusted IPI Score Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Oral candidiasis	Second-line age-adjusted IPI score 0 - 1	9/97 (9)	3/93 (3)	NE	NE
	Second-line age-adjusted IPI score 2 - 3	5/73 (7)	2/75 (3)	NE	
Injury, poisoning and procedural complications	Second-line age-adjusted IPI score 0 - 1	4/97 (4)	20/93 (22)	-17.38 (-27.74, -7.27), 0.0004	0.0113
	Second-line age-adjusted IPI score 2 - 3	12/73 (16)	13/75 (17)	-0.89 (-13.97, 12.30), 0.8784	
Infusion related reaction	Second-line age-adjusted IPI score 0 - 1	0	9/93 (10)	NE	NE
	Second-line age-adjusted IPI score 2 - 3	1/73 (1)	4/75 (5)	NE	
Investigations					
Alanine aminotransferase increased	Second-line age-adjusted IPI score 0 - 1	14/97 (14)	10/93 (11)	3.68 (-6.79, 14.02), 0.4532	0.1732
	Second-line age-adjusted IPI score 2 - 3	17/73 (23)	6/75 (8)	15.29 (2.57, 27.82), 0.0102	
Platelet count decreased	Second-line age-adjusted IPI score 0 - 1	16/97 (16)	37/93 (40)	-23.29 (-35.80, -9.81), 0.0003	0.5018
	Second-line age-adjusted IPI score 2 - 3	14/73 (19)	27/75 (36)	-16.82 (-31.18, -1.42), 0.0229	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.3. Subject Incidence of TEAEs by SOC and Preferred Term by Second-line Age-adjusted IPI Score Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
C-reactive protein increased	Second-line age-adjusted IPI score 0 - 1	12/97 (12)	2/93 (2)	10.22 (1.95, 19.02), 0.0062	0.2336
	Second-line age-adjusted IPI score 2 - 3	3/73 (4)	2/75 (3)	1.44 (-6.66, 9.96), 0.6169	
Serum ferritin increased	Second-line age-adjusted IPI score 0 - 1	12/97 (12)	0	12.37 (4.95, 20.99), 0.0005	0.9997
	Second-line age-adjusted IPI score 2 - 3	3/73 (4)	0	4.11 (-2.68, 12.34), 0.0877	
Weight increased	Second-line age-adjusted IPI score 0 - 1	0	7/93 (8)	NE	NE
	Second-line age-adjusted IPI score 2 - 3	1/73 (1)	5/75 (7)	NE	
Metabolism and nutrition disorders	Second-line age-adjusted IPI score 0 - 1	61/97 (63)	49/93 (53)	10.20 (-4.51, 24.36), 0.1459	0.8110
	Second-line age-adjusted IPI score 2 - 3	52/73 (71)	44/75 (59)	12.57 (-3.72, 27.96), 0.1218	
Hypophosphataemia	Second-line age-adjusted IPI score 0 - 1	19/97 (20)	13/93 (14)	5.61 (-5.93, 16.91), 0.3118	0.5519
	Second-line age-adjusted IPI score 2 - 3	26/73 (36)	16/75 (21)	14.28 (-1.21, 28.99), 0.0544	
Hyponatraemia	Second-line age-adjusted IPI score 0 - 1	10/97 (10)	4/93 (4)	6.01 (-2.55, 14.76), 0.1040	0.8190
	Second-line age-adjusted IPI score 2 - 3	11/73 (15)	4/75 (5)	9.74 (-1.22, 21.05), 0.0471	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.3. Subject Incidence of TEAEs by SOC and Preferred Term by Second-line Age-adjusted IPI Score Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Hypomagnesaemia	Second-line age-adjusted IPI score 0 - 1	13/97 (13)	19/93 (20)	-7.03 (-18.48, 4.45), 0.1977	0.5758
	Second-line age-adjusted IPI score 2 - 3	7/73 (10)	15/75 (20)	-10.41 (-22.76, 2.21), 0.0733	
Nervous system disorders	Second-line age-adjusted IPI score 0 - 1	70/97 (72)	50/93 (54)	18.40 (3.93, 31.92), 0.0088	0.2357
	Second-line age-adjusted IPI score 2 - 3	58/73 (79)	37/75 (49)	30.12 (13.80, 44.37), 0.0002	
Headache	Second-line age-adjusted IPI score 0 - 1	44/97 (45)	25/93 (27)	18.48 (4.06, 31.86), 0.0076	0.5863
	Second-line age-adjusted IPI score 2 - 3	26/73 (36)	18/75 (24)	11.62 (-4.03, 26.61), 0.1157	
Tremor	Second-line age-adjusted IPI score 0 - 1	22/97 (23)	1/93 (1)	21.61 (12.13, 31.50), <.0001	0.9908
	Second-line age-adjusted IPI score 2 - 3	22/73 (30)	0	30.14 (18.52, 42.15), <.0001	
Aphasia	Second-line age-adjusted IPI score 0 - 1	21/97 (22)	0	21.65 (12.70, 31.40), <.0001	1.0000
	Second-line age-adjusted IPI score 2 - 3	15/73 (21)	0	20.55 (10.32, 31.93), <.0001	
Dizziness	Second-line age-adjusted IPI score 0 - 1	18/97 (19)	13/93 (14)	4.58 (-6.84, 15.79), 0.4155	0.2729
	Second-line age-adjusted IPI score 2 - 3	18/73 (25)	8/75 (11)	13.99 (0.68, 26.99), 0.0289	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.3. Subject Incidence of TEAEs by SOC and Preferred Term by Second-line Age-adjusted IPI Score Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Encephalopathy	Second-line age-adjusted IPI score 0 - 1	8/97 (8)	1/93 (1)	7.17 (0.06, 15.06), 0.0214	0.3880
	Second-line age-adjusted IPI score 2 - 3	21/73 (29)	1/75 (1)	27.43 (15.54, 39.46), <.0001	
Somnolence	Second-line age-adjusted IPI score 0 - 1	10/97 (10)	1/93 (1)	9.23 (1.73, 17.55), 0.0072	0.9922
	Second-line age-adjusted IPI score 2 - 3	9/73 (12)	1/75 (1)	11.00 (1.74, 21.35), 0.0089	
Dysgeusia	Second-line age-adjusted IPI score 0 - 1	2/97 (2)	7/93 (8)	NE	NE
	Second-line age-adjusted IPI score 2 - 3	2/73 (3)	7/75 (9)	NE	
Peripheral sensory neuropathy	Second-line age-adjusted IPI score 0 - 1	0	3/93 (3)	NE	NE
	Second-line age-adjusted IPI score 2 - 3	0	7/75 (9)	NE	
Psychiatric disorders	Second-line age-adjusted IPI score 0 - 1	35/97 (36)	27/93 (29)	7.05 (-6.97, 20.65), 0.3061	0.0136
	Second-line age-adjusted IPI score 2 - 3	36/73 (49)	13/75 (17)	31.98 (15.96, 45.98), <.0001	
Confusional state	Second-line age-adjusted IPI score 0 - 1	16/97 (16)	3/93 (3)	13.27 (4.03, 22.79), 0.0025	0.1379
	Second-line age-adjusted IPI score 2 - 3	24/73 (33)	1/75 (1)	31.54 (19.17, 43.71), <.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.3. Subject Incidence of TEAEs by SOC and Preferred Term by Second-line Age-adjusted IPI Score Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Agitation	Second-line age-adjusted IPI score 0 - 1	6/97 (6)	2/93 (2)	NE	NE
	Second-line age-adjusted IPI score 2 - 3	4/73 (5)	0	NE	
Mental status changes	Second-line age-adjusted IPI score 0 - 1	4/97 (4)	0	NE	NE
	Second-line age-adjusted IPI score 2 - 3	6/73 (8)	0	NE	
Respiratory, thoracic and mediastinal disorders	Second-line age-adjusted IPI score 0 - 1	51/97 (53)	38/93 (41)	11.72 (-3.16, 25.91), 0.1095	0.7920
	Second-line age-adjusted IPI score 2 - 3	44/73 (60)	34/75 (45)	14.94 (-2.04, 30.81), 0.0775	
Cough	Second-line age-adjusted IPI score 0 - 1	19/97 (20)	14/93 (15)	4.53 (-7.13, 15.97), 0.4250	0.0088
	Second-line age-adjusted IPI score 2 - 3	23/73 (32)	4/75 (5)	26.17 (12.99, 38.76), <.0001	
Hypoxia	Second-line age-adjusted IPI score 0 - 1	20/97 (21)	8/93 (9)	12.02 (1.11, 22.69), 0.0209	0.5163
	Second-line age-adjusted IPI score 2 - 3	17/73 (23)	5/75 (7)	16.62 (4.15, 28.97), 0.0036	
Pleural effusion	Second-line age-adjusted IPI score 0 - 1	2/97 (2)	2/93 (2)	NE	NE
	Second-line age-adjusted IPI score 2 - 3	9/73 (12)	1/75 (1)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.3. Subject Incidence of TEAEs by SOC and Preferred Term by Second-line Age-adjusted IPI Score Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Hiccups	Second-line age-adjusted IPI score 0 - 1	5/97 (5)	10/93 (11)	-5.60 (-14.75, 3.14), 0.1473	0.9911
	Second-line age-adjusted IPI score 2 - 3	0	11/75 (15)	-14.67 (-25.15, -5.47), 0.0007	
Vascular disorders	Second-line age-adjusted IPI score 0 - 1	54/97 (56)	32/93 (34)	21.26 (6.36, 34.92), 0.0036	0.8507
	Second-line age-adjusted IPI score 2 - 3	40/73 (55)	24/75 (32)	22.79 (5.87, 38.08), 0.0056	
Hypotension	Second-line age-adjusted IPI score 0 - 1	43/97 (44)	15/93 (16)	28.20 (14.50, 40.50), <.0001	0.7057
	Second-line age-adjusted IPI score 2 - 3	32/73 (44)	10/75 (13)	30.50 (15.14, 44.17), <.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.4. Subject Incidence of TEAEs by SOC and Preferred Term by Sex (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders					
Neutropenia	Male	39/106 (37)	16/120 (13)	23.46 (11.61, 34.74), <.0001	0.8324
	Female	36/64 (56)	13/48 (27)	29.17 (9.36, 45.80), 0.0014	
Anaemia	Male	40/106 (38)	60/120 (50)	-12.26 (-25.20, 1.32), 0.0543	0.7577
	Female	31/64 (48)	31/48 (65)	-16.15 (-34.11, 3.66), 0.0862	
Thrombocytopenia	Male	10/106 (9)	32/120 (27)	-17.23 (-27.31, -6.56), 0.0006	0.0508
	Female	12/64 (19)	9/48 (19)	0.00 (-16.57, 15.27), 0.5487	
Febrile neutropenia	Male	2/106 (2)	28/120 (23)	-21.45 (-30.35, -12.57), <.0001	0.6379
	Female	4/64 (6)	18/48 (38)	-31.25 (-46.99, -14.85), <.0001	
Cardiac disorders	Male	54/106 (51)	23/120 (19)	31.78 (18.83, 43.45), <.0001	0.2454
	Female	30/64 (47)	13/48 (27)	19.79 (0.31, 36.89), 0.0270	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.4. Subject Incidence of TEAEs by SOC and Preferred Term by Sex (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Sinus tachycardia	Male	35/106 (33)	11/120 (9)	23.85 (12.73, 34.63), <.0001	0.7267
	Female	23/64 (36)	6/48 (13)	23.44 (5.86, 38.38), 0.0043	
Ear and labyrinth disorders	Male	1/106 (1)	12/120 (10)	-9.06 (-16.28, -2.36), 0.0034	0.2531
	Female	3/64 (5)	6/48 (13)	-7.81 (-21.69, 4.00), 0.1385	
Tinnitus	Male	0	8/120 (7)	NE	NE
	Female	0	3/48 (6)	NE	
Gastrointestinal disorders					
Nausea	Male	40/106 (38)	80/120 (67)	-28.93 (-41.15, -15.31), <.0001	0.8710
	Female	29/64 (45)	36/48 (75)	-29.69 (-46.12, -10.01), 0.0015	
Constipation	Male	19/106 (18)	39/120 (33)	-14.58 (-25.89, -2.54), 0.0120	0.9188
	Female	15/64 (23)	19/48 (40)	-16.15 (-33.91, 2.26), 0.0901	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.4. Subject Incidence of TEAEs by SOC and Preferred Term by Sex (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Vomiting	Male	18/106 (17)	33/120 (28)	-10.52 (-21.55, 1.08), 0.0489	0.5108
	Female	15/64 (23)	22/48 (46)	-22.40 (-39.93, -3.45), 0.0114	
Dyspepsia	Male	2/106 (2)	12/120 (10)	-8.11 (-15.44, -1.06), 0.0133	0.1219
	Female	3/64 (5)	2/48 (4)	0.52 (-11.26, 10.41), 0.8151	
Stomatitis	Male	2/106 (2)	17/120 (14)	-12.28 (-20.26, -4.58), 0.0012	0.8723
	Female	3/64 (5)	12/48 (25)	-20.31 (-35.61, -6.01), 0.0038	
General disorders and administration site conditions	Male	98/106 (92)	86/120 (72)	20.79 (10.25, 30.70), <.0001	0.5991
	Female	62/64 (97)	39/48 (81)	15.63 (2.89, 30.21), 0.0048	
Pyrexia	Male	97/106 (92)	29/120 (24)	67.34 (55.80, 75.67), <.0001	0.5263
	Female	61/64 (95)	14/48 (29)	66.15 (48.43, 78.41), <.0001	
Chills	Male	32/106 (30)	10/120 (8)	21.86 (11.07, 32.45), <.0001	0.6047
	Female	15/64 (23)	4/48 (8)	15.10 (-0.51, 28.85), 0.0514	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.4. Subject Incidence of TEAEs by SOC and Preferred Term by Sex (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Mucosal inflammation	Male	1/106 (1)	11/120 (9)	-8.22 (-15.28, -1.68), 0.0052	0.9915
	Female	0	5/48 (10)	-10.42 (-23.44, -0.81), 0.0043	
Hepatobiliary disorders	Male	11/106 (10)	3/120 (3)	7.88 (0.79, 15.91), 0.0146	0.9916
	Female	4/64 (6)	0	6.25 (-3.90, 16.02), 0.0898	
Hypertransaminasaemia	Male	8/106 (8)	1/120 (1)	NE	NE
	Female	3/64 (5)	0	NE	
Immune system disorders	Male	12/106 (11)	2/120 (2)	9.65 (2.65, 17.76), 0.0021	0.9768
	Female	9/64 (14)	1/48 (2)	11.98 (-0.57, 23.61), 0.0375	
Hypogammaglobulinaemia	Male	11/106 (10)	0	10.38 (4.19, 18.19), 0.0002	0.9912
	Female	8/64 (13)	1/48 (2)	10.42 (-1.87, 21.79), 0.0605	
Infections and infestations	Male	47/106 (44)	36/120 (30)	14.34 (1.12, 27.02), 0.0355	0.9871
	Female	34/64 (53)	19/48 (40)	13.54 (-6.27, 31.86), 0.1697	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.4. Subject Incidence of TEAEs by SOC and Preferred Term by Sex (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Oral candidiasis	Male	7/106 (7)	1/120 (1)	NE	NE
	Female	7/64 (11)	4/48 (8)	NE	
Injury, poisoning and procedural complications	Male	11/106 (10)	17/120 (14)	-3.79 (-12.99, 5.75), 0.3266	0.0651
	Female	5/64 (8)	16/48 (33)	-25.52 (-41.47, -9.37), 0.0014	
Infusion related reaction	Male	0	6/120 (5)	NE	NE
	Female	1/64 (2)	7/48 (15)	NE	
Investigations					
Alanine aminotransferase increased	Male	23/106 (22)	11/120 (9)	12.53 (2.50, 22.74), 0.0105	0.2883
	Female	8/64 (13)	5/48 (10)	2.08 (-12.51, 15.04), 0.8576	
Platelet count decreased	Male	21/106 (20)	42/120 (35)	-15.19 (-26.75, -2.85), 0.0091	0.1458
	Female	9/64 (14)	22/48 (46)	-31.77 (-48.21, -13.52), 0.0002	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.4. Subject Incidence of TEAEs by SOC and Preferred Term by Sex (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
C-reactive protein increased	Male	11/106 (10)	3/120 (3)	7.88 (0.79, 15.91), 0.0170	0.8690
	Female	4/64 (6)	1/48 (2)	4.17 (-7.05, 14.13), 0.2373	
Serum ferritin increased	Male	11/106 (10)	0	10.38 (4.19, 18.19), 0.0003	0.9999
	Female	4/64 (6)	0	6.25 (-3.90, 16.02), 0.1021	
Weight increased	Male	0	10/120 (8)	-8.33 (-15.17, -2.39), 0.0024	0.9931
	Female	1/64 (2)	2/48 (4)	-2.60 (-13.96, 6.09), 0.5085	
Metabolism and nutrition disorders	Male	68/106 (64)	61/120 (51)	13.32 (-0.23, 26.16), 0.0299	0.4442
	Female	45/64 (70)	32/48 (67)	3.65 (-14.33, 22.07), 0.6117	
Hypophosphataemia	Male	27/106 (25)	16/120 (13)	12.14 (1.21, 23.06), 0.0247	0.2732
	Female	18/64 (28)	13/48 (27)	1.04 (-17.09, 18.17), 0.7435	
Hyponatraemia	Male	14/106 (13)	7/120 (6)	7.37 (-0.97, 16.28), 0.0690	0.3869
	Female	7/64 (11)	1/48 (2)	8.85 (-3.17, 19.94), 0.0596	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.4. Subject Incidence of TEAEs by SOC and Preferred Term by Sex (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Hypomagnesaemia	Male	8/106 (8)	17/120 (14)	-6.62 (-15.41, 2.44), 0.1007	0.9113
	Female	12/64 (19)	17/48 (35)	-16.67 (-33.96, 0.99), 0.0826	
Nervous system disorders	Male	79/106 (75)	62/120 (52)	22.86 (9.63, 34.93), 0.0006	0.7589
	Female	49/64 (77)	25/48 (52)	24.48 (5.39, 41.90), 0.0115	
Headache	Male	43/106 (41)	32/120 (27)	13.90 (0.97, 26.37), 0.0296	0.5477
	Female	27/64 (42)	11/48 (23)	19.27 (0.24, 35.89), 0.0323	
Tremor	Male	32/106 (30)	0	30.19 (21.00, 39.99), <.0001	0.9878
	Female	12/64 (19)	1/48 (2)	16.67 (3.38, 28.92), 0.0100	
Aphasia	Male	21/106 (20)	0	19.81 (11.93, 28.91), <.0001	0.9999
	Female	15/64 (23)	0	23.44 (10.32, 35.98), 0.0002	
Dizziness	Male	23/106 (22)	11/120 (9)	12.53 (2.50, 22.74), 0.0088	0.0661
	Female	13/64 (20)	10/48 (21)	-0.52 (-17.46, 15.23), 0.6910	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.4. Subject Incidence of TEAEs by SOC and Preferred Term by Sex (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Encephalopathy	Male	16/106 (15)	0	15.09 (7.99, 23.66), <.0001	0.9893
	Female	13/64 (20)	2/48 (4)	16.15 (1.95, 28.88), 0.0099	
Somnolence	Male	9/106 (8)	1/120 (1)	7.66 (1.51, 15.14), 0.0070	0.8837
	Female	10/64 (16)	1/48 (2)	13.54 (0.74, 25.41), 0.0187	
Dysgeusia	Male	1/106 (1)	12/120 (10)	-9.06 (-16.28, -2.36), 0.0035	0.0741
	Female	3/64 (5)	2/48 (4)	0.52 (-11.26, 10.41), 0.8683	
Peripheral sensory neuropathy	Male	0	8/120 (7)	NE	NE
	Female	0	2/48 (4)	NE	
Psychiatric disorders	Male	41/106 (39)	24/120 (20)	18.68 (6.19, 30.61), 0.0031	0.6398
	Female	30/64 (47)	16/48 (33)	13.54 (-6.07, 31.45), 0.1700	
Confusional state	Male	28/106 (26)	2/120 (2)	24.75 (15.52, 34.46), <.0001	0.2377
	Female	12/64 (19)	2/48 (4)	14.58 (0.61, 27.16), 0.0227	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.4. Subject Incidence of TEAEs by SOC and Preferred Term by Sex (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Agitation	Male	6/106 (6)	1/120 (1)	NE	NE
	Female	4/64 (6)	1/48 (2)	NE	
Mental status changes	Male	4/106 (4)	0	NE	NE
	Female	6/64 (9)	0	NE	
Respiratory, thoracic and mediastinal disorders	Male	63/106 (59)	53/120 (44)	15.27 (1.59, 28.18), 0.0239	0.6884
	Female	32/64 (50)	19/48 (40)	10.42 (-9.29, 28.88), 0.3611	
Cough	Male	28/106 (26)	13/120 (11)	15.58 (4.84, 26.28), 0.0033	0.9190
	Female	14/64 (22)	5/48 (10)	11.46 (-4.37, 25.48), 0.0665	
Hypoxia	Male	24/106 (23)	8/120 (7)	15.97 (6.21, 25.97), 0.0008	0.4780
	Female	13/64 (20)	5/48 (10)	9.90 (-5.74, 23.78), 0.1433	
Pleural effusion	Male	5/106 (5)	3/120 (3)	NE	NE
	Female	6/64 (9)	0	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.4. Subject Incidence of TEAEs by SOC and Preferred Term by Sex (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Hiccups	Male	5/106 (5)	21/120 (18)	-12.78 (-21.54, -3.89), 0.0028	0.9996
	Female	0	0	NE	
Vascular disorders	Male	56/106 (53)	36/120 (30)	22.83 (9.35, 35.30), 0.0010	0.7048
	Female	38/64 (59)	20/48 (42)	17.71 (-2.18, 35.86), 0.0942	
Hypotension	Male	43/106 (41)	16/120 (13)	27.23 (15.15, 38.53), <.0001	0.9947
	Female	32/64 (50)	9/48 (19)	31.25 (12.13, 46.94), 0.0013	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.5. Subject Incidence of TEAEs by SOC and Preferred Term by Geographic Region (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders					
Neutropenia	North America	57/132 (43)	22/120 (18)	24.85 (12.95, 35.72), <.0001	0.6354
	Europe	14/32 (44)	6/44 (14)	30.11 (7.89, 50.14), 0.0072	
Anaemia	North America	57/132 (43)	68/120 (57)	-13.48 (-25.80, -0.58), 0.0267	0.8455
	Europe	10/32 (31)	21/44 (48)	-16.48 (-37.62, 7.64), 0.1763	
Thrombocytopenia	North America	18/132 (14)	27/120 (23)	-8.86 (-18.97, 1.20), 0.0691	0.3122
	Europe	3/32 (9)	12/44 (27)	-17.90 (-35.12, 2.64), 0.0294	
Febrile neutropenia	North America	5/132 (4)	34/120 (28)	-24.55 (-33.93, -15.24), <.0001	0.9887
	Europe	0	11/44 (25)	-25.00 (-40.65, -7.52), 0.0012	
Cardiac disorders	North America	71/132 (54)	29/120 (24)	29.62 (17.11, 40.83), <.0001	0.6972
	Europe	9/32 (28)	5/44 (11)	16.76 (-2.84, 36.91), 0.1115	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.5. Subject Incidence of TEAEs by SOC and Preferred Term by Geographic Region (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Sinus tachycardia	North America	53/132 (40)	14/120 (12)	28.48 (17.31, 38.65), <.0001	0.6347
	Europe	4/32 (13)	2/44 (5)	7.95 (-6.83, 25.78), 0.2086	
Ear and labyrinth disorders	North America	2/132 (2)	11/120 (9)	-7.65 (-14.77, -1.51), 0.0063	0.4112
	Europe	2/32 (6)	7/44 (16)	-9.66 (-25.30, 8.55), 0.2784	
Tinnitus	North America	0	7/120 (6)	NE	NE
	Europe	0	4/44 (9)	NE	
Gastrointestinal disorders					
Nausea	North America	57/132 (43)	85/120 (71)	-27.65 (-39.16, -14.91), <.0001	0.2659
	Europe	8/32 (25)	29/44 (66)	-40.91 (-59.32, -16.32), 0.0003	
Constipation	North America	31/132 (23)	40/120 (33)	-9.85 (-21.31, 1.82), 0.0895	0.0616
	Europe	3/32 (9)	17/44 (39)	-29.26 (-46.56, -7.47), 0.0107	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.5. Subject Incidence of TEAEs by SOC and Preferred Term by Geographic Region (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Vomiting	North America	25/132 (19)	41/120 (34)	-15.23 (-26.33, -3.77), 0.0076	0.6261
	Europe	7/32 (22)	13/44 (30)	-7.67 (-27.51, 14.60), 0.3741	
Dyspepsia	North America	5/132 (4)	12/120 (10)	-6.21 (-13.76, 0.72), 0.0509	0.9928
	Europe	0	2/44 (5)	-4.55 (-16.70, 9.32), 0.1573	
Stomatitis	North America	5/132 (4)	22/120 (18)	-14.55 (-23.21, -6.37), 0.0002	0.9910
	Europe	0	6/44 (14)	-13.64 (-28.05, 1.91), 0.0453	
General disorders and administration site conditions	North America	125/132 (95)	90/120 (75)	19.70 (10.46, 29.06), <.0001	0.4369
	Europe	29/32 (91)	32/44 (73)	17.90 (-2.64, 35.12), 0.0626	
Pyrexia	North America	125/132 (95)	28/120 (23)	71.36 (60.89, 78.99), <.0001	0.0345
	Europe	28/32 (88)	15/44 (34)	53.41 (29.81, 69.03), <.0001	
Chills	North America	38/132 (29)	13/120 (11)	17.95 (7.57, 27.79), 0.0005	0.1778
	Europe	8/32 (25)	1/44 (2)	22.73 (5.64, 41.60), 0.0033	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.5. Subject Incidence of TEAEs by SOC and Preferred Term by Geographic Region (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Mucosal inflammation	North America	1/132 (1)	8/120 (7)	NE	NE
	Europe	0	7/44 (16)	NE	
Hepatobiliary disorders	North America	13/132 (10)	3/120 (3)	7.35 (0.62, 14.32), 0.0155	0.9920
	Europe	2/32 (6)	0	6.25 (-5.00, 22.22), 0.1513	
Hypertransaminasaemia	North America	11/132 (8)	1/120 (1)	7.50 (1.62, 13.98), 0.0041	0.9993
	Europe	0	0	NE	
Immune system disorders	North America	16/132 (12)	3/120 (3)	9.62 (2.55, 16.96), 0.0043	0.9905
	Europe	4/32 (13)	0	12.50 (-0.57, 29.93), 0.0309	
Hypogammaglobulinaemia	North America	15/132 (11)	1/120 (1)	10.53 (4.13, 17.56), 0.0007	0.9922
	Europe	4/32 (13)	0	12.50 (-0.57, 29.93), 0.0309	
Infections and infestations	North America	61/132 (46)	38/120 (32)	14.55 (1.91, 26.50), 0.0141	0.6986
	Europe	16/32 (50)	17/44 (39)	11.36 (-12.44, 33.91), 0.4557	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.5. Subject Incidence of TEAEs by SOC and Preferred Term by Geographic Region (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Oral candidiasis	North America	12/132 (9)	4/120 (3)	5.76 (-1.09, 12.72), 0.0593	0.5962
	Europe	1/32 (3)	1/44 (2)	0.85 (-10.77, 15.88), 1.0000	
Injury, poisoning and procedural complications	North America	14/132 (11)	22/120 (18)	-7.73 (-17.18, 1.55), 0.0874	0.3320
	Europe	2/32 (6)	10/44 (23)	-16.48 (-32.81, 2.76), 0.0745	
Infusion related reaction	North America	1/132 (1)	10/120 (8)	-7.58 (-14.45, -1.88), 0.0043	0.9940
	Europe	0	3/44 (7)	-6.82 (-19.71, 7.45), 0.1003	
Investigations					
Alanine aminotransferase increased	North America	28/132 (21)	12/120 (10)	11.21 (1.58, 20.52), 0.0161	0.3737
	Europe	3/32 (9)	4/44 (9)	0.28 (-14.88, 18.16), 0.9458	
Platelet count decreased	North America	28/132 (21)	46/120 (38)	-17.12 (-28.47, -5.28), 0.0033	0.0691
	Europe	2/32 (6)	18/44 (41)	-34.66 (-51.26, -13.29), 0.0010	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.5. Subject Incidence of TEAEs by SOC and Preferred Term by Geographic Region (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
C-reactive protein increased	North America	9/132 (7)	0	NE	NE
	Europe	5/32 (16)	4/44 (9)	NE	
Serum ferritin increased	North America	5/132 (4)	0	NE	NE
	Europe	8/32 (25)	0	NE	
Weight increased	North America	0	6/120 (5)	NE	NE
	Europe	0	6/44 (14)	NE	
Metabolism and nutrition disorders	North America	95/132 (72)	68/120 (57)	15.30 (2.92, 27.16), 0.0104	0.0808
	Europe	15/32 (47)	24/44 (55)	-7.67 (-30.46, 16.18), 0.6402	
Hypophosphataemia	North America	40/132 (30)	22/120 (18)	11.97 (0.74, 22.68), 0.0231	0.2461
	Europe	4/32 (13)	7/44 (16)	-3.41 (-20.40, 16.09), 0.7382	
Hyponatraemia	North America	20/132 (15)	7/120 (6)	9.32 (1.04, 17.51), 0.0149	0.6555
	Europe	1/32 (3)	1/44 (2)	0.85 (-10.77, 15.88), 0.4795	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.5. Subject Incidence of TEAEs by SOC and Preferred Term by Geographic Region (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Hypomagnesaemia	North America	16/132 (12)	26/120 (22)	-9.55 (-19.44, 0.28), 0.0496	0.8746
	Europe	3/32 (9)	8/44 (18)	-8.81 (-25.38, 10.47), 0.2538	
Nervous system disorders	North America	105/132 (80)	64/120 (53)	26.21 (14.05, 37.46), <.0001	0.3426
	Europe	20/32 (63)	20/44 (45)	17.05 (-7.31, 38.70), 0.2403	
Headache	North America	56/132 (42)	28/120 (23)	19.09 (6.91, 30.43), 0.0013	0.4541
	Europe	13/32 (41)	13/44 (30)	11.08 (-11.73, 33.37), 0.5157	
Tremor	North America	40/132 (30)	1/120 (1)	29.47 (20.75, 38.21), <.0001	0.9916
	Europe	2/32 (6)	0	6.25 (-5.00, 22.22), 0.0896	
Dizziness	North America	32/132 (24)	15/120 (13)	11.74 (1.53, 21.55), 0.0180	0.2250
	Europe	3/32 (9)	5/44 (11)	-1.99 (-17.60, 16.24), 0.7719	
Aphasia	North America	30/132 (23)	0	22.73 (15.04, 31.00), <.0001	0.9999
	Europe	4/32 (13)	0	12.50 (-0.57, 29.93), 0.0224	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.5. Subject Incidence of TEAEs by SOC and Preferred Term by Geographic Region (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Encephalopathy	North America	25/132 (19)	1/120 (1)	18.11 (10.59, 26.09), <.0001	0.4159
	Europe	4/32 (13)	1/44 (2)	10.23 (-3.81, 27.79), 0.1645	
Somnolence	North America	17/132 (13)	2/120 (2)	11.21 (4.28, 18.56), 0.0008	0.9922
	Europe	2/32 (6)	0	6.25 (-5.00, 22.22), 0.1513	
Dysgeusia	North America	3/132 (2)	10/120 (8)	-6.06 (-13.10, 0.16), 0.0281	0.9928
	Europe	0	4/44 (9)	-9.09 (-22.58, 5.60), 0.0649	
Peripheral sensory neuropathy	North America	0	7/120 (6)	NE	NE
	Europe	0	3/44 (7)	NE	
Psychiatric disorders	North America	61/132 (46)	33/120 (28)	18.71 (6.21, 30.37), 0.0019	0.8552
	Europe	9/32 (28)	7/44 (16)	12.22 (-7.94, 33.00), 0.3334	
Confusional state	North America	36/132 (27)	4/120 (3)	23.94 (14.88, 32.79), <.0001	0.9892
	Europe	3/32 (9)	0	9.38 (-2.79, 26.17), 0.0604	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.5. Subject Incidence of TEAEs by SOC and Preferred Term by Geographic Region (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Agitation	North America	9/132 (7)	2/120 (2)	NE	NE
	Europe	1/32 (3)	0	NE	
Mental status changes	North America	10/132 (8)	0	7.58 (2.24, 13.85), 0.0017	0.9978
	Europe	0	0	NE	
Respiratory, thoracic and mediastinal disorders	North America	79/132 (60)	56/120 (47)	13.18 (0.31, 25.50), 0.0375	0.8387
	Europe	14/32 (44)	15/44 (34)	9.66 (-13.56, 32.25), 0.4980	
Cough	North America	35/132 (27)	14/120 (12)	14.85 (4.54, 24.68), 0.0027	0.9816
	Europe	7/32 (22)	4/44 (9)	12.78 (-5.23, 32.34), 0.1869	
Hypoxia	North America	31/132 (23)	12/120 (10)	13.48 (3.64, 22.95), 0.0045	0.3535
	Europe	5/32 (16)	1/44 (2)	13.35 (-1.51, 31.40), 0.0437	
Pleural effusion	North America	10/132 (8)	3/120 (3)	5.08 (-1.28, 11.61), 0.0790	0.9928
	Europe	1/32 (3)	0	3.13 (-7.31, 18.00), 0.3173	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.5. Subject Incidence of TEAEs by SOC and Preferred Term by Geographic Region (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Hiccups	North America	3/132 (2)	16/120 (13)	-11.06 (-18.95, -3.97), 0.0010	0.2171
	Europe	2/32 (6)	4/44 (9)	-2.84 (-17.28, 14.26), 0.5594	
Vascular disorders	North America	71/132 (54)	42/120 (35)	18.79 (5.94, 30.79), 0.0024	0.5456
	Europe	18/32 (56)	13/44 (30)	26.70 (2.44, 47.62), 0.0229	
Hypotension	North America	55/132 (42)	22/120 (18)	23.33 (11.49, 34.21), <.0001	0.0575
	Europe	16/32 (50)	3/44 (7)	43.18 (21.24, 61.64), <.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:03

Table 14.3.1.1.12.6. Subject Incidence of TEAEs by SOC and Preferred Term by ECOG Performance (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders					
Neutropenia	ECOG = 0	44/92 (48)	20/94 (21)	26.55 (12.17, 39.55), 0.0001	0.6564
	ECOG = 1	31/78 (40)	9/74 (12)	27.58 (12.81, 40.81), 0.0003	
Anaemia	ECOG = 0	37/92 (40)	43/94 (46)	-5.53 (-20.02, 9.30), 0.6312	0.0848
	ECOG = 1	34/78 (44)	48/74 (65)	-21.28 (-36.51, -4.50), 0.0124	
Thrombocytopenia	ECOG = 0	14/92 (15)	24/94 (26)	-10.31 (-22.35, 2.10), 0.1002	0.4340
	ECOG = 1	8/78 (10)	17/74 (23)	-12.72 (-25.43, 0.12), 0.0242	
Febrile neutropenia	ECOG = 0	4/92 (4)	25/94 (27)	-22.25 (-32.95, -11.34), <.0001	0.4625
	ECOG = 1	2/78 (3)	21/74 (28)	-25.81 (-37.85, -13.81), <.0001	
Cardiac disorders	ECOG = 0	47/92 (51)	24/94 (26)	25.56 (10.85, 38.86), 0.0002	0.4985
	ECOG = 1	37/78 (47)	12/74 (16)	31.22 (15.59, 44.84), <.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:04

Table 14.3.1.1.12.6. Subject Incidence of TEAEs by SOC and Preferred Term by ECOG Performance (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Sinus tachycardia	ECOG = 0	34/92 (37)	11/94 (12)	25.25 (12.28, 37.30), <.0001	0.7765
	ECOG = 1	24/78 (31)	6/74 (8)	22.66 (9.22, 35.21), 0.0002	
Ear and labyrinth disorders	ECOG = 0	0	11/94 (12)	-11.70 (-20.38, -4.32), 0.0007	0.9910
	ECOG = 1	4/78 (5)	7/74 (9)	-4.33 (-14.57, 5.39), 0.3774	
Tinnitus	ECOG = 0	0	7/94 (7)	NE	NE
	ECOG = 1	0	4/74 (5)	NE	
Gastrointestinal disorders					
Nausea	ECOG = 0	30/92 (33)	68/94 (72)	-39.73 (-52.25, -24.87), <.0001	0.0381
	ECOG = 1	39/78 (50)	48/74 (65)	-14.86 (-30.39, 1.75), 0.0555	
Constipation	ECOG = 0	18/92 (20)	36/94 (38)	-18.73 (-31.61, -4.93), 0.0068	0.4482
	ECOG = 1	16/78 (21)	22/74 (30)	-9.22 (-23.55, 5.46), 0.2004	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.6. Subject Incidence of TEAEs by SOC and Preferred Term by ECOG Performance (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Vomiting	ECOG = 0	16/92 (17)	30/94 (32)	-14.52 (-27.07, -1.34), 0.0308	0.8527
	ECOG = 1	17/78 (22)	25/74 (34)	-11.99 (-26.57, 3.15), 0.1000	
Dyspepsia	ECOG = 0	2/92 (2)	12/94 (13)	-10.59 (-19.63, -2.16), 0.0073	0.0594
	ECOG = 1	3/78 (4)	2/74 (3)	1.14 (-6.98, 9.20), 0.5785	
Stomatitis	ECOG = 0	2/92 (2)	19/94 (20)	-18.04 (-28.00, -8.45), 0.0001	0.2899
	ECOG = 1	3/78 (4)	10/74 (14)	-9.67 (-20.44, 0.44), 0.0606	
General disorders and administration site conditions	ECOG = 0	87/92 (95)	70/94 (74)	20.10 (9.08, 30.87), <.0001	0.5878
	ECOG = 1	73/78 (94)	55/74 (74)	19.27 (6.74, 31.64), 0.0032	
Pyrexia	ECOG = 0	85/92 (92)	26/94 (28)	64.73 (51.69, 74.22), <.0001	0.8303
	ECOG = 1	73/78 (94)	17/74 (23)	70.62 (56.28, 80.16), <.0001	
Chills	ECOG = 0	26/92 (28)	10/94 (11)	17.62 (5.50, 29.31), 0.0014	0.3180
	ECOG = 1	21/78 (27)	4/74 (5)	21.52 (8.99, 33.52), 0.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.6. Subject Incidence of TEAEs by SOC and Preferred Term by ECOG Performance (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Mucosal inflammation	ECOG = 0	0	11/94 (12)	-11.70 (-20.38, -4.32), 0.0008	0.9926
	ECOG = 1	1/78 (1)	5/74 (7)	-5.47 (-14.53, 2.40), 0.0834	
Hepatobiliary disorders	ECOG = 0	10/92 (11)	2/94 (2)	8.74 (0.71, 17.56), 0.0150	0.8606
	ECOG = 1	5/78 (6)	1/74 (1)	5.06 (-2.99, 13.71), 0.1124	
Hypertransaminasaemia	ECOG = 0	6/92 (7)	0	NE	NE
	ECOG = 1	5/78 (6)	1/74 (1)	NE	
Immune system disorders	ECOG = 0	11/92 (12)	2/94 (2)	9.83 (1.60, 18.84), 0.0081	0.6642
	ECOG = 1	10/78 (13)	1/74 (1)	11.47 (2.16, 21.50), 0.0047	
Hypogammaglobulinaemia	ECOG = 0	10/92 (11)	1/94 (1)	9.81 (2.16, 18.51), 0.0036	0.9934
	ECOG = 1	9/78 (12)	0	11.54 (3.08, 21.26), 0.0018	
Infections and infestations	ECOG = 0	41/92 (45)	35/94 (37)	7.33 (-7.43, 21.69), 0.1894	0.1642
	ECOG = 1	40/78 (51)	20/74 (27)	24.26 (7.79, 38.99), 0.0022	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.6. Subject Incidence of TEAEs by SOC and Preferred Term by ECOG Performance (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Oral candidiasis	ECOG = 0	10/92 (11)	2/94 (2)	8.74 (0.71, 17.56), 0.0113	0.1437
	ECOG = 1	4/78 (5)	3/74 (4)	1.07 (-7.76, 9.79), 0.7284	
Injury, poisoning and procedural complications	ECOG = 0	3/92 (3)	16/94 (17)	-13.76 (-23.51, -4.33), 0.0031	0.0812
	ECOG = 1	13/78 (17)	17/74 (23)	-6.31 (-19.85, 7.31), 0.4456	
Infusion related reaction	ECOG = 0	0	5/94 (5)	NE	NE
	ECOG = 1	1/78 (1)	8/74 (11)	NE	
Investigations					
Alanine aminotransferase increased	ECOG = 0	12/92 (13)	7/94 (7)	5.60 (-4.14, 15.52), 0.2038	0.7074
	ECOG = 1	19/78 (24)	9/74 (12)	12.20 (-1.19, 25.02), 0.0417	
Platelet count decreased	ECOG = 0	11/92 (12)	37/94 (39)	-27.41 (-39.40, -14.24), <.0001	0.0895
	ECOG = 1	19/78 (24)	27/74 (36)	-12.13 (-27.00, 3.38), 0.0916	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.6. Subject Incidence of TEAEs by SOC and Preferred Term by ECOG Performance (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
C-reactive protein increased	ECOG = 0	9/92 (10)	3/94 (3)	NE	NE
	ECOG = 1	6/78 (8)	1/74 (1)	NE	
Serum ferritin increased	ECOG = 0	11/92 (12)	0	11.96 (4.56, 20.79), 0.0007	0.9998
	ECOG = 1	4/78 (5)	0	5.13 (-1.93, 13.31), 0.0850	
Weight increased	ECOG = 0	1/92 (1)	10/94 (11)	-9.55 (-18.10, -1.90), 0.0054	0.9933
	ECOG = 1	0	2/74 (3)	-2.70 (-10.31, 3.56), 0.1241	
Metabolism and nutrition disorders	ECOG = 0	54/92 (59)	51/94 (54)	4.44 (-10.39, 19.00), 0.5107	0.1642
	ECOG = 1	59/78 (76)	42/74 (57)	18.88 (2.93, 33.71), 0.0175	
Hypophosphataemia	ECOG = 0	20/92 (22)	14/94 (15)	6.85 (-5.10, 18.67), 0.1625	0.8449
	ECOG = 1	25/78 (32)	15/74 (20)	11.78 (-3.19, 25.98), 0.0736	
Hyponatraemia	ECOG = 0	13/92 (14)	5/94 (5)	8.81 (-0.65, 18.58), 0.0409	0.9917
	ECOG = 1	8/78 (10)	3/74 (4)	6.20 (-3.56, 16.14), 0.0880	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.6. Subject Incidence of TEAEs by SOC and Preferred Term by ECOG Performance (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Hypomagnesaemia	ECOG = 0	9/92 (10)	18/94 (19)	-9.37 (-20.24, 1.66), 0.0936	0.7896
	ECOG = 1	11/78 (14)	16/74 (22)	-7.52 (-20.64, 5.66), 0.2691	
Nervous system disorders	ECOG = 0	64/92 (70)	52/94 (55)	14.25 (-0.42, 28.10), 0.0406	0.0438
	ECOG = 1	64/78 (82)	35/74 (47)	34.75 (18.79, 48.53), <.0001	
Headache	ECOG = 0	38/92 (41)	24/94 (26)	15.77 (1.46, 29.29), 0.0267	0.9647
	ECOG = 1	32/78 (41)	19/74 (26)	15.35 (-0.59, 30.21), 0.0587	
Tremor	ECOG = 0	20/92 (22)	1/94 (1)	20.68 (11.22, 30.79), <.0001	0.9908
	ECOG = 1	24/78 (31)	0	30.77 (19.29, 42.38), <.0001	
Aphasia	ECOG = 0	18/92 (20)	0	19.57 (10.81, 29.42), <.0001	0.9999
	ECOG = 1	18/78 (23)	0	23.08 (12.60, 34.25), <.0001	
Dizziness	ECOG = 0	17/92 (18)	11/94 (12)	6.78 (-4.40, 17.93), 0.1485	0.8719
	ECOG = 1	19/78 (24)	10/74 (14)	10.85 (-2.71, 23.85), 0.0795	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.6. Subject Incidence of TEAEs by SOC and Preferred Term by ECOG Performance (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Encephalopathy	ECOG = 0	8/92 (9)	0	8.70 (1.98, 16.90), 0.0047	0.9927
	ECOG = 1	21/78 (27)	2/74 (3)	24.22 (12.34, 35.87), <.0001	
Somnolence	ECOG = 0	6/92 (7)	1/94 (1)	5.46 (-1.30, 13.20), 0.0416	0.6507
	ECOG = 1	13/78 (17)	1/74 (1)	15.32 (5.33, 25.91), 0.0015	
Dysgeusia	ECOG = 0	4/92 (4)	10/94 (11)	-6.29 (-15.27, 2.42), 0.1187	0.9927
	ECOG = 1	0	4/74 (5)	-5.41 (-13.98, 1.49), 0.0494	
Peripheral sensory neuropathy	ECOG = 0	0	4/94 (4)	NE	NE
	ECOG = 1	0	6/74 (8)	NE	
Psychiatric disorders	ECOG = 0	31/92 (34)	27/94 (29)	4.97 (-8.99, 18.72), 0.4047	0.0076
	ECOG = 1	40/78 (51)	13/74 (18)	33.71 (17.82, 47.35), <.0001	
Confusional state	ECOG = 0	13/92 (14)	4/94 (4)	9.88 (0.67, 19.50), 0.0179	0.9895
	ECOG = 1	27/78 (35)	0	34.62 (22.72, 46.32), <.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:04

Table 14.3.1.1.12.6. Subject Incidence of TEAEs by SOC and Preferred Term by ECOG Performance (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Agitation	ECOG = 0	4/92 (4)	1/94 (1)	NE	NE
	ECOG = 1	6/78 (8)	1/74 (1)	NE	
Mental status changes	ECOG = 0	5/92 (5)	0	NE	NE
	ECOG = 1	5/78 (6)	0	NE	
Respiratory, thoracic and mediastinal disorders	ECOG = 0	49/92 (53)	41/94 (44)	9.64 (-5.38, 24.11), 0.1453	0.6169
	ECOG = 1	46/78 (59)	31/74 (42)	17.08 (0.29, 32.65), 0.0424	
Cough	ECOG = 0	23/92 (25)	11/94 (12)	13.30 (1.37, 24.95), 0.0182	0.7444
	ECOG = 1	19/78 (24)	7/74 (9)	14.90 (1.92, 27.33), 0.0154	
Hypoxia	ECOG = 0	22/92 (24)	7/94 (7)	16.47 (5.28, 27.51), 0.0015	0.6307
	ECOG = 1	15/78 (19)	6/74 (8)	11.12 (-0.98, 22.94), 0.0205	
Pleural effusion	ECOG = 0	6/92 (7)	3/94 (3)	NE	NE
	ECOG = 1	5/78 (6)	0	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.6. Subject Incidence of TEAEs by SOC and Preferred Term by ECOG Performance (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Hiccups	ECOG = 0	3/92 (3)	12/94 (13)	-9.51 (-18.68, -0.74), 0.0160	0.7849
	ECOG = 1	2/78 (3)	9/74 (12)	-9.60 (-19.98, -0.12), 0.0079	
Vascular disorders	ECOG = 0	47/92 (51)	30/94 (32)	19.17 (4.25, 33.00), 0.0042	0.8050
	ECOG = 1	47/78 (60)	26/74 (35)	25.12 (8.30, 40.12), 0.0025	
Hypotension	ECOG = 0	36/92 (39)	15/94 (16)	23.17 (9.62, 35.72), 0.0002	0.3569
	ECOG = 1	39/78 (50)	10/74 (14)	36.49 (21.03, 49.64), <.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.7. Subject Incidence of TEAEs by SOC and Preferred Term by Central Lab Disease Type (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders					
Anaemia	DLBCL NOS/without further classification possible	53/121 (44)	65/119 (55)	-10.82 (-23.53, 2.38), 0.0861	0.9045
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	14/29 (48)	13/25 (52)	-3.72 (-30.64, 23.92), 0.6738	
Neutropenia	DLBCL NOS/without further classification possible	50/121 (41)	18/119 (15)	26.20 (14.33, 37.11), <.0001	0.6489
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	14/29 (48)	6/25 (24)	24.28 (-4.03, 47.64), 0.0440	
Thrombocytopenia	DLBCL NOS/without further classification possible	16/121 (13)	29/119 (24)	-11.15 (-21.46, -0.64), 0.0242	0.9667
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/29 (14)	7/25 (28)	-14.21 (-37.72, 9.91), 0.3011	
Febrile neutropenia	DLBCL NOS/without further classification possible	4/121 (3)	34/119 (29)	-25.27 (-34.66, -15.82), <.0001	0.7706
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/29 (3)	6/25 (24)	-20.55 (-42.32, 0.74), 0.0362	
Cardiac disorders	DLBCL NOS/without further classification possible	59/121 (49)	26/119 (22)	26.91 (14.30, 38.38), <.0001	0.5847
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	17/29 (59)	6/25 (24)	34.62 (5.59, 56.77), 0.0084	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.7. Subject Incidence of TEAEs by SOC and Preferred Term by Central Lab Disease Type (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Sinus tachycardia	DLBCL NOS/without further classification possible	40/121 (33)	13/119 (11)	22.13 (11.17, 32.50), <.0001	0.5334
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	12/29 (41)	2/25 (8)	33.38 (7.32, 53.95), 0.0132	
Ear and labyrinth disorders	DLBCL NOS/without further classification possible	3/121 (2)	15/119 (13)	-10.13 (-17.98, -2.85), 0.0035	0.5166
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/29 (3)	2/25 (8)	-4.55 (-24.33, 12.92), 0.4831	
Tinnitus	DLBCL NOS/without further classification possible	0	10/119 (8)	-8.40 (-15.29, -2.81), 0.0013	0.9998
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0	1/25 (4)	-4.00 (-22.32, 11.05), 0.6171	
Gastrointestinal disorders					
Nausea	DLBCL NOS/without further classification possible	44/121 (36)	87/119 (73)	-36.75 (-48.03, -23.78), <.0001	0.0020
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	20/29 (69)	15/25 (60)	8.97 (-18.01, 34.90), 0.8007	
Constipation	DLBCL NOS/without further classification possible	24/121 (20)	47/119 (39)	-19.66 (-31.08, -7.53), 0.0009	0.1148
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	7/29 (24)	5/25 (20)	4.14 (-20.88, 27.49), 0.8330	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.7. Subject Incidence of TEAEs by SOC and Preferred Term by Central Lab Disease Type (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Vomiting	DLBCL NOS/without further classification possible	25/121 (21)	39/119 (33)	-12.11 (-23.51, -0.32), 0.0269	0.9112
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	6/29 (21)	8/25 (32)	-11.31 (-35.97, 14.14), 0.3853	
Dyspepsia	DLBCL NOS/without further classification possible	3/121 (2)	8/119 (7)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/29 (7)	2/25 (8)	NE	
Stomatitis	DLBCL NOS/without further classification possible	5/121 (4)	21/119 (18)	-13.51 (-22.21, -5.11), 0.0006	0.9913
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0	3/25 (12)	-12.00 (-32.34, 5.04), 0.1019	
General disorders and administration site conditions	DLBCL NOS/without further classification possible	111/121 (92)	92/119 (77)	14.42 (4.70, 24.06), 0.0020	0.9882
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	29/29 (100)	19/25 (76)	24.00 (3.91, 45.52), 0.0113	
Pyrexia	DLBCL NOS/without further classification possible	110/121 (91)	31/119 (26)	64.86 (53.49, 73.40), <.0001	0.9895
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	29/29 (100)	5/25 (20)	80.00 (54.20, 92.39), <.0001	
Chills	DLBCL NOS/without further classification possible	34/121 (28)	5/119 (4)	23.90 (14.32, 33.30), <.0001	0.3739
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	11/29 (38)	3/25 (12)	25.93 (-0.34, 47.53), 0.0843	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.7. Subject Incidence of TEAEs by SOC and Preferred Term by Central Lab Disease Type (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Mucosal inflammation	DLBCL NOS/without further classification possible	0	13/119 (11)	-10.92 (-18.29, -4.82), 0.0001	0.9910
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/29 (3)	3/25 (12)	-8.55 (-29.15, 9.89), 0.2824	
Hepatobiliary disorders	DLBCL NOS/without further classification possible	8/121 (7)	2/119 (2)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/29 (10)	0	NE	
Hypertransaminasaemia	DLBCL NOS/without further classification possible	5/121 (4)	1/119 (1)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/29 (10)	0	NE	
Immune system disorders	DLBCL NOS/without further classification possible	16/121 (13)	3/119 (3)	10.70 (3.30, 18.58), 0.0026	0.9919
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	5/29 (17)	0	17.24 (-2.50, 36.49), 0.0057	
Hypogammaglobulinaemia	DLBCL NOS/without further classification possible	15/121 (12)	1/119 (1)	11.56 (4.83, 19.13), 0.0005	0.9934
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/29 (14)	0	13.79 (-5.20, 32.57), 0.0316	
Infections and infestations	DLBCL NOS/without further classification possible	58/121 (48)	40/119 (34)	14.32 (1.30, 26.69), 0.0307	0.1420
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	15/29 (52)	5/25 (20)	31.72 (3.30, 53.90), 0.0444	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.7. Subject Incidence of TEAEs by SOC and Preferred Term by Central Lab Disease Type (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Oral candidiasis	DLBCL NOS/without further classification possible	9/121 (7)	5/119 (4)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/29 (10)	0	NE	
Injury, poisoning and procedural complications	DLBCL NOS/without further classification possible	12/121 (10)	25/119 (21)	-11.09 (-20.80, -1.31), 0.0155	0.7712
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/29 (7)	4/25 (16)	-9.10 (-30.78, 11.27), 0.3667	
Infusion related reaction	DLBCL NOS/without further classification possible	1/121 (1)	10/119 (8)	-7.58 (-14.51, -1.60), 0.0038	0.9950
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0	2/25 (8)	-8.00 (-27.50, 7.99), 0.0881	
Investigations					
Platelet count decreased	DLBCL NOS/without further classification possible	21/121 (17)	49/119 (41)	-23.82 (-35.00, -11.79), <.0001	0.0679
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/29 (28)	6/25 (24)	3.59 (-22.16, 27.83), 0.9753	
Alanine aminotransferase increased	DLBCL NOS/without further classification possible	19/121 (16)	14/119 (12)	3.94 (-5.52, 13.34), 0.3466	0.1319
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/29 (28)	1/25 (4)	23.59 (0.44, 43.84), 0.0279	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.12.7. Subject Incidence of TEAEs by SOC and Preferred Term by Central Lab Disease Type (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
C-reactive protein increased	DLBCL NOS/without further classification possible	7/121 (6)	3/119 (3)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/29 (28)	1/25 (4)	NE	
Serum ferritin increased	DLBCL NOS/without further classification possible	9/121 (7)	0	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	5/29 (17)	0	NE	
Weight increased	DLBCL NOS/without further classification possible	1/121 (1)	9/119 (8)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0	1/25 (4)	NE	
Metabolism and nutrition disorders	DLBCL NOS/without further classification possible	77/121 (64)	63/119 (53)	10.70 (-2.33, 23.26), 0.0968	0.0818
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	27/29 (93)	16/25 (64)	29.10 (4.64, 51.23), 0.0056	
Hypophosphataemia	DLBCL NOS/without further classification possible	29/121 (24)	23/119 (19)	4.64 (-6.40, 15.52), 0.3653	0.0367
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	12/29 (41)	2/25 (8)	33.38 (7.32, 53.95), 0.0256	
Hyponatraemia	DLBCL NOS/without further classification possible	12/121 (10)	6/119 (5)	4.88 (-2.65, 12.58), 0.1299	0.3681
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/29 (28)	2/25 (8)	19.59 (-4.50, 40.55), 0.0137	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:04

Table 14.3.1.1.12.7. Subject Incidence of TEAEs by SOC and Preferred Term by Central Lab Disease Type (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Hypomagnesaemia	DLBCL NOS/without further classification possible	15/121 (12)	22/119 (18)	-6.09 (-15.88, 3.73), 0.2040	0.6877
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/29 (14)	7/25 (28)	-14.21 (-37.72, 9.91), 0.4509	
Nervous system disorders	DLBCL NOS/without further classification possible	91/121 (75)	65/119 (55)	20.58 (7.93, 32.39), 0.0011	0.5278
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	23/29 (79)	12/25 (48)	31.31 (3.15, 54.34), 0.0759	
Headache	DLBCL NOS/without further classification possible	51/121 (42)	34/119 (29)	13.58 (0.89, 25.68), 0.0249	0.8204
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	9/29 (31)	4/25 (16)	15.03 (-10.74, 37.67), 0.4970	
Tremor	DLBCL NOS/without further classification possible	30/121 (25)	1/119 (1)	23.95 (15.50, 32.82), <.0001	0.9915
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	11/29 (38)	0	37.93 (14.45, 57.64), 0.0008	
Dizziness	DLBCL NOS/without further classification possible	25/121 (21)	16/119 (13)	7.22 (-2.98, 17.26), 0.1682	0.5762
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	10/29 (34)	4/25 (16)	18.48 (-7.78, 41.06), 0.1521	
Aphasia	DLBCL NOS/without further classification possible	23/121 (19)	0	19.01 (11.57, 27.37), <.0001	0.9999
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	9/29 (31)	0	31.03 (8.64, 50.95), 0.0075	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:04

Table 14.3.1.1.12.7. Subject Incidence of TEAEs by SOC and Preferred Term by Central Lab Disease Type (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Encephalopathy	DLBCL NOS/without further classification possible	19/121 (16)	1/119 (1)	14.86 (7.60, 22.89), <.0001	0.9930
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	7/29 (24)	0	24.14 (3.00, 43.93), 0.0067	
Somnolence	DLBCL NOS/without further classification possible	12/121 (10)	0	9.92 (3.99, 17.03), 0.0006	0.9911
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/29 (14)	1/25 (4)	9.79 (-10.75, 28.95), 0.3014	
Dysgeusia	DLBCL NOS/without further classification possible	3/121 (2)	8/119 (7)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0	2/25 (8)	NE	
Peripheral sensory neuropathy	DLBCL NOS/without further classification possible	0	10/119 (8)	-8.40 (-15.29, -2.81), 0.0016	0.9979
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	0	0	NE	
Psychiatric disorders	DLBCL NOS/without further classification possible	49/121 (40)	26/119 (22)	18.65 (6.34, 30.21), 0.0018	0.6924
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	17/29 (59)	8/25 (32)	26.62 (-2.43, 50.36), 0.0640	
Confusional state	DLBCL NOS/without further classification possible	28/121 (23)	2/119 (2)	21.46 (12.96, 30.28), <.0001	0.9907
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	11/29 (38)	0	37.93 (14.45, 57.64), 0.0015	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:04

Table 14.3.1.1.12.7. Subject Incidence of TEAEs by SOC and Preferred Term by Central Lab Disease Type (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Agitation	DLBCL NOS/without further classification possible	6/121 (5)	2/119 (2)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/29 (10)	0	NE	
Mental status changes	DLBCL NOS/without further classification possible	7/121 (6)	0	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/29 (3)	0	NE	
Respiratory, thoracic and mediastinal disorders	DLBCL NOS/without further classification possible	66/121 (55)	50/119 (42)	12.53 (-0.68, 25.16), 0.0559	0.5955
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	19/29 (66)	11/25 (44)	21.52 (-7.19, 46.27), 0.1349	
Cough	DLBCL NOS/without further classification possible	33/121 (27)	14/119 (12)	15.51 (4.89, 25.76), 0.0022	0.4396
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	6/29 (21)	1/25 (4)	16.69 (-5.20, 36.63), 0.0342	
Hypoxia	DLBCL NOS/without further classification possible	28/121 (23)	10/119 (8)	14.74 (4.94, 24.36), 0.0011	0.7182
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	6/29 (21)	1/25 (4)	16.69 (-5.20, 36.63), 0.1685	
Pleural effusion	DLBCL NOS/without further classification possible	8/121 (7)	2/119 (2)	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/29 (10)	0	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:04

Table 14.3.1.1.12.7. Subject Incidence of TEAEs by SOC and Preferred Term by Central Lab Disease Type (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Hiccups	DLBCL NOS/without further classification possible	3/121 (2)	15/119 (13)	-10.13 (-17.98, -2.85), 0.0024	0.9530
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/29 (3)	5/25 (20)	-16.55 (-38.10, 3.83), 0.1023	
Vascular disorders	DLBCL NOS/without further classification possible	65/121 (54)	40/119 (34)	20.11 (6.97, 32.33), 0.0016	0.4300
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	19/29 (66)	8/25 (32)	33.52 (4.22, 56.26), 0.0094	
Hypotension	DLBCL NOS/without further classification possible	49/121 (40)	17/119 (14)	26.21 (14.46, 37.04), <.0001	0.6443
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	18/29 (62)	5/25 (20)	42.07 (13.05, 62.81), 0.0054	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_sg.sas Output Generated: 20230419T15:04

Tabelle 4-31 (Anhang): Subgruppenanalysen für häufige UE von Grad ≥3 nach SOC und PT - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

Kite Pharma, Inc. Confidential Protocol: KTE-C19-107

Table 14.3.1.1.13.1. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by Response to First-line Therapy Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders					
Neutropenia	Primary refractory	58/123 (47)	19/123 (15)	31.71 (19.75, 42.48), <.0001	0.1001
	Relapse ≤ 12 months of first line therapy	15/47 (32)	9/45 (20)	11.91 (-7.58, 30.18), 0.1935	
Thrombocytopenia	Primary refractory	9/123 (7)	25/123 (20)	-13.01 (-22.19, -3.81), 0.0028	0.9227
	Relapse ≤ 12 months of first line therapy	5/47 (11)	12/45 (27)	-16.03 (-32.93, 1.57), 0.0502	
Febrile neutropenia	Primary refractory	5/123 (4)	34/123 (28)	-23.58 (-32.85, -14.20), <.0001	0.6032
	Relapse ≤ 12 months of first line therapy	1/47 (2)	12/45 (27)	-24.54 (-40.21, -8.85), 0.0008	
Gastrointestinal disorders	Primary refractory	12/123 (10)	21/123 (17)	-7.32 (-16.51, 1.88), 0.0991	0.4107
	Relapse ≤ 12 months of first line therapy	3/47 (6)	9/45 (20)	-13.62 (-29.39, 2.09), 0.0544	
General disorders and administration site conditions	Primary refractory	18/123 (15)	9/123 (7)	7.32 (-1.20, 15.93), 0.0694	0.7466
	Relapse ≤ 12 months of first line therapy	10/47 (21)	4/45 (9)	12.39 (-4.25, 28.35), 0.1016	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_g3_sg.sas Output Generated: 20230419T14:57

Table 14.3.1.1.13.1. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by Response to First-line Therapy Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Pyrexia	Primary refractory	10/123 (8)	0	8.13 (2.67, 14.81), 0.0013	0.9921
	Relapse ≤ 12 months of first line therapy	5/47 (11)	1/45 (2)	8.42 (-4.45, 21.84), 0.1020	
Investigations					
Platelet count decreased	Primary refractory	9/123 (7)	40/123 (33)	-25.20 (-35.05, -14.89), <.0001	0.4053
	Relapse ≤ 12 months of first line therapy	3/47 (6)	20/45 (44)	-38.06 (-54.20, -19.13), <.0001	
Nervous system disorders	Primary refractory	26/123 (21)	10/123 (8)	13.01 (3.59, 22.36), 0.0036	0.9962
	Relapse ≤ 12 months of first line therapy	13/47 (28)	5/45 (11)	16.55 (-1.41, 33.27), 0.0479	
Encephalopathy	Primary refractory	15/123 (12)	0	12.20 (5.95, 19.62), <.0001	1.0000
	Relapse ≤ 12 months of first line therapy	5/47 (11)	0	10.64 (-1.20, 23.89), 0.0257	
Aphasia	Primary refractory	8/123 (7)	0	NE	NE
	Relapse ≤ 12 months of first line therapy	4/47 (9)	0	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_g3_sg.sas Output Generated: 20230419T14:57

Table 14.3.1.1.13.1. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by Response to First-line Therapy Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Psychiatric disorders	Primary refractory	11/123 (9)	2/123 (2)	7.32 (1.02, 14.30), 0.0096	0.9918
	Relapse ≤ 12 months of first line therapy	5/47 (11)	0	10.64 (-1.20, 23.89), 0.0261	
Confusional state	Primary refractory	7/123 (6)	0	NE	NE
	Relapse ≤ 12 months of first line therapy	2/47 (4)	0	NE	
Vascular disorders	Primary refractory	18/123 (15)	9/123 (7)	7.32 (-1.20, 15.93), 0.0611	0.3617
	Relapse ≤ 12 months of first line therapy	9/47 (19)	2/45 (4)	14.70 (-0.54, 29.74), 0.0315	
Hypotension	Primary refractory	13/123 (11)	4/123 (3)	7.32 (0.25, 14.80), 0.0232	0.6366
	Relapse ≤ 12 months of first line therapy	6/47 (13)	1/45 (2)	10.54 (-2.76, 24.38), 0.0587	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_g3_sg.sas Output Generated: 20230419T14:57

Table 14.3.1.1.13.2. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by Age (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders					
Neutropenia	Age < 65	51/121 (42)	15/113 (13)	28.87 (16.98, 39.65), <.0001	0.5099
	Age ≥ 65	22/49 (45)	13/55 (24)	21.26 (1.71, 39.08), 0.0164	
Thrombocytopenia	Age < 65	6/121 (5)	27/113 (24)	-18.94 (-28.51, -9.50), <.0001	0.0078
	Age ≥ 65	8/49 (16)	10/55 (18)	-1.86 (-17.55, 14.50), 0.7426	
Febrile neutropenia	Age < 65	5/121 (4)	34/113 (30)	-25.96 (-35.77, -16.05), <.0001	0.8632
	Age ≥ 65	1/49 (2)	12/55 (22)	-19.78 (-33.46, -5.79), 0.0065	
Gastrointestinal disorders	Age < 65	12/121 (10)	23/113 (20)	-10.44 (-20.32, -0.62), 0.0287	0.9045
	Age ≥ 65	3/49 (6)	7/55 (13)	-6.60 (-19.77, 7.09), 0.3340	
General disorders and administration site conditions	Age < 65	20/121 (17)	7/113 (6)	10.33 (1.48, 19.13), 0.0266	0.6145
	Age ≥ 65	8/49 (16)	6/55 (11)	5.42 (-9.32, 20.70), 0.3281	
Pyrexia	Age < 65	11/121 (9)	1/113 (1)	8.21 (1.90, 15.21), 0.0120	0.9914
	Age ≥ 65	4/49 (8)	0	8.16 (-1.66, 20.48), 0.0335	
Investigations					

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_g3_sg.sas Output Generated: 20230419T14:58

Table 14.3.1.1.13.2. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by Age (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Platelet count decreased	Age < 65	6/121 (5)	35/113 (31)	-26.01 (-35.95, -15.89), <.0001	0.4718
	Age ≥ 65	6/49 (12)	25/55 (45)	-33.21 (-48.84, -14.49), 0.0004	
Nervous system disorders	Age < 65	23/121 (19)	12/113 (11)	8.39 (-1.47, 18.01), 0.0675	0.0898
	Age ≥ 65	16/49 (33)	3/55 (5)	27.20 (10.96, 42.74), 0.0014	
Encephalopathy	Age < 65	13/121 (11)	0	10.74 (4.53, 18.00), 0.0001	1.0000
	Age ≥ 65	7/49 (14)	0	14.29 (2.96, 27.86), 0.0120	
Aphasia	Age < 65	9/121 (7)	0	NE	NE
	Age ≥ 65	3/49 (6)	0	NE	
Psychiatric disorders	Age < 65	7/121 (6)	1/113 (1)	NE	NE
	Age ≥ 65	9/49 (18)	1/55 (2)	NE	
Confusional state	Age < 65	3/121 (2)	0	NE	NE
	Age ≥ 65	6/49 (12)	0	NE	
Vascular disorders	Age < 65	19/121 (16)	7/113 (6)	9.51 (0.75, 18.21), 0.0269	0.9377
	Age ≥ 65	8/49 (16)	4/55 (7)	9.05 (-4.99, 23.78), 0.1871	
Hypotension	Age < 65	13/121 (11)	4/113 (4)	7.20 (-0.25, 14.85), 0.0391	0.5080
	Age ≥ 65	6/49 (12)	1/55 (2)	10.43 (-1.22, 23.76), 0.0501	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_g3_sg.sas Output Generated: 20230419T14:58

Table 14.3.1.1.13.3. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by Second-line Age-adjusted IPI Score Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders					
Neutropenia	Second-line age-adjusted IPI score 0 - 1	45/97 (46)	19/93 (20)	25.96 (11.84, 38.69), 0.0002	0.5380
	Second-line age-adjusted IPI score 2 - 3	28/73 (38)	9/75 (12)	26.36 (11.52, 39.92), 0.0002	
Thrombocytopenia	Second-line age-adjusted IPI score 0 - 1	7/97 (7)	26/93 (28)	-20.74 (-31.91, -9.30), 0.0002	0.1084
	Second-line age-adjusted IPI score 2 - 3	7/73 (10)	11/75 (15)	-5.08 (-16.84, 6.79), 0.3300	
Febrile neutropenia	Second-line age-adjusted IPI score 0 - 1	4/97 (4)	27/93 (29)	-24.91 (-35.75, -13.92), <.0001	0.8000
	Second-line age-adjusted IPI score 2 - 3	2/73 (3)	19/75 (25)	-22.59 (-34.40, -10.73), <.0001	
Gastrointestinal disorders	Second-line age-adjusted IPI score 0 - 1	7/97 (7)	16/93 (17)	-9.99 (-20.33, 0.17), 0.0347	0.5891
	Second-line age-adjusted IPI score 2 - 3	8/73 (11)	14/75 (19)	-7.71 (-20.13, 4.95), 0.1965	
General disorders and administration site conditions	Second-line age-adjusted IPI score 0 - 1	16/97 (16)	9/93 (10)	6.82 (-3.76, 17.24), 0.1709	0.4160
	Second-line age-adjusted IPI score 2 - 3	12/73 (16)	4/75 (5)	11.11 (-0.08, 22.60), 0.0344	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.13.3. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by Second-line Age-adjusted IPI Score Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Pyrexia	Second-line age-adjusted IPI score 0 - 1	10/97 (10)	1/93 (1)	9.23 (1.73, 17.55), 0.0065	0.9911
	Second-line age-adjusted IPI score 2 - 3	5/73 (7)	0	6.85 (-0.59, 15.93), 0.0237	
Investigations					
Platelet count decreased	Second-line age-adjusted IPI score 0 - 1	7/97 (7)	35/93 (38)	-30.42 (-41.84, -18.14), <.0001	0.8488
	Second-line age-adjusted IPI score 2 - 3	5/73 (7)	25/75 (33)	-26.48 (-39.17, -12.82), <.0001	
Nervous system disorders	Second-line age-adjusted IPI score 0 - 1	17/97 (18)	9/93 (10)	7.85 (-2.86, 18.38), 0.1210	0.1626
	Second-line age-adjusted IPI score 2 - 3	22/73 (30)	6/75 (8)	22.14 (8.62, 35.04), 0.0006	
Encephalopathy	Second-line age-adjusted IPI score 0 - 1	7/97 (7)	0	7.22 (0.85, 14.80), 0.0091	0.9997
	Second-line age-adjusted IPI score 2 - 3	13/73 (18)	0	17.81 (8.06, 28.89), 0.0001	
Aphasia	Second-line age-adjusted IPI score 0 - 1	7/97 (7)	0	NE	NE
	Second-line age-adjusted IPI score 2 - 3	5/73 (7)	0	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_g3_sg.sas Output Generated: 20230419T14:58

Table 14.3.1.1.13.3. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by Second-line Age-adjusted IPI Score Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Psychiatric disorders	Second-line age-adjusted IPI score 0 - 1	7/97 (7)	1/93 (1)	NE	NE
	Second-line age-adjusted IPI score 2 - 3	9/73 (12)	1/75 (1)	NE	
Confusional state	Second-line age-adjusted IPI score 0 - 1	5/97 (5)	0	NE	NE
	Second-line age-adjusted IPI score 2 - 3	4/73 (5)	0	NE	
Vascular disorders	Second-line age-adjusted IPI score 0 - 1	12/97 (12)	6/93 (6)	5.92 (-3.48, 15.34), 0.1757	0.4533
	Second-line age-adjusted IPI score 2 - 3	15/73 (21)	5/75 (7)	13.88 (1.79, 26.01), 0.0147	
Hypotension	Second-line age-adjusted IPI score 0 - 1	8/97 (8)	3/93 (3)	5.02 (-2.87, 13.20), 0.1462	0.4164
	Second-line age-adjusted IPI score 2 - 3	11/73 (15)	2/75 (3)	12.40 (2.17, 23.35), 0.0092	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_g3_sg.sas Output Generated: 20230419T14:58

Table 14.3.1.1.13.4. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by Sex (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders					
Neutropenia	Male	38/106 (36)	16/120 (13)	22.52 (10.73, 33.79), <.0001	0.9910
	Female	35/64 (55)	12/48 (25)	29.69 (10.01, 46.12), 0.0007	
Thrombocytopenia	Male	8/106 (8)	28/120 (23)	-15.79 (-25.42, -5.71), 0.0009	0.4872
	Female	6/64 (9)	9/48 (19)	-9.38 (-24.75, 4.71), 0.0507	
Febrile neutropenia	Male	2/106 (2)	28/120 (23)	-21.45 (-30.35, -12.57), <.0001	0.6379
	Female	4/64 (6)	18/48 (38)	-31.25 (-46.99, -14.85), <.0001	
Gastrointestinal disorders	Male	8/106 (8)	20/120 (17)	-9.12 (-18.19, 0.24), 0.0413	0.7941
	Female	7/64 (11)	10/48 (21)	-9.90 (-25.68, 4.82), 0.2089	
General disorders and administration site conditions	Male	16/106 (15)	7/120 (6)	9.26 (0.63, 18.42), 0.0233	0.3505
	Female	12/64 (19)	6/48 (13)	6.25 (-9.54, 20.39), 0.5372	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_g3_sg.sas Output Generated: 20230419T14:58

Table 14.3.1.1.13.4. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by Sex (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Pyrexia	Male	9/106 (8)	1/120 (1)	NE	NE
	Female	6/64 (9)	0	NE	
Investigations					
Platelet count decreased	Male	9/106 (8)	40/120 (33)	-24.84 (-35.05, -13.79), <.0001	0.2226
	Female	3/64 (5)	20/48 (42)	-36.98 (-52.43, -20.41), <.0001	
Nervous system disorders	Male	21/106 (20)	9/120 (8)	12.31 (2.75, 22.17), 0.0097	0.9980
	Female	18/64 (28)	6/48 (13)	15.63 (-1.24, 30.39), 0.0514	
Encephalopathy	Male	8/106 (8)	0	7.55 (1.99, 14.77), 0.0027	0.9998
	Female	12/64 (19)	0	18.75 (6.35, 30.85), 0.0011	
Aphasia	Male	9/106 (8)	0	NE	NE
	Female	3/64 (5)	0	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.13.4. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by Sex (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Psychiatric disorders	Male	11/106 (10)	1/120 (1)	9.54 (3.01, 17.40), 0.0020	0.4662
	Female	5/64 (8)	1/48 (2)	5.73 (-5.76, 16.11), 0.1794	
Confusional state	Male	6/106 (6)	0	NE	NE
	Female	3/64 (5)	0	NE	
Vascular disorders	Male	15/106 (14)	8/120 (7)	7.48 (-1.16, 16.63), 0.0793	0.6258
	Female	12/64 (19)	3/48 (6)	12.50 (-2.05, 25.45), 0.0823	
Hypotension	Male	10/106 (9)	4/120 (3)	6.10 (-1.04, 14.06), 0.0639	0.5107
	Female	9/64 (14)	1/48 (2)	11.98 (-0.57, 23.61), 0.0596	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.13.5. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by Geographic Region (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders					
Neutropenia	North America	55/132 (42)	22/120 (18)	23.33 (11.49, 34.21), <.0001	0.4006
	Europe	14/32 (44)	5/44 (11)	32.39 (10.44, 52.08), 0.0032	
Thrombocytopenia	North America	12/132 (9)	24/120 (20)	-10.91 (-20.34, -1.64), 0.0146	0.1881
	Europe	1/32 (3)	11/44 (25)	-21.88 (-37.80, -3.20), 0.0054	
Febrile neutropenia	North America	5/132 (4)	34/120 (28)	-24.55 (-33.93, -15.24), <.0001	0.9887
	Europe	0	11/44 (25)	-25.00 (-40.65, -7.52), 0.0012	
Gastrointestinal disorders	North America	10/132 (8)	20/120 (17)	-9.09 (-18.03, -0.45), 0.0256	0.4897
	Europe	5/32 (16)	10/44 (23)	-7.10 (-25.40, 13.79), 0.5251	
General disorders and administration site conditions	North America	22/132 (17)	6/120 (5)	11.67 (3.37, 19.92), 0.0035	0.2027
	Europe	6/32 (19)	6/44 (14)	5.11 (-12.95, 25.07), 0.6858	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.13.5. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by Geographic Region (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Pyrexia	North America	12/132 (9)	0	9.09 (3.46, 15.67), 0.0008	0.9917
	Europe	3/32 (9)	1/44 (2)	7.10 (-6.10, 24.03), 0.2956	
Investigations					
Platelet count decreased	North America	11/132 (8)	43/120 (36)	-27.50 (-37.60, -16.92), <.0001	0.2870
	Europe	1/32 (3)	17/44 (39)	-35.51 (-51.64, -15.16), 0.0006	
Nervous system disorders	North America	31/132 (23)	12/120 (10)	13.48 (3.64, 22.95), 0.0039	0.2701
	Europe	8/32 (25)	2/44 (5)	20.45 (2.75, 39.58), 0.0146	
Encephalopathy	North America	16/132 (12)	0	12.12 (5.94, 19.22), <.0001	0.9999
	Europe	4/32 (13)	0	12.50 (-0.57, 29.93), 0.0409	
Aphasia	North America	11/132 (8)	0	8.33 (2.85, 14.76), 0.0012	0.9998
	Europe	1/32 (3)	0	3.13 (-7.31, 18.00), 0.3173	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

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Table 14.3.1.1.13.5. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by Geographic Region (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Psychiatric disorders	North America	14/132 (11)	1/120 (1)	9.77 (3.50, 16.67), 0.0011	0.3569
	Europe	2/32 (6)	1/44 (2)	3.98 (-8.39, 20.09), 0.3946	
Confusional state	North America	8/132 (6)	0	NE	NE
	Europe	1/32 (3)	0	NE	
Vascular disorders	North America	20/132 (15)	8/120 (7)	8.48 (0.05, 16.80), 0.0334	0.5377
	Europe	7/32 (22)	3/44 (7)	15.06 (-2.51, 34.30), 0.0266	
Hypotension	North America	13/132 (10)	4/120 (3)	6.52 (-0.45, 13.61), 0.0437	0.3339
	Europe	6/32 (19)	1/44 (2)	16.48 (0.83, 34.90), 0.0154	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_g3_sg.sas Output Generated: 20230419T14:58

Table 14.3.1.1.13.6. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by ECOG Performance (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders					
Neutropenia	ECOG = 0	43/92 (47)	19/94 (20)	26.53 (12.26, 39.44), <.0001	0.7423
	ECOG = 1	30/78 (38)	9/74 (12)	26.30 (11.62, 39.53), 0.0004	
Thrombocytopenia	ECOG = 0	8/92 (9)	23/94 (24)	-15.77 (-26.91, -4.30), 0.0050	0.8897
	ECOG = 1	6/78 (8)	14/74 (19)	-11.23 (-23.23, 0.62), 0.0421	
Febrile neutropenia	ECOG = 0	4/92 (4)	25/94 (27)	-22.25 (-32.95, -11.34), <.0001	0.4625
	ECOG = 1	2/78 (3)	21/74 (28)	-25.81 (-37.85, -13.81), <.0001	
Gastrointestinal disorders	ECOG = 0	5/92 (5)	13/94 (14)	-8.40 (-18.04, 1.09), 0.0536	0.6566
	ECOG = 1	10/78 (13)	17/74 (23)	-10.15 (-23.21, 3.03), 0.1138	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_g3_sg.sas Output Generated: 20230419T14:58

Table 14.3.1.1.13.6. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by ECOG Performance (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
General disorders and administration site conditions	ECOG = 0	11/92 (12)	10/94 (11)	1.32 (-8.82, 11.54), 0.6041	0.0433
	ECOG = 1	17/78 (22)	3/74 (4)	17.74 (6.17, 29.21), 0.0008	
Pyrexia	ECOG = 0	5/92 (5)	1/94 (1)	4.37 (-2.15, 11.81), 0.0554	0.9920
	ECOG = 1	10/78 (13)	0	12.82 (4.11, 22.77), 0.0007	
Investigations					
Platelet count decreased	ECOG = 0	2/92 (2)	34/94 (36)	-34.00 (-44.77, -22.67), <.0001	0.0307
	ECOG = 1	10/78 (13)	26/74 (35)	-22.31 (-35.85, -7.86), 0.0015	
Nervous system disorders	ECOG = 0	18/92 (20)	12/94 (13)	6.80 (-4.65, 18.19), 0.2041	0.0275
	ECOG = 1	21/78 (27)	3/74 (4)	22.87 (10.65, 34.69), 0.0001	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_g3_sg.sas Output Generated: 20230419T14:58

Table 14.3.1.1.13.6. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by ECOG Performance (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Encephalopathy	ECOG = 0	7/92 (8)	0	7.61 (1.14, 15.56), 0.0082	0.9998
	ECOG = 1	13/78 (17)	0	16.67 (7.23, 27.18), 0.0002	
Aphasia	ECOG = 0	5/92 (5)	0	NE	NE
	ECOG = 1	7/78 (9)	0	NE	
Psychiatric disorders	ECOG = 0	4/92 (4)	2/94 (2)	2.22 (-4.54, 9.47), 0.4264	0.9900
	ECOG = 1	12/78 (15)	0	15.38 (6.18, 25.73), 0.0005	
Confusional state	ECOG = 0	2/92 (2)	0	NE	NE
	ECOG = 1	7/78 (9)	0	NE	
Vascular disorders	ECOG = 0	12/92 (13)	5/94 (5)	7.72 (-1.56, 17.34), 0.0451	0.9486
	ECOG = 1	15/78 (19)	6/74 (8)	11.12 (-0.98, 22.94), 0.0308	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_g3_sg.sas Output Generated: 20230419T14:58

Table 14.3.1.1.13.6. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by ECOG Performance (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Hypotension	ECOG = 0	10/92 (11)	3/94 (3)	7.68 (-0.69, 16.64), 0.0221	0.8722
	ECOG = 1	9/78 (12)	2/74 (3)	8.84 (-0.73, 18.81), 0.0138	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_g3_sg.sas Output Generated: 20230419T14:58

Table 14.3.1.1.13.7. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by Central Lab Disease Type (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders					
Neutropenia	DLBCL NOS/without further classification possible	49/121 (40)	18/119 (15)	25.37 (13.55, 36.28), <.0001	0.7920
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	13/29 (45)	5/25 (20)	24.83 (-2.98, 47.67), 0.0275	
Thrombocytopenia	DLBCL NOS/without further classification possible	10/121 (8)	27/119 (23)	-14.42 (-24.06, -4.70), 0.0019	0.7629
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/29 (10)	6/25 (24)	-13.66 (-36.49, 9.17), 0.3638	
Febrile neutropenia	DLBCL NOS/without further classification possible	4/121 (3)	34/119 (29)	-25.27 (-34.66, -15.82), <.0001	0.7706
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/29 (3)	6/25 (24)	-20.55 (-42.32, 0.74), 0.0362	
Gastrointestinal disorders	DLBCL NOS/without further classification possible	10/121 (8)	22/119 (18)	-10.22 (-19.52, -0.97), 0.0227	0.9324
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/29 (10)	5/25 (20)	-9.66 (-32.28, 12.32), 0.3552	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_g3_sg.sas Output Generated: 20230419T14:58

Table 14.3.1.1.13.7. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by Central Lab Disease Type (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
General disorders and administration site conditions	DLBCL NOS/without further classification possible	19/121 (16)	9/119 (8)	8.14 (-0.69, 17.00), 0.0683	0.8675
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	5/29 (17)	2/25 (8)	9.24 (-13.01, 29.59), 0.5451	
Pyrexia	DLBCL NOS/without further classification possible	12/121 (10)	0	9.92 (3.99, 17.03), 0.0006	0.9998
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/29 (3)	0	3.45 (-13.45, 19.63), 0.4795	
Investigations					
Platelet count decreased	DLBCL NOS/without further classification possible	9/121 (7)	45/119 (38)	-30.38 (-40.49, -19.54), <.0001	0.6285
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/29 (7)	6/25 (24)	-17.10 (-39.36, 5.06), 0.1224	
Nervous system disorders	DLBCL NOS/without further classification possible	27/121 (22)	14/119 (12)	10.55 (0.38, 20.52), 0.0288	0.9878
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/29 (28)	0	27.59 (5.80, 47.49), 0.0062	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_g3_sg.sas Output Generated: 20230419T14:58

Table 14.3.1.1.13.7. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by Central Lab Disease Type (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Encephalopathy	DLBCL NOS/without further classification possible	14/121 (12)	0	11.57 (5.33, 18.97), 0.0001	1.0000
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/29 (10)	0	10.34 (-7.91, 28.50), 0.0538	
Aphasia	DLBCL NOS/without further classification possible	7/121 (6)	0	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/29 (10)	0	NE	
Psychiatric disorders	DLBCL NOS/without further classification possible	12/121 (10)	2/119 (2)	8.24 (1.64, 15.48), 0.0050	0.9939
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/29 (10)	0	10.34 (-7.91, 28.50), 0.1462	
Confusional state	DLBCL NOS/without further classification possible	7/121 (6)	0	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/29 (7)	0	NE	
Vascular disorders	DLBCL NOS/without further classification possible	22/121 (18)	4/119 (3)	14.82 (6.51, 23.40), 0.0002	0.0023
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/29 (10)	5/25 (20)	-9.66 (-32.28, 12.32), 0.3469	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_g3_sg.sas Output Generated: 20230419T14:58

Table 14.3.1.1.13.7. Subject Incidence of Frequent Grade 3 or Higher TEAEs by SOC and Preferred Term by Central Lab Disease Type (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Hypotension	DLBCL NOS/without further classification possible	15/121 (12)	1/119 (1)	11.56 (4.83, 19.13), 0.0004	0.0103
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/29 (7)	3/25 (12)	-5.10 (-26.22, 14.34), 0.3857	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_g3_sg.sas Output Generated: 20230419T14:58

Table 14.3.1.1.13. Subject Incidence of Frequent Grade 3 or Higher TEAEs by System Organ Class and Preferred Term (Safety Analysis Set)

Response Category	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	RD (95% CI), p-value	RR (95% CI), p-value	OR (95% CI), p-value
Blood and lymphatic system disorders	105 (62)	106 (63)	-1.33 (-11.94, 9.33), 0.7410	0.98 (0.83, 1.16), 0.8006	0.93 (0.58, 1.48), 0.8209
Neutropenia	73 (43)	28 (17)	26.27 (16.23, 35.62), <.0001	2.58 (1.76, 3.77), <.0001	3.77 (2.21, 6.54), <.0001
Anaemia	51 (30)	65 (39)	-8.69 (-18.97, 1.84), 0.0848	0.78 (0.58, 1.04), 0.0946	0.67 (0.41, 1.08), 0.1040
Thrombocytopenia	14 (8)	37 (22)	-13.79 (-21.77, -5.77), 0.0004	0.37 (0.21, 0.67), 0.0008	0.32 (0.15, 0.63), 0.0004
Febrile neutropenia	6 (4)	46 (27)	-23.85 (-31.64, -16.08), <.0001	0.13 (0.06, 0.29), <.0001	0.10 (0.03, 0.24), <.0001
Cardiac disorders	11 (6)	5 (3)	3.49 (-1.69, 8.93), 0.1355	2.17 (0.77, 6.12), 0.1415	2.24 (0.70, 8.37), 0.1995
Gastrointestinal disorders	15 (9)	30 (18)	-9.03 (-16.76, -1.34), 0.0156	0.49 (0.28, 0.88), 0.0176	0.45 (0.22, 0.90), 0.0168
Nausea	3 (2)	9 (5)	-3.59 (-8.65, 1.01), 0.0719	0.33 (0.09, 1.20), 0.0914	0.32 (0.05, 1.29), 0.0837
General disorders and administration site conditions	28 (16)	13 (8)	8.73 (1.32, 16.18), 0.0167	2.13 (1.14, 3.97), 0.0173	2.29 (1.10, 5.02), 0.0194
Pyrexia	15 (9)	1 (1)	8.23 (3.40, 13.83), 0.0004	14.82 (1.98, 110.96), 0.0087	16.06 (2.37, 666.27), 0.0004
Fatigue	11 (6)	4 (2)	4.09 (-0.92, 9.44), 0.0765	2.72 (0.88, 8.37), 0.0814	2.78 (0.79, 12.14), 0.1101
Infections and infestations	28 (16)	20 (12)	4.57 (-3.37, 12.47), 0.2158	1.38 (0.81, 2.36), 0.2323	1.49 (0.76, 2.90), 0.2757
Pneumonia	9 (5)	4 (2)	2.91 (-1.90, 8.00), 0.1677	2.22 (0.70, 7.08), 0.1763	2.27 (0.62, 10.20), 0.2602

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; MedDRA, Medical Dictionary for Regulatory Activities; NE, not evaluable; OR, odds ratio; RD, risk difference; RR, relative risk; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleuce column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.

Data Source: ADSL, ADAE Program Name: t_teae_socpt.sas Output Generated: 20230419T14:57

Table 14.3.1.1.13. Subject Incidence of Frequent Grade 3 or Higher TEAEs by System Organ Class and Preferred Term (Safety Analysis Set)

Response Category	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	RD (95% CI), p-value	RR (95% CI), p-value	OR (95% CI), p-value
Investigations	77 (45)	77 (46)	-0.54 (-11.44, 10.38), 0.8789	0.99 (0.78, 1.25), 0.9207	0.97 (0.61, 1.52), 0.9128
Neutrophil count decreased	49 (29)	47 (28)	0.85 (-9.14, 10.80), 0.9228	1.03 (0.73, 1.45), 0.8629	1.02 (0.62, 1.70), 1.0000
White blood cell count decreased	43 (25)	31 (18)	6.84 (-2.42, 15.95), 0.1444	1.37 (0.91, 2.06), 0.1313	1.48 (0.85, 2.57), 0.1502
Lymphocyte count decreased	29 (17)	18 (11)	6.34 (-1.52, 14.17), 0.1080	1.59 (0.92, 2.75), 0.0963	1.68 (0.85, 3.38), 0.1151
Platelet count decreased	12 (7)	60 (36)	-28.66 (-37.08, -19.81), <.0001	0.20 (0.11, 0.35), <.0001	0.14 (0.06, 0.27), <.0001
Metabolism and nutrition disorders	54 (32)	40 (24)	7.96 (-2.02, 17.71), 0.0940	1.33 (0.94, 1.89), 0.1053	1.52 (0.90, 2.56), 0.1082
Hypophosphataemia	31 (18)	21 (13)	5.74 (-2.44, 13.85), 0.1345	1.46 (0.87, 2.43), 0.1477	1.60 (0.83, 3.10), 0.1667
Hypokalaemia	10 (6)	11 (7)	-0.67 (-6.57, 5.18), 0.7991	0.90 (0.39, 2.06), 0.8001	0.89 (0.33, 2.39), 0.8255
Hyponatraemia	10 (6)	4 (2)	3.50 (-1.41, 8.73), 0.0959	2.47 (0.79, 7.72), 0.1199	2.58 (0.74, 11.84), 0.1079
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	13 (8)	9 (5)	2.29 (-3.63, 8.29), 0.3984	1.43 (0.63, 3.25), 0.3965	1.47 (0.56, 4.01), 0.5067
Nervous system disorders	39 (23)	15 (9)	14.01 (5.83, 22.09), 0.0004	2.57 (1.47, 4.48), 0.0009	3.05 (1.56, 6.24), 0.0005
Encephalopathy	20 (12)	0 (0)	11.76 (6.68, 17.81), <.0001	NE (NE, NE), NE	NE (7.02, NE), <.0001
Aphasia	12 (7)	0 (0)	7.06 (2.82, 12.29), 0.0005	NE (NE, NE), NE	NE (3.70, NE), 0.0004

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; MedDRA, Medical Dictionary for Regulatory Activities; NE, not evaluable; OR, odds ratio; RD, risk difference; RR, relative risk; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleuce column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.

Data Source: ADSL, ADAE Program Name: t_teae_socpt.sas Output Generated: 20230419T14:57

Table 14.3.1.1.13. Subject Incidence of Frequent Grade 3 or Higher TEAEs by System Organ Class and Preferred Term (Safety Analysis Set)

Response Category	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	RD (95% CI), p-value	RR (95% CI), p-value	OR (95% CI), p-value
Syncope	3 (2)	9 (5)	-3.59 (-8.65, 1.01), 0.0733	0.33 (0.09, 1.20), 0.0914	0.32 (0.05, 1.30), 0.0848
Psychiatric disorders	16 (9)	2 (1)	8.22 (3.09, 13.98), 0.0007	7.91 (1.85, 33.85), 0.0053	8.71 (1.98, 78.72), 0.0010
Confusional state	9 (5)	0 (0)	5.29 (1.42, 10.12), 0.0025	NE (NE, NE), NE	NE (2.59, NE), 0.0035
Respiratory, thoracic and mediastinal disorders	26 (15)	15 (9)	6.37 (-1.09, 13.83), 0.0756	1.71 (0.94, 3.12), 0.0781	1.82 (0.89, 3.86), 0.0960
Hypoxia	16 (9)	7 (4)	5.25 (-0.67, 11.38), 0.0509	2.26 (0.95, 5.35), 0.0640	2.37 (0.91, 7.14), 0.0552
Vascular disorders	27 (16)	11 (7)	9.33 (2.16, 16.58), 0.0070	2.43 (1.24, 4.73), 0.0093	2.70 (1.23, 6.21), 0.0091
Hypotension	19 (11)	5 (3)	8.20 (2.30, 14.45), 0.0038	3.76 (1.44, 9.83), 0.0070	4.03 (1.41, 14.07), 0.0051

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; MedDRA, Medical Dictionary for Regulatory Activities; NE, not evaluable; OR, odds ratio; RD, risk difference; RR, relative risk; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleuce column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.

Data Source: ADSL, ADAE Program Name: t_teae_socpt.sas Output Generated: 20230419T14:57

Tabelle 4-32 (Anhang): Subgruppenanalysen für häufige SUE nach SOC und PT - RCT mit dem zu bewertenden Arzneimittel (ZUMA-7)

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Table 14.3.1.1.14.1. Subject Incidence of Frequent Serious TEAEs by SOC and Preferred Term by Response to First-line Therapy Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders	Primary refractory	9/123 (7)	19/123 (15)	-8.13 (-16.84, 0.49), 0.0466	0.8566
	Relapse ≤ 12 months of first line therapy	3/47 (6)	7/45 (16)	-9.17 (-24.43, 5.72), 0.1603	
Febrile neutropenia	Primary refractory	5/123 (4)	17/123 (14)	-9.76 (-17.84, -2.00), 0.0080	0.7298
	Relapse ≤ 12 months of first line therapy	1/47 (2)	5/45 (11)	-8.98 (-22.87, 3.68), 0.0845	
General disorders and administration site conditions	Primary refractory	22/123 (18)	7/123 (6)	12.20 (3.56, 20.95), 0.0032	0.3798
	Relapse ≤ 12 months of first line therapy	7/47 (15)	4/45 (9)	6.00 (-9.57, 21.26), 0.3711	
Pyrexia	Primary refractory	22/123 (18)	5/123 (4)	13.82 (5.51, 22.38), 0.0006	0.2189
	Relapse ≤ 12 months of first line therapy	5/47 (11)	3/45 (7)	3.97 (-10.32, 18.11), 0.5042	
Nervous system disorders	Primary refractory	22/123 (18)	5/123 (4)	13.82 (5.51, 22.38), 0.0006	0.7260
	Relapse ≤ 12 months of first line therapy	10/47 (21)	3/45 (7)	14.61 (-1.56, 30.20), 0.0459	
Encephalopathy	Primary refractory	13/123 (11)	1/123 (1)	9.76 (3.46, 16.95), 0.0008	0.9929
	Relapse ≤ 12 months of first line therapy	4/47 (9)	0	8.51 (-2.85, 21.27), 0.0462	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_ser_sg.sas Output Generated: 20230419T14:59

Table 14.3.1.1.14.1. Subject Incidence of Frequent Serious TEAEs by SOC and Preferred Term by Response to First-line Therapy Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Aphasia	Primary refractory	7/123 (6)	0	NE	NE
	Relapse ≤ 12 months of first line therapy	2/47 (4)	0	NE	
Psychiatric disorders	Primary refractory	7/123 (6)	0	NE	NE
	Relapse ≤ 12 months of first line therapy	3/47 (6)	0	NE	
Vascular disorders	Primary refractory	15/123 (12)	2/123 (2)	10.57 (3.71, 18.11), 0.0011	0.4651
	Relapse ≤ 12 months of first line therapy	3/47 (6)	1/45 (2)	4.16 (-7.82, 16.52), 0.3212	
Hypotension	Primary refractory	13/123 (11)	2/123 (2)	8.94 (2.36, 16.22), 0.0035	0.3799
	Relapse ≤ 12 months of first line therapy	2/47 (4)	1/45 (2)	2.03 (-9.53, 13.70), 0.5775	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_ser_sg.sas Output Generated: 20230419T14:59

Table 14.3.1.1.14.2. Subject Incidence of Frequent Serious TEAEs by SOC and Preferred Term by Age (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders	Age < 65	5/121 (4)	17/113 (15)	-10.91 (-19.55, -2.77), 0.0045	0.0447
	Age ≥ 65	7/49 (14)	9/55 (16)	-2.08 (-17.23, 13.76), 0.6392	
Febrile neutropenia	Age < 65	5/121 (4)	16/113 (14)	-10.03 (-18.55, -2.02), 0.0081	0.7939
	Age ≥ 65	1/49 (2)	6/55 (11)	-8.87 (-21.04, 3.17), 0.1494	
General disorders and administration site conditions	Age < 65	17/121 (14)	7/113 (6)	7.85 (-0.68, 16.36), 0.0412	0.7188
	Age ≥ 65	12/49 (24)	4/55 (7)	17.22 (1.77, 32.71), 0.0604	
Pyrexia	Age < 65	15/121 (12)	6/113 (5)	7.09 (-1.04, 15.24), 0.0649	0.2739
	Age ≥ 65	12/49 (24)	2/55 (4)	20.85 (6.24, 35.85), 0.0121	
Nervous system disorders	Age < 65	22/121 (18)	5/113 (4)	13.76 (5.06, 22.49), 0.0010	0.9386
	Age ≥ 65	10/49 (20)	3/55 (5)	14.95 (0.59, 29.86), 0.0187	
Encephalopathy	Age < 65	11/121 (9)	1/113 (1)	8.21 (1.90, 15.21), 0.0020	0.9924
	Age ≥ 65	6/49 (12)	0	12.24 (1.40, 25.46), 0.0280	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_ser_sg.sas Output Generated: 20230419T15:00

Table 14.3.1.1.14.2. Subject Incidence of Frequent Serious TEAEs by SOC and Preferred Term by Age (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Aphasia	Age < 65	7/121 (6)	0	NE	NE
	Age ≥ 65	2/49 (4)	0	NE	
Psychiatric disorders	Age < 65	6/121 (5)	0	NE	NE
	Age ≥ 65	4/49 (8)	0	NE	
Vascular disorders	Age < 65	12/121 (10)	2/113 (2)	8.15 (1.37, 15.41), 0.0157	0.7936
	Age ≥ 65	6/49 (12)	1/55 (2)	10.43 (-1.22, 23.76), 0.0495	
Hypotension	Age < 65	9/121 (7)	2/113 (2)	NE	NE
	Age ≥ 65	6/49 (12)	1/55 (2)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_ser_sg.sas Output Generated: 20230419T15:00

Table 14.3.1.1.14.3. Subject Incidence of Frequent Serious TEAEs by SOC and Preferred Term by Second-line Age-adjusted IPI Score Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders	Second-line age-adjusted IPI score 0 - 1	8/97 (8)	14/93 (15)	-6.81 (-17.04, 3.23), 0.1433	0.4916
	Second-line age-adjusted IPI score 2 - 3	4/73 (5)	12/75 (16)	-10.52 (-21.82, 0.70), 0.0365	
Febrile neutropenia	Second-line age-adjusted IPI score 0 - 1	4/97 (4)	10/93 (11)	-6.63 (-15.63, 1.85), 0.0855	0.3583
	Second-line age-adjusted IPI score 2 - 3	2/73 (3)	12/75 (16)	-13.26 (-24.17, -2.78), 0.0052	
General disorders and administration site conditions	Second-line age-adjusted IPI score 0 - 1	14/97 (14)	6/93 (6)	7.98 (-1.72, 17.69), 0.0706	0.6150
	Second-line age-adjusted IPI score 2 - 3	15/73 (21)	5/75 (7)	13.88 (1.79, 26.01), 0.0153	
Pyrexia	Second-line age-adjusted IPI score 0 - 1	14/97 (14)	4/93 (4)	10.13 (0.92, 19.53), 0.0165	0.9803
	Second-line age-adjusted IPI score 2 - 3	13/73 (18)	4/75 (5)	12.47 (1.08, 24.13), 0.0187	
Nervous system disorders	Second-line age-adjusted IPI score 0 - 1	17/97 (18)	7/93 (8)	10.00 (-0.34, 20.23), 0.0403	0.0808
	Second-line age-adjusted IPI score 2 - 3	15/73 (21)	1/75 (1)	19.21 (8.49, 30.66), 0.0002	
Encephalopathy	Second-line age-adjusted IPI score 0 - 1	5/97 (5)	1/93 (1)	4.08 (-2.40, 11.18), 0.1117	0.9915
	Second-line age-adjusted IPI score 2 - 3	12/73 (16)	0	16.44 (6.95, 27.35), 0.0002	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_ser_sg.sas Output Generated: 20230419T15:00

Table 14.3.1.1.14.3. Subject Incidence of Frequent Serious TEAEs by SOC and Preferred Term by Second-line Age-adjusted IPI Score Per IXRS (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Aphasia	Second-line age-adjusted IPI score 0 - 1	5/97 (5)	0	NE	NE
	Second-line age-adjusted IPI score 2 - 3	4/73 (5)	0	NE	
Psychiatric disorders	Second-line age-adjusted IPI score 0 - 1	4/97 (4)	0	NE	NE
	Second-line age-adjusted IPI score 2 - 3	6/73 (8)	0	NE	
Vascular disorders	Second-line age-adjusted IPI score 0 - 1	10/97 (10)	2/93 (2)	8.16 (0.25, 16.60), 0.0229	0.6590
	Second-line age-adjusted IPI score 2 - 3	8/73 (11)	1/75 (1)	9.63 (0.64, 19.73), 0.0122	
Hypotension	Second-line age-adjusted IPI score 0 - 1	9/97 (9)	2/93 (2)	NE	NE
	Second-line age-adjusted IPI score 2 - 3	6/73 (8)	1/75 (1)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_ser_sg.sas Output Generated: 20230419T15:00

Table 14.3.1.1.14.4. Subject Incidence of Frequent Serious TEAEs by SOC and Preferred Term by Sex (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders	Male	4/106 (4)	17/120 (14)	-10.39 (-18.63, -2.16), 0.0078	0.2614
	Female	8/64 (13)	9/48 (19)	-6.25 (-22.04, 8.32), 0.4685	
Febrile neutropenia	Male	2/106 (2)	13/120 (11)	-8.95 (-16.42, -1.76), 0.0092	0.7005
	Female	4/64 (6)	9/48 (19)	-12.50 (-27.46, 0.99), 0.0525	
General disorders and administration site conditions	Male	14/106 (13)	7/120 (6)	7.37 (-0.97, 16.28), 0.0332	0.7798
	Female	15/64 (23)	4/48 (8)	15.10 (-0.51, 28.85), 0.0173	
Pyrexia	Male	12/106 (11)	5/120 (4)	7.15 (-0.53, 15.56), 0.0272	0.6577
	Female	15/64 (23)	3/48 (6)	17.19 (2.03, 30.55), 0.0080	
Nervous system disorders	Male	20/106 (19)	3/120 (3)	16.37 (7.90, 25.56), <.0001	0.1046
	Female	12/64 (19)	5/48 (10)	8.33 (-7.10, 22.07), 0.1710	
Encephalopathy	Male	9/106 (8)	0	NE	NE
	Female	8/64 (13)	1/48 (2)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_ser_sg.sas Output Generated: 20230419T15:00

Table 14.3.1.1.14.4. Subject Incidence of Frequent Serious TEAEs by SOC and Preferred Term by Sex (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Aphasia	Male	7/106 (7)	0	NE	NE
	Female	2/64 (3)	0	NE	
Psychiatric disorders	Male	5/106 (5)	0	NE	NE
	Female	5/64 (8)	0	NE	
Vascular disorders	Male	10/106 (9)	2/120 (2)	7.77 (1.12, 15.52), 0.0118	0.9033
	Female	8/64 (13)	1/48 (2)	10.42 (-1.87, 21.79), 0.0419	
Hypotension	Male	7/106 (7)	2/120 (2)	NE	NE
	Female	8/64 (13)	1/48 (2)	NE	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_ser_sg.sas Output Generated: 20230419T15:00

Table 14.3.1.1.14.5. Subject Incidence of Frequent Serious TEAEs by SOC and Preferred Term by Geographic Region (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders	North America	11/132 (8)	21/120 (18)	-9.17 (-18.28, -0.30), 0.0283	0.9891
	Europe	0	5/44 (11)	-11.36 (-25.35, 3.75), 0.0501	
Febrile neutropenia	North America	5/132 (4)	17/120 (14)	-10.38 (-18.56, -2.79), 0.0031	0.9913
	Europe	0	5/44 (11)	-11.36 (-25.35, 3.75), 0.0501	
General disorders and administration site conditions	North America	26/132 (20)	8/120 (7)	13.03 (4.07, 21.79), 0.0029	0.1966
	Europe	2/32 (6)	3/44 (7)	-0.57 (-14.45, 16.17), 0.7097	
Pyrexia	North America	24/132 (18)	6/120 (5)	13.18 (4.71, 21.58), 0.0015	0.3382
	Europe	2/32 (6)	2/44 (5)	1.70 (-11.50, 18.11), 0.9182	
Nervous system disorders	North America	24/132 (18)	5/120 (4)	14.02 (5.72, 22.31), 0.0005	0.7122
	Europe	7/32 (22)	3/44 (7)	15.06 (-2.51, 34.30), 0.1350	
Encephalopathy	North America	13/132 (10)	0	9.85 (4.08, 16.57), 0.0004	0.9919
	Europe	4/32 (13)	1/44 (2)	10.23 (-3.81, 27.79), 0.1645	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_ser_sg.sas Output Generated: 20230419T15:01

Table 14.3.1.1.14.5. Subject Incidence of Frequent Serious TEAEs by SOC and Preferred Term by Geographic Region (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Aphasia	North America	8/132 (6)	0	NE	NE
	Europe	1/32 (3)	0	NE	
Psychiatric disorders	North America	8/132 (6)	0	NE	NE
	Europe	2/32 (6)	0	NE	
Vascular disorders	North America	15/132 (11)	3/120 (3)	8.86 (1.90, 16.09), 0.0066	0.9909
	Europe	3/32 (9)	0	9.38 (-2.79, 26.17), 0.0745	
Hypotension	North America	12/132 (9)	3/120 (3)	6.59 (-0.01, 13.43), 0.0285	0.9912
	Europe	3/32 (9)	0	9.38 (-2.79, 26.17), 0.0745	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_ser_sg.sas Output Generated: 20230419T15:01

Table 14.3.1.1.14.6. Subject Incidence of Frequent Serious TEAEs by SOC and Preferred Term by ECOG Performance (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders	ECOG = 0	5/92 (5)	13/94 (14)	-8.40 (-18.04, 1.09), 0.0710	0.8156
	ECOG = 1	7/78 (9)	13/74 (18)	-8.59 (-20.64, 3.29), 0.1646	
Febrile neutropenia	ECOG = 0	4/92 (4)	10/94 (11)	-6.29 (-15.27, 2.42), 0.1243	0.2993
	ECOG = 1	2/78 (3)	12/74 (16)	-13.65 (-24.65, -3.44), 0.0109	
General disorders and administration site conditions	ECOG = 0	12/92 (13)	2/94 (2)	10.92 (2.49, 20.10), 0.0059	0.1716
	ECOG = 1	17/78 (22)	9/74 (12)	9.63 (-3.45, 22.27), 0.1317	
Pyrexia	ECOG = 0	12/92 (13)	1/94 (1)	11.98 (3.92, 21.05), 0.0017	0.1317
	ECOG = 1	15/78 (19)	7/74 (9)	9.77 (-2.57, 21.79), 0.0806	
Nervous system disorders	ECOG = 0	12/92 (13)	5/94 (5)	7.72 (-1.56, 17.34), 0.0629	0.2079
	ECOG = 1	20/78 (26)	3/74 (4)	21.59 (9.52, 33.33), 0.0002	
Encephalopathy	ECOG = 0	6/92 (7)	0	6.52 (0.30, 14.20), 0.0142	0.9940
	ECOG = 1	11/78 (14)	1/74 (1)	12.75 (3.21, 22.98), 0.0018	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_ser_sg.sas Output Generated: 20230419T15:01

Table 14.3.1.1.14.6. Subject Incidence of Frequent Serious TEAEs by SOC and Preferred Term by ECOG Performance (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Aphasia	ECOG = 0	4/92 (4)	0	NE	NE
	ECOG = 1	5/78 (6)	0	NE	
Psychiatric disorders	ECOG = 0	3/92 (3)	0	NE	NE
	ECOG = 1	7/78 (9)	0	NE	
Vascular disorders	ECOG = 0	10/92 (11)	2/94 (2)	8.74 (0.71, 17.56), 0.0145	0.7396
	ECOG = 1	8/78 (10)	1/74 (1)	8.91 (0.08, 18.46), 0.0126	
Hypotension	ECOG = 0	10/92 (11)	2/94 (2)	8.74 (0.71, 17.56), 0.0145	0.9573
	ECOG = 1	5/78 (6)	1/74 (1)	5.06 (-2.99, 13.71), 0.0697	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_ser_sg.sas Output Generated: 20230419T15:01

Table 14.3.1.1.14.7. Subject Incidence of Frequent Serious TEAEs by SOC and Preferred Term by Central Lab Disease Type (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Blood and lymphatic system disorders	DLBCL NOS/without further classification possible	7/121 (6)	17/119 (14)	-8.50 (-17.02, -0.21), 0.0319	0.5328
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/29 (14)	4/25 (16)	-2.21 (-25.09, 19.43), 0.8479	
Febrile neutropenia	DLBCL NOS/without further classification possible	4/121 (3)	13/119 (11)	-7.62 (-15.32, -0.39), 0.0238	0.6111
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	1/29 (3)	4/25 (16)	-12.55 (-33.72, 6.87), 0.1788	
General disorders and administration site conditions	DLBCL NOS/without further classification possible	18/121 (15)	9/119 (8)	7.31 (-1.41, 16.08), 0.0945	0.2072
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	7/29 (24)	1/25 (4)	20.14 (-2.40, 40.28), 0.0275	
Pyrexia	DLBCL NOS/without further classification possible	16/121 (13)	7/119 (6)	7.34 (-0.85, 15.67), 0.0598	0.9902
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	7/29 (24)	0	24.14 (3.00, 43.93), 0.0128	
Nervous system disorders	DLBCL NOS/without further classification possible	20/121 (17)	8/119 (7)	9.81 (1.02, 18.65), 0.0181	0.9895
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	8/29 (28)	0	27.59 (5.80, 47.49), 0.0057	
Encephalopathy	DLBCL NOS/without further classification possible	10/121 (8)	1/119 (1)	7.42 (1.44, 14.25), 0.0058	0.9942
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	4/29 (14)	0	13.79 (-5.20, 32.57), 0.0374	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_ser_sg.sas Output Generated: 20230419T15:01

Table 14.3.1.1.14.7. Subject Incidence of Frequent Serious TEAEs by SOC and Preferred Term by Central Lab Disease Type (Safety Analysis Set)

MedDRA SOC PT	Level	Axicabtagene Ciloleucel n/N (%)	Standard of Care n/N (%)	RD (95% CI), p-value	p-value for interaction
Aphasia	DLBCL NOS/without further classification possible	5/121 (4)	0	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/29 (7)	0	NE	
Psychiatric disorders	DLBCL NOS/without further classification possible	7/121 (6)	0	NE	NE
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	3/29 (10)	0	NE	
Vascular disorders	DLBCL NOS/without further classification possible	15/121 (12)	1/119 (1)	11.56 (4.83, 19.13), 0.0002	0.1354
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/29 (7)	1/25 (4)	2.90 (-16.29, 20.62), 0.5658	
Hypotension	DLBCL NOS/without further classification possible	12/121 (10)	1/119 (1)	9.08 (2.79, 16.23), 0.0016	0.2042
	HGBL with or without MYC and BCL2 and/or BCL6 rearrangement	2/29 (7)	1/25 (4)	2.90 (-16.29, 20.62), 0.5658	

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; ASCT, autologous stem cell transplant; CRS, cytokine release syndrome; CTCAE, Common Terminology Criteria for Adverse Events; IXRS, interactive voice/web response system; NA, not applicable; NE, not evaluated; PT, preferred term; RD, risk difference; SOC; system organ class; TE, treatment-emergent; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleucel column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.
Note: The percentages are based on the number of subjects in the subgroup (N) as the denominator.
Note: For RD, two-sided p-value from CMH test is presented. P-value for interaction is calculated based on stratified logistic regression model.

Data Source: ADSL, ADAE Program Name: t_socpt_ser_sg.sas Output Generated: 20230419T15:01

Table 14.3.1.1.14. Subject Incidence of Frequent Serious TEAEs by System Organ Class and Preferred Term (Safety Analysis Set)

Response Category	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	RD (95% CI), p-value	RR (95% CI), p-value	OR (95% CI), p-value
Blood and lymphatic system disorders	12 (7)	26 (15)	-8.42 (-15.72, -1.22), 0.0136	0.46 (0.24, 0.87), 0.0179	0.41 (0.18, 0.88), 0.0157
Febrile neutropenia	6 (4)	22 (13)	-9.57 (-16.18, -3.29), 0.0015	0.27 (0.11, 0.65), 0.0034	0.24 (0.08, 0.64), 0.0014
Cardiac disorders	12 (7)	6 (4)	3.49 (-1.94, 9.13), 0.1514	1.98 (0.76, 5.14), 0.1627	2.06 (0.69, 6.82), 0.2263
Gastrointestinal disorders	9 (5)	13 (8)	-2.44 (-8.48, 3.45), 0.3750	0.68 (0.30, 1.56), 0.3659	0.67 (0.25, 1.76), 0.3885
General disorders and administration site conditions	29 (17)	11 (7)	10.51 (3.21, 17.87), 0.0028	2.61 (1.35, 5.04), 0.0045	2.95 (1.36, 6.78), 0.0037
Pyrexia	27 (16)	8 (5)	11.12 (4.25, 18.16), 0.0008	3.34 (1.56, 7.13), 0.0019	3.70 (1.60, 9.88), 0.0011
Infections and infestations	31 (18)	18 (11)	7.52 (-0.45, 15.45), 0.0517	1.70 (0.99, 2.92), 0.0537	1.84 (0.95, 3.66), 0.0643
Pneumonia	11 (6)	4 (2)	4.09 (-0.92, 9.44), 0.0730	2.72 (0.88, 8.37), 0.0814	2.76 (0.81, 12.09), 0.1129
Metabolism and nutrition disorders	3 (2)	9 (5)	-3.59 (-8.65, 1.01), 0.0771	0.33 (0.09, 1.20), 0.0914	0.32 (0.06, 1.32), 0.0869
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	15 (9)	8 (5)	4.06 (-1.90, 10.18), 0.1446	1.85 (0.81, 4.25), 0.1458	1.94 (0.74, 5.36), 0.1948
Nervous system disorders	32 (19)	8 (5)	14.06 (6.87, 21.38), <.0001	3.95 (1.88, 8.33), 0.0003	4.54 (1.99, 11.88), <.0001
Encephalopathy	17 (10)	1 (1)	9.40 (4.38, 15.21), <.0001	16.80 (2.26, 124.82), 0.0058	17.71 (2.93, 814.91), <.0001
Aphasia	9 (5)	0 (0)	5.29 (1.42, 10.12), 0.0022	NE (NE, NE), NE	NE (2.67, NE), 0.0016

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; MedDRA, Medical Dictionary for Regulatory Activities; NE, not evaluable; OR, odds ratio; RD, risk difference; RR, relative risk; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleuce column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.

Data Source: ADSL, ADAE Program Name: t_teae_socpt.sas Output Generated: 20230419T14:57

Table 14.3.1.1.14. Subject Incidence of Frequent Serious TEAEs by System Organ Class and Preferred Term (Safety Analysis Set)

Response Category	Axicabtagene Ciloleucel (N = 170)	Standard of Care (N = 168)	RD (95% CI), p-value	RR (95% CI), p-value	OR (95% CI), p-value
Psychiatric disorders	10 (6)	0 (0)	5.88 (1.89, 10.85), 0.0012	NE (NE, NE), NE	NE (3.05, NE), 0.0007
Respiratory, thoracic and mediastinal disorders	10 (6)	7 (4)	1.72 (-3.68, 7.20), 0.4846	1.41 (0.55, 3.62), 0.4731	1.42 (0.48, 4.50), 0.6211
Vascular disorders	18 (11)	3 (2)	8.80 (3.30, 14.82), 0.0008	5.93 (1.78, 19.76), 0.0037	6.59 (1.85, 35.42), 0.0010
Hypotension	15 (9)	3 (2)	7.04 (1.81, 12.76), 0.0040	4.94 (1.46, 16.76), 0.0103	5.33 (1.46, 29.16), 0.0061

Data cutoff date = 25JAN2023
Abbreviations: AE, adverse event; MedDRA, Medical Dictionary for Regulatory Activities; NE, not evaluable; OR, odds ratio; RD, risk difference; RR, relative risk; TEAE, treatment-emergent adverse event.
Note: TEAE includes all AEs with an onset on or after the axicabtagene ciloleucel infusion date in the axicabtagene ciloleucel arm or the first dose of salvage chemotherapy in the standard of care arm.
Note: Multiple incidences of the same AE in one subject are counted once at the worst grade for each subject.
Note: System organ class is sorted by alphabetical order. Preferred terms are sorted in descending order of frequency count in the axicabtagene ciloleuce column within each system organ class.
Note: AEs are coded using MedDRA version 25.1 and graded per CTCAE version 4.03.

Data Source: ADSL, ADAE Program Name: t_teae_socpt.sas Output Generated: 20230419T14:57

Anhang 4-G4: Ergänzende Darstellung der Ergebnisse aus weiteren Untersuchungen (ALYCANTE)

Anhang 4-G4.1: Ergänzende Darstellung zu unerwünschte Ereignisse - weitere Untersuchungen mit dem zu bewertenden Arzneimittel (ALYCANTE)

Tabelle 4-33 (Anhang): UESI nach SOC und PT - weitere Untersuchungen mit dem zu bewertenden Arzneimittel (ALYCANTE)

4.9.1.8 AESI

Table 92 Description of AESI by type of special interest and PT - mFAS

System Organ Class Preferred Term	mFAS (40 first patients) N=40		mFAS N=62	
	Patients	Events	Patients	Events
AESI	**40 (100.0%)**	**199**	**62 (100.0%)**	**283**
IMMUNE SYSTEM DISORDERS	**36 (90.0%)**	**61**	**58 (93.5%)**	**97**
CYTOKINE RELEASE SYNDROME	36 (90.0%)	38	58 (93.5%)	60
HYPOGAMMAGLOBULINAEMIA	20 (50.0%)	23	33 (53.2%)	37
BLOOD AND LYMPHATIC SYSTEM DISORDERS*	**26 (65.0%)**	**58**	**40 (64.5%)**	**84**
ANAEMIA	19 (47.5%)	19	29 (46.8%)	29
NEUTROPENIA	18 (45.0%)	20	26 (41.9%)	28
THROMBOCYTOPENIA	18 (45.0%)	18	26 (41.9%)	26
PANCYTOPENIA	1 (2.5%)	1	1 (1.6%)	1
INFECTIONS AND INFESTATIONS	**24 (60.0%)**	**54**	**32 (51.6%)**	**65**
COVID-19	12 (30.0%)	12	15 (24.2%)	16
RESPIRATORY TRACT INFECTION	6 (15.0%)	8	7 (11.3%)	9
SEPSIS	5 (12.5%)	7	5 (8.1%)	7
URINARY TRACT INFECTION	5 (12.5%)	6	5 (8.1%)	6
BACTERIAL INFECTION	3 (7.5%)	3	4 (6.5%)	4
VIRAL INFECTION	3 (7.5%)	4	4 (6.5%)	5
GASTROINTESTINAL INFECTION	2 (5.0%)	2	3 (4.8%)	3
POST-ACUTE COVID-19 SYNDROME	2 (5.0%)	2	4 (6.5%)	4
SKIN INFECTION	2 (5.0%)	2	2 (3.2%)	2
ASPERGILLUS INFECTION	1 (2.5%)	1	1 (1.6%)	1
CANDIDA INFECTION	1 (2.5%)	1	1 (1.6%)	1
FUNGAL INFECTION DISORDER	1 (2.5%)	1	1 (1.6%)	1
HERPES VIRUS INFECTION	1 (2.5%)	1	1 (1.6%)	1
MENINGOENCEPHALITIS VIRAL	1 (2.5%)	1	1 (1.6%)	1
MUCORMYCOSIS	1 (2.5%)	1	1 (1.6%)	1
PERINEAL INFECTION	1 (2.5%)	1	1 (1.6%)	1
SUPERINFECTION BACTERIAL	1 (2.5%)	1	1 (1.6%)	1
BACILLUS INFECTION	0 (0.0%)	0	1 (1.6%)	1
NERVOUS SYSTEM DISORDERS	**22 (55.0%)**	**23**	**32 (51.6%)**	**34**
IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME	22 (55.0%)	23	32 (51.6%)	34
INVESTIGATION	**3 (7.5%)**	**3**	**3 (4.8%)**	**3**
BLOOD ELECTROLYTE DECREASED	3 (7.5%)	3	3 (4.8%)	3

* prolonged cytopenia

Tabelle 4-34 (Anhang): Häufige UE nach SOC und PT (jeglicher Grad)- weitere Untersuchungen mit dem zu bewertenden Arzneimittel (ALYCANTE)

AE (Any Grade)

SYSTEM ORGAN CLASS PREFERRED TERM	**PATIENTS**
AE	62 (100.0%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	59 (95.2%)
ANAEMIA	45 (72.6%)
NEUTROPENIA	45 (72.6%)
THROMBOCYTOPENIA	35 (56.5%)
LEUKOPENIA	15 (24.2%)
LYMPHOPENIA	20 (32.3%)
IMMUNE SYSTEM DISORDERS	58 (93.5%)
CYTOKINE RELEASE SYNDROME	58 (93.5%)
HYPOGAMMAGLOBULINAEMIA	34 (54.8%)
INFECTIONS AND INFESTATIONS	33 (53.2%)
COVID-19	15 (24.2%)
URINARY TRACT INFECTION	7 (11.3%)
RESPIRATORY TRACT INFECTION	7 (11.3%)
NERVOUS SYSTEM DISORDERS	33 (53.2%)
IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME	32 (51.6%)
GASTROINTESTINAL DISORDERS	20 (32.3%)
NAUSEA	11 (17.7%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	14 (22.6%)
INVESTIGATIONS	10 (16.1%)
BLOOD ELECTROLYTE DECREASED	8 (12.9%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	8 (12.9%)

Tabelle 4-35 (Anhang): Häufige UE von Grad ≥3 nach SOC und PT - weitere Untersuchungen mit dem zu bewertenden Arzneimittel (ALYCANTE)

AE ≥3

SYSTEM ORGAN CLASS PREFERRED TERM	**PATIENTS**
AE with CTCAE grade (or ASTCT if CRS) ≥3	59 (95.2%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	55 (88.7%)
NEUTROPENIA	41 (66.1%)
ANAEMIA	24 (38.7%)
THROMBOCYTOPENIA	24 (38.7%)
LEUKOPENIA	15 (24.2%)
LYMPHOPENIA	18 (29.0%)
FEBRILE BONE MARROW APLASIA	5 (8.1%)
INFECTIONS AND INFESTATIONS	15 (24.2%)
COVID-19	7 (11.3%)
SEPSIS	5 (8.1%)
NERVOUS SYSTEM DISORDERS	9 (14.5%)
IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME	9 (14.5%)
IMMUNE SYSTEM DISORDERS	6 (9.7%)
CYTOKINE RELEASE SYNDROME	5 (8.1%)

Tabelle 4-36 (Anhang): Häufige SUE nach SOC und PT - weitere Untersuchungen mit dem zu bewertenden Arzneimittel (ALYCANTE)

SAE

SYSTEM ORGAN CLASS PREFERRED TERM	**PATIENTS**
SAE	27 (43.5%)
NERVOUS SYSTEM DISORDERS	13 (21.0%)
IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME	13 (21.0%)
INFECTIONS AND INFESTATIONS	9 (14.5%)
IMMUNE SYSTEM DISORDERS	9 (14.5%)
CYTOKINE RELEASE SYNDROME	9 (14.5%)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	5 (8.1%)