Eigene Vorlage

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Bempedoinsäure/Ezetimib (NUSTENDI®)

Daiichi Sankyo Deutschland GmbH

Modul 4 A – Anhang 4-G

Erwachsene Patienten mit primärer Hypercholesterinämie (heterozygot familiär und nicht-familiär) oder gemischter Dyslipidämie

Medizinischer Nutzen und
medizinischer Zusatznutzen,
Patientengruppen mit therapeutisch
bedeutsamem Zusatznutzen

Stand: 29.10.2020

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Bempedoic Acid (ETC-1002), Study 1002FDC-053
Duration of Treatment
Full Analysis Set

	FDC (N= 108)	Placebo (N= 55)	Total (N= 163)
Duration of treatment (days)			
n	107	55	162
Mean	82.1	77.7	80.6
Median	84.0	84.0	84.0
Range	8 - 112	9 - 98	8 - 112
Duration category (days)			
0-<35	3 (2.8%)	6 (10.9%)	9 (5.6%)
35-<63	3 (2.8%)	0	3 (1.9%)
63-<80	8 (7.5%)	3 (5.5%)	11 (6.8%)
80-<91	86 (80.4%)	44 (80.0%)	130 (80.2%)
>=91	7 (6.5%)	2 (3.6%)	9 (5.6%)

Abbreviations: FDC=fixed dose combination, N=number of patients.
Note: Duration of treatment = the day of end of treatment - the day of start of treatment + 1.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12
Full Analysis Set

	FDC vs. Placebo	FDC (N= 108)	Placebo (N= 55)	Total (N= 163)
Number of patients at risk		108 (100.0%)	55 (100.0%)	163 (100.0%)
Number of patients with events		29 (26.9%)	1 (1.8%)	30 (18.4%)
Number of patients without events		79 (73.1%)	54 (98.2%)	133 (81.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	19.823 [2.621, 149.92]			
Stratified OR, 95% CI	7.874 [2.053, 30.202]			
Relative Risk [a]				
Unstratified RR, 95% CI	14.769 [2.066, 105.57]			
Stratified RR, 95% CI	5.877 [1.680, 20.558]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.250 [0.160, 0.341]			
Stratified ARR, 95% CI (CMH method)	0.252 [0.161, 0.342]			
Test on Differences [c]				
Unstratified p-value	<.0001			
Stratified p-value	<.0001			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Gender
Full Analysis Set

Gender: Male

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)	Total (N= 83)
Number of patients at risk		50 (100.0%)	33 (100.0%)	83 (100.0%)
Number of patients with events		12 (24.0%)	1 (3.0%)	13 (15.7%)
Number of patients without events		38 (76.0%)	32 (97.0%)	70 (84.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	10.105 [1.246, 81.986]			
Stratified OR, 95% CI	4.716 [0.942, 23.626]			
Relative Risk [a]				
Unstratified RR, 95% CI	7.920 [1.080, 58.059]			
Stratified RR, 95% CI	3.645 [0.844, 15.732]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.210 [0.078, 0.342]			
Stratified ARR, 95% CI (CMH method)	0.209 [0.076, 0.341]			
Test on Differences [c]				
Unstratified p-value	0.0122			
Stratified p-value	0.0099			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Gender
Full Analysis Set

Gender: Female

	FDC vs. Placebo	FDC (N= 58)	Placebo (N= 22)	Total (N= 80)
Number of patients at risk		58 (100.0%)	22 (100.0%)	80 (100.0%)
Number of patients with events		17 (29.3%)	0	17 (21.3%)
Number of patients without events		41 (70.7%)	22 (100.0%)	63 (78.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	18.976 [1.089, 330.55]			
Stratified OR, 95% CI	4.987 [1.056, 23.544]			
Relative Risk [a]				
Unstratified RR, 95% CI	13.644 [0.855, 217.64]			
Stratified RR, 95% CI	3.727 [0.934, 14.877]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.293 [0.176, 0.410]			
Stratified ARR, 95% CI (CMH method)	0.283 [0.165, 0.401]			
Test on Differences [c]				
Unstratified p-value	0.0042			
Stratified p-value	0.0062			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with LDL-C <70 mg/dL at Week 12 by Gender
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.2762
Female vs. Male		0.0417	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia,
LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, LR=likelihood ratio.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Age
Full Analysis Set

Age (years): < 65

	FDC vs. Placebo	FDC (N= 58)	Placebo (N= 27)	Total (N= 85)
Number of patients at risk		58 (100.0%)	27 (100.0%)	85 (100.0%)
Number of patients with events		11 (19.0%)	1 (3.7%)	12 (14.1%)
Number of patients without events		47 (81.0%)	26 (96.3%)	73 (85.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.085 [0.743, 49.812]			
Stratified OR, 95% CI	2.595 [0.606, 11.125]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.121 [0.696, 37.669]			
Stratified RR, 95% CI	2.207 [0.613, 7.943]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.153 [0.029, 0.276]			
Stratified ARR, 95% CI (CMH method)	0.145 [0.018, 0.271]			
Test on Differences [c]				
Unstratified p-value	0.0928			
Stratified p-value	0.0753			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Age
Full Analysis Set

Age (years): >= 65

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)	Total (N= 78)
Number of patients at risk		50 (100.0%)	28 (100.0%)	78 (100.0%)
Number of patients with events		18 (36.0%)	0	18 (23.1%)
Number of patients without events		32 (64.0%)	28 (100.0%)	60 (76.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	32.446 [1.870, 563.00]			
Stratified OR, 95% CI	8.218 [1.743, 38.748]			
Relative Risk [a]				
Unstratified RR, 95% CI	21.039 [1.316, 336.36]			
Stratified RR, 95% CI	5.391 [1.344, 21.624]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.360 [0.227, 0.493]			
Stratified ARR, 95% CI (CMH method)	0.367 [0.232, 0.501]			
Test on Differences [c]				
Unstratified p-value	0.0001			
Stratified p-value	0.0003			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with LDL-C <70 mg/dL at Week 12 by Age
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.1416
>= 65 vs. < 65		0.1087	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia,
LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, LR=likelihood ratio.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by CVD Risk Category
Full Analysis Set

CVD Risk Category: ASCVD and/or HeFH

	FDC vs. Placebo	FDC (N= 60)	Placebo (N= 31)	Total (N= 91)
Number of patients at risk		60 (100.0%)	31 (100.0%)	91 (100.0%)
Number of patients with events		20 (33.3%)	1 (3.2%)	21 (23.1%)
Number of patients without events		40 (66.7%)	30 (96.8%)	70 (76.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	15.000 [1.905, 118.09]			
Stratified OR, 95% CI	9.844 [1.745, 55.521]			
Relative Risk [a]				
Unstratified RR, 95% CI	10.333 [1.454, 73.434]			
Stratified RR, 95% CI	6.837 [1.378, 33.929]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.301 [0.167, 0.436]			
Stratified ARR, 95% CI (CMH method)	0.301 [0.166, 0.436]			
Test on Differences [c]				
Unstratified p-value	0.0012			
Stratified p-value	0.0014			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by CVD Risk Category
Full Analysis Set

CVD Risk Category: Multiple CV risk factors

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		9 (18.8%)	0	9 (12.5%)
Number of patients without events		39 (81.3%)	24 (100.0%)	63 (87.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	11.785 [0.656, 211.65]			
Stratified OR, 95% CI	5.897 [0.700, 49.681]			
Relative Risk [a]				
Unstratified RR, 95% CI	9.694 [0.588, 159.85]			
Stratified RR, 95% CI	4.848 [0.655, 35.862]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.188 [0.077, 0.298]			
Stratified ARR, 95% CI (CMH method)	0.188 [0.077, 0.298]			
Test on Differences [c]				
Unstratified p-value	0.0247			
Stratified p-value	0.0254			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Table 1002FDC.053.101.1.3.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with LDL-C <70 mg/dL at Week 12 by CVD Risk Category
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.3967
Multiple CV risk factors vs. ASCVD and/or HeFH		0.0196	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia,
LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, LR=likelihood ratio.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Baseline Statin Intensity I
Full Analysis Set

Baseline Statin Dose Intensity I: Other

	FDC vs. Placebo	FDC (N= 66)	Placebo (N= 34)	Total (N= 100)
Number of patients at risk		66 (100.0%)	34 (100.0%)	100 (100.0%)
Number of patients with events		17 (25.8%)	1 (2.9%)	18 (18.0%)
Number of patients without events		49 (74.2%)	33 (97.1%)	82 (82.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	11.449 [1.453, 90.235]			
Stratified OR, 95% CI	7.964 [1.409, 45.024]			
Relative Risk [a]				
Unstratified RR, 95% CI	8.758 [1.217, 63.042]			
Stratified RR, 95% CI	5.976 [1.194, 29.913]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.228 [0.108, 0.348]			
Stratified ARR, 95% CI (CMH method)	0.227 [0.108, 0.345]			
Test on Differences [c]				
Unstratified p-value	0.0049			
Stratified p-value	0.0051			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Baseline Statin Intensity I
Full Analysis Set

Baseline Statin Dose Intensity I: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		12 (28.6%)	0	12 (19.0%)
Number of patients without events		30 (71.4%)	21 (100.0%)	51 (81.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	17.623 [0.989, 313.96]			
Stratified OR, 95% CI	8.133 [0.970, 68.224]			
Relative Risk [a]				
Unstratified RR, 95% CI	12.791 [0.794, 206.10]			
Stratified RR, 95% CI	5.981 [0.822, 43.518]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.286 [0.149, 0.422]			
Stratified ARR, 95% CI (CMH method)	0.291 [0.154, 0.428]			
Test on Differences [c]				
Unstratified p-value	0.0055			
Stratified p-value	0.0062			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with LDL-C <70 mg/dL at Week 12 by Baseline Statin Intensity I
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.3080
High Intensity Statin vs. Other		0.0312	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia,
LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, LR=likelihood ratio.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Baseline Statin Intensity II
Full Analysis Set

Baseline Statin Dose Intensity II: Other Intensity Statin

	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 20)	Total (N= 53)
Number of patients at risk		33 (100.0%)	20 (100.0%)	53 (100.0%)
Number of patients with events		10 (30.3%)	1 (5.0%)	11 (20.8%)
Number of patients without events		23 (69.7%)	19 (95.0%)	42 (79.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	8.261 [0.968, 70.462]			
Stratified OR, 95% CI	5.832 [0.928, 36.632]			
Relative Risk [a]				
Unstratified RR, 95% CI	6.061 [0.837, 43.859]			
Stratified RR, 95% CI	4.113 [0.820, 20.638]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.253 [0.069, 0.437]			
Stratified ARR, 95% CI (CMH method)	0.243 [0.065, 0.420]			
Test on Differences [c]				
Unstratified p-value	0.0371			
Stratified p-value	0.0294			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Baseline Statin Intensity II
Full Analysis Set

Baseline Statin Dose Intensity II: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		12 (28.6%)	0	12 (19.0%)
Number of patients without events		30 (71.4%)	21 (100.0%)	51 (81.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	17.623 [0.989, 313.96]			
Stratified OR, 95% CI	8.133 [0.970, 68.224]			
Relative Risk [a]				
Unstratified RR, 95% CI	12.791 [0.794, 206.10]			
Stratified RR, 95% CI	5.981 [0.822, 43.518]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.286 [0.149, 0.422]			
Stratified ARR, 95% CI (CMH method)	0.291 [0.154, 0.428]			
Test on Differences [c]				
Unstratified p-value	0.0055			
Stratified p-value	0.0062			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Baseline Statin Intensity II
Full Analysis Set

Baseline Statin Dose Intensity II: None

	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)	Total (N= 47)
Number of patients at risk		33 (100.0%)	14 (100.0%)	47 (100.0%)
Number of patients with events		7 (21.2%)	0	7 (14.9%)
Number of patients without events		26 (78.8%)	14 (100.0%)	40 (85.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	8.208 [0.437, 154.24]			
Stratified OR, 95% CI	4.417 [0.502, 38.843]			
Relative Risk [a]				
Unstratified RR, 95% CI	6.618 [0.403, 108.55]			
Stratified RR, 95% CI	3.635 [0.495, 26.715]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.212 [0.073, 0.352]			
Stratified ARR, 95% CI (CMH method)	0.212 [0.072, 0.351]			
Test on Differences [c]				
Unstratified p-value	0.0864			
Stratified p-value	0.0677			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with LDL-C <70 mg/dL at Week 12 by Baseline Statin Intensity II
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.4052
High Intensity Statin vs. Other Intensity Statin		0.0744	<.0001	-	
None vs. Other Intensity Statin		0.0744	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia,
LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, LR=likelihood ratio.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Race
Full Analysis Set

Race: White

	FDC vs. Placebo	FDC (N= 85)	Placebo (N= 48)	Total (N= 133)
Number of patients at risk		85 (100.0%)	48 (100.0%)	133 (100.0%)
Number of patients with events		24 (28.2%)	1 (2.1%)	25 (18.8%)
Number of patients without events		61 (71.8%)	47 (97.9%)	108 (81.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	18.492 [2.414, 141.68]			
Stratified OR, 95% CI	7.373 [1.885, 28.843]			
Relative Risk [a]				
Unstratified RR, 95% CI	13.553 [1.892, 97.070]			
Stratified RR, 95% CI	5.404 [1.539, 18.976]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.262 [0.158, 0.365]			
Stratified ARR, 95% CI (CMH method)	0.268 [0.163, 0.372]			
Test on Differences [c]				
Unstratified p-value	0.0001			
Stratified p-value	0.0002			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Race
Full Analysis Set

Race: non-White

	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)	Total (N= 30)
Number of patients at risk		23 (100.0%)	7 (100.0%)	30 (100.0%)
Number of patients with events		5 (21.7%)	0	5 (16.7%)
Number of patients without events		18 (78.3%)	7 (100.0%)	25 (83.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.459 [0.218, 91.090]			
Stratified OR, 95% CI	2.191 [0.283, 16.940]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.667 [0.227, 59.238]			
Stratified RR, 95% CI	1.747 [0.357, 8.549]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.217 [0.049, 0.386]			
Stratified ARR, 95% CI (CMH method)	0.225 [0.048, 0.402]			
Test on Differences [c]				
Unstratified p-value	0.3041			
Stratified p-value	0.1786			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with LDL-C <70 mg/dL at Week 12 by Race
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.6448
non-White vs. White		0.0095	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia,
LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, LR=likelihood ratio.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Baseline LDL-C Category
Full Analysis Set

Baseline LDL-C (mg/dL): < 130

	FDC vs. Placebo	FDC (N= 39)	Placebo (N= 16)	Total (N= 55)
Number of patients at risk		39 (100.0%)	16 (100.0%)	55 (100.0%)
Number of patients with events		16 (41.0%)	1 (6.3%)	17 (30.9%)
Number of patients without events		23 (59.0%)	15 (93.8%)	38 (69.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	10.435 [1.249, 87.144]			
Stratified OR, 95% CI	7.702 [1.189, 49.894]			
Relative Risk [a]				
Unstratified RR, 95% CI	6.564 [0.948, 45.435]			
Stratified RR, 95% CI	4.570 [0.933, 22.391]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.348 [0.153, 0.542]			
Stratified ARR, 95% CI (CMH method)	0.387 [0.170, 0.603]			
Test on Differences [c]				
Unstratified p-value	0.0116			
Stratified p-value	0.0089			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Baseline LDL-C Category
Full Analysis Set

Baseline LDL-C (mg/dL): 130 - < 160

	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)	Total (N= 47)
Number of patients at risk		31 (100.0%)	16 (100.0%)	47 (100.0%)
Number of patients with events		10 (32.3%)	0	10 (21.3%)
Number of patients without events		21 (67.7%)	16 (100.0%)	37 (78.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	16.116 [0.879, 295.44]			
Stratified OR, 95% CI	4.982 [0.967, 25.669]			
Relative Risk [a]				
Unstratified RR, 95% CI	11.156 [0.695, 179.00]			
Stratified RR, 95% CI	3.506 [0.874, 14.068]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.323 [0.158, 0.487]			
Stratified ARR, 95% CI (CMH method)	0.330 [0.164, 0.496]			
Test on Differences [c]				
Unstratified p-value	0.0098			
Stratified p-value	0.0128			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Baseline LDL-C Category
Full Analysis Set

Baseline LDL-C (mg/dL): >= 160

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)	Total (N= 61)
Number of patients at risk		38 (100.0%)	23 (100.0%)	61 (100.0%)
Number of patients with events		3 (7.9%)	0	3 (4.9%)
Number of patients without events		35 (92.1%)	23 (100.0%)	58 (95.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.634 [0.229, 93.884]			
Stratified OR, 95% CI	3.080 [0.135, 70.332]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.308 [0.233, 79.809]			
Stratified RR, 95% CI	2.625 [0.158, 43.632]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.079 [-0.007, 0.165]			
Stratified ARR, 95% CI (CMH method)	0.055 [-0.021, 0.131]			
Test on Differences [c]				
Unstratified p-value	0.2836			
Stratified p-value	0.2904			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with LDL-C <70 mg/dL at Week 12 by Baseline LDL-C Category
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	WARNING: Negative of Hessian not positive definite				-
130 - < 160 vs. < 130		0.0566	<.0001	-	
>= 160 vs. < 130		0.0566	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia,
LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, LR=likelihood ratio.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by History of Diabetes
Full Analysis Set

History of Diabetes: Yes

	FDC vs. Placebo	FDC (N= 49)	Placebo (N= 24)	Total (N= 73)
Number of patients at risk		49 (100.0%)	24 (100.0%)	73 (100.0%)
Number of patients with events		14 (28.6%)	0	14 (19.2%)
Number of patients without events		35 (71.4%)	24 (100.0%)	59 (80.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	20.014 [1.140, 351.51]			
Stratified OR, 95% CI	5.642 [1.186, 26.846]			
Relative Risk [a]				
Unstratified RR, 95% CI	14.500 [0.901, 233.26]			
Stratified RR, 95% CI	4.148 [1.029, 16.724]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.286 [0.159, 0.412]			
Stratified ARR, 95% CI (CMH method)	0.294 [0.165, 0.423]			
Test on Differences [c]				
Unstratified p-value	0.0031			
Stratified p-value	0.0037			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by History of Diabetes
Full Analysis Set

History of Diabetes: No

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		15 (25.4%)	1 (3.2%)	16 (17.8%)
Number of patients without events		44 (74.6%)	30 (96.8%)	74 (82.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	10.227 [1.282, 81.599]			
Stratified OR, 95% CI	5.345 [1.128, 25.323]			
Relative Risk [a]				
Unstratified RR, 95% CI	7.881 [1.091, 56.912]			
Stratified RR, 95% CI	4.104 [1.003, 16.785]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.222 [0.095, 0.349]			
Stratified ARR, 95% CI (CMH method)	0.214 [0.087, 0.341]			
Test on Differences [c]				
Unstratified p-value	0.0086			
Stratified p-value	0.0112			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with LDL-C <70 mg/dL at Week 12 by History of Diabetes
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.2643
No vs. Yes		<.0001	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia,
LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, LR=likelihood ratio.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by BMI
Full Analysis Set

BMI (kg/m^2): < 25

	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)	Total (N= 19)
Number of patients at risk		13 (100.0%)	6 (100.0%)	19 (100.0%)
Number of patients with events		6 (46.2%)	0	6 (31.6%)
Number of patients without events		7 (53.8%)	6 (100.0%)	13 (68.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	11.267 [0.527, 240.82]			
Stratified OR, 95% CI	7.598 [0.832, 69.435]			
Relative Risk [a]				
Unstratified RR, 95% CI	6.500 [0.424, 99.624]			
Stratified RR, 95% CI	3.397 [0.730, 15.808]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.462 [0.191, 0.733]			
Stratified ARR, 95% CI (CMH method)	0.640 [0.314, 0.966]			
Test on Differences [c]				
Unstratified p-value	0.1093			
Stratified p-value	0.0272			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by BMI
Full Analysis Set

BMI (kg/m^2): 25 - < 30

	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)	Total (N= 49)
Number of patients at risk		27 (100.0%)	22 (100.0%)	49 (100.0%)
Number of patients with events		6 (22.2%)	1 (4.5%)	7 (14.3%)
Number of patients without events		21 (77.8%)	21 (95.5%)	42 (85.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.000 [0.664, 54.243]			
Stratified OR, 95% CI	2.774 [0.541, 14.225]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.889 [0.635, 37.628]			
Stratified RR, 95% CI	2.235 [0.559, 8.943]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.177 [-0.003, 0.356]			
Stratified ARR, 95% CI (CMH method)	0.181 [-0.013, 0.375]			
Test on Differences [c]				
Unstratified p-value	0.1116			
Stratified p-value	0.0837			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by BMI
Full Analysis Set

BMI (kg/m^2): >= 30

	FDC vs. Placebo	FDC (N= 68)	Placebo (N= 27)	Total (N= 95)
Number of patients at risk		68 (100.0%)	27 (100.0%)	95 (100.0%)
Number of patients with events		17 (25.0%)	0	17 (17.9%)
Number of patients without events		51 (75.0%)	27 (100.0%)	78 (82.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	18.689 [1.082, 322.77]			
Stratified OR, 95% CI	6.746 [1.181, 38.547]			
Relative Risk [a]				
Unstratified RR, 95% CI	14.203 [0.884, 228.16]			
Stratified RR, 95% CI	4.986 [1.008, 24.657]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.250 [0.147, 0.353]			
Stratified ARR, 95% CI (CMH method)	0.239 [0.135, 0.342]			
Test on Differences [c]				
Unstratified p-value	0.0024			
Stratified p-value	0.0053			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with LDL-C <70 mg/dL at Week 12 by BMI
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	WARNING: Negative of Hessian not positive definite				-
25 - < 30 vs. < 25		<.0001	<.0001	-	
>= 30 vs. < 25		<.0001	0.9978	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia,
LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, LR=likelihood ratio.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data)
Full Analysis Set

Statistic	FDC vs. Placebo	FDC (N= 108)	Placebo (N= 55)
Observed data:			
LDL-C at Baseline:			
n		108	55
Mean		152.02	152.63
Standard deviation		38.869	42.357
Percent Change from Baseline:			
n		105	53
Mean (SE)		-32.62 (2.566)	-3.03 (3.132)
Standard deviation		26.295	22.799
Median		-38.27	-6.22
Minimum		-83.5	-44.2
Maximum		43.3	75.3
Imputed data:			
n		108	55
LS Mean for Percent Change from Baseline (SE)		-31.48 (2.497)	-2.47 (3.075)
95%-CI		[-36.37 , -26.59]	[-8.50 , 3.56]
Difference of LS Means (SE)	-29.01 (3.958)		
95%-CI	[-36.77 , -21.25]		
p-value	<.0001		
Hedges' g (SE)	-1.16 (0.177)		
95%-CI	[-1.51 , -0.81]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Gender
Full Analysis Set

Gender: Male

Statistic	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)
Observed data:			
LDL-C at Baseline:			
n		50	33
Mean		148.25	139.92
Standard deviation		33.437	38.271
Percent Change from Baseline:			
n		48	32
Mean (SE)		-34.37 (3.395)	-2.79 (4.269)
Standard deviation		23.521	24.150
Median		-38.42	-7.67
Minimum		-70.3	-44.2
Maximum		30.5	75.3
Imputed data:			
n		50	33
LS Mean for Percent Change from Baseline (SE)		-32.53 (3.402)	-2.74 (4.300)
95%-CI		[-39.20 , -25.86]	[-11.17 , 5.68]
Difference of LS Means (SE)	-29.79 (5.484)		
95%-CI	[-40.53 , -19.04]		
p-value	<.0001		
Hedges' g (SE)	-1.21 (0.241)		
95%-CI	[-1.69 , -0.73]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Gender
Full Analysis Set

Gender: Female

Statistic	FDC vs. Placebo	FDC (N= 58)	Placebo (N= 22)
Observed data:			
LDL-C at Baseline:			
n		58	22
Mean		155.27	171.68
Standard deviation		43.032	41.805
Percent Change from Baseline:			
n		57	21
Mean (SE)		-31.15 (3.781)	-3.38 (4.615)
Standard deviation		28.547	21.149
Median		-38.27	-4.95
Minimum		-83.5	-43.4
Maximum		43.3	44.3
Imputed data:			
n		58	22
LS Mean for Percent Change from Baseline (SE)		-30.95 (3.693)	-1.20 (4.347)
95%-CI		[-38.18 , -23.71]	[-9.72 , 7.32]
Difference of LS Means (SE)	-29.75 (5.719)		
95%-CI	[-40.96 , -18.54]		
p-value	<.0001		
Hedges' g (SE)	-1.12 (0.263)		
95%-CI	[-1.65 , -0.60]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Gender
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Gender	Convergence criteria met				0.9041
Female vs. Male		<.0001	0.8937	0.9041	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other),subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Age
Full Analysis Set

Age (years): < 65

Statistic	FDC vs. Placebo	FDC (N= 58)	Placebo (N= 27)
Observed data:			
LDL-C at Baseline:			
n		58	27
Mean		155.34	153.78
Standard deviation		41.673	43.400
Percent Change from Baseline:			
n		55	25
Mean (SE)		-31.14 (3.295)	-0.69 (4.969)
Standard deviation		24.436	24.845
Median		-35.31	-4.95
Minimum		-70.5	-44.2
Maximum		30.5	75.3
Imputed data:			
n		58	27
LS Mean for Percent Change from Baseline (SE)		-28.86 (3.135)	-0.93 (4.457)
95%-CI		[-35.00 , -22.72]	[-9.67 , 7.80]
Difference of LS Means (SE)	-27.93 (5.460)		
95%-CI	[-38.63 , -17.23]		
p-value	<.0001		
Hedges' g (SE)	-1.17 (0.248)		
95%-CI	[-1.66 , -0.68]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Age
Full Analysis Set

Age (years): >= 65

Statistic	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)
Observed data:			
LDL-C at Baseline:			
n		50	28
Mean		148.16	151.52
Standard deviation		35.363	42.094
Percent Change from Baseline:			
n		50	28
Mean (SE)		-34.26 (4.011)	-5.11 (3.977)
Standard deviation		28.360	21.046
Median		-43.27	-7.91
Minimum		-83.5	-43.4
Maximum		43.3	44.3
Imputed data:			
n		50	28
LS Mean for Percent Change from Baseline (SE)		-33.50 (4.056)	-4.43 (4.083)
95%-CI		[-41.65 , -25.35]	[-12.84 , 3.97]
Difference of LS Means (SE)	-29.07 (5.746)		
95%-CI	[-40.53 , -17.60]		
p-value	<.0001		
Hedges' g (SE)	-1.09 (0.249)		
95%-CI	[-1.59 , -0.59]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Age
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Age (years)	Convergence criteria met				0.8347
>= 65 vs. < 65		<.0001	0.5507	0.8347	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other),subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by CVD Risk Category
Full Analysis Set

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Placebo	FDC (N= 60)	Placebo (N= 31)
Observed data:			
LDL-C at Baseline:			
n		60	31
Mean		148.22	138.26
Standard deviation		44.055	42.057
Percent Change from Baseline:			
n		57	30
Mean (SE)		-38.48 (2.777)	-0.31 (4.431)
Standard deviation		20.963	24.267
Median		-42.86	-4.28
Minimum		-70.5	-44.2
Maximum		24.2	75.3
Imputed data:			
n		60	31
LS Mean for Percent Change from Baseline (SE)		-35.90 (2.815)	-0.50 (4.423)
95%-CI		[-41.41 , -30.38]	[-9.17 , 8.17]
Difference of LS Means (SE)	-35.39 (5.247)		
95%-CI	[-45.68 , -25.11]		
p-value	<.0001		
Hedges' g (SE)	-1.54 (0.247)		
95%-CI	[-2.03 , -1.05]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline statin dose intensity (high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by CVD Risk Category
Full Analysis Set

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)
Observed data:			
LDL-C at Baseline:			
n		48	24
Mean		156.77	171.19
Standard deviation		31.009	35.601
Percent Change from Baseline:			
n		48	23
Mean (SE)		-25.67 (4.367)	-6.57 (4.320)
Standard deviation		30.256	20.717
Median		-37.36	-8.33
Minimum		-83.5	-43.4
Maximum		43.3	44.3
Imputed data:			
n		48	24
LS Mean for Percent Change from Baseline (SE)		-26.13 (4.356)	-4.83 (4.089)
95%-CI		[-34.67 , -17.59]	[-12.85 , 3.18]
Difference of LS Means (SE)	-21.30 (5.993)		
95%-CI	[-33.04 , -9.55]		
p-value	0.0004		
Hedges' g (SE)	-0.77 (0.256)		
95%-CI	[-1.28 , -0.26]		
p-value	0.0035		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline statin dose intensity (high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by CVD Risk Category
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
CVD Risk Category	Convergence criteria met				0.0641
Multiple CV risk factors vs. ASCVD and/or HeFH		<.0001	0.6147	0.0641	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol.
[a] Two-sided t-test p-value from ANCOVA including treatment, baseline statin dose intensity (high statin intensity vs other), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline Statin Intensity I
Full Analysis Set

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Placebo	FDC (N= 66)	Placebo (N= 34)
Observed data:			
LDL-C at Baseline:			
n		66	34
Mean		156.73	156.51
Standard deviation		38.619	40.647
Percent Change from Baseline:			
n		64	33
Mean (SE)		-32.94 (3.324)	-5.61 (2.991)
Standard deviation		26.592	17.182
Median		-38.34	-5.92
Minimum		-70.3	-44.2
Maximum		43.3	35.8
Imputed data:			
n		66	34
LS Mean for Percent Change from Baseline (SE)		-31.56 (3.216)	-5.09 (2.928)
95%-CI		[-37.86 , -25.25]	[-10.83 , 0.65]
Difference of LS Means (SE)	-26.46 (4.344)		
95%-CI	[-34.98 , -17.95]		
p-value	<.0001		
Hedges' g (SE)	-1.12 (0.224)		
95%-CI	[-1.56 , -0.67]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline Statin Intensity I
Full Analysis Set

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)
Observed data:			
LDL-C at Baseline:			
n		42	21
Mean		144.62	146.33
Standard deviation		38.556	45.286
Percent Change from Baseline:			
n		41	20
Mean (SE)		-32.13 (4.083)	1.23 (6.689)
Standard deviation		26.145	29.913
Median		-38.27	-6.76
Minimum		-83.5	-43.4
Maximum		30.5	75.3
Imputed data:			
n		42	21
LS Mean for Percent Change from Baseline (SE)		-31.35 (4.029)	1.75 (6.531)
95%-CI		[-39.25 , -23.46]	[-11.05 , 14.55]
Difference of LS Means (SE)	-33.11 (7.673)		
95%-CI	[-48.14 , -18.07]		
p-value	<.0001		
Hedges' g (SE)	-1.19 (0.285)		
95%-CI	[-1.76 , -0.62]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline Statin Intensity I
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Baseline Statin Dose Intensity I	Convergence criteria met				0.4232
High Intensity Statin vs. Other		<.0001	0.2979	0.4232	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol.
[a] Two-sided t-test p-value from ANCOVA including treatment, baseline CVD risk category (ASCVD and/or HeFH vs. multiple cardiovascular risk factors), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline Statin Intensity II
Full Analysis Set

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 20)
Observed data:			
LDL-C at Baseline:			
n		33	20
Mean		142.11	148.50
Standard deviation		31.614	46.120
Percent Change from Baseline:			
n		31	20
Mean (SE)		-26.49 (4.792)	-9.45 (3.892)
Standard deviation		26.682	17.406
Median		-28.06	-11.97
Minimum		-70.3	-44.2
Maximum		40.1	35.8
Imputed data:			
n		33	20
LS Mean for Percent Change from Baseline (SE)		-24.60 (4.503)	-8.44 (3.916)
95%-CI		[-33.42 , -15.77]	[-16.11 , -0.76]
Difference of LS Means (SE)	-16.16 (5.955)		
95%-CI	[-27.83 , -4.49]		
p-value	0.0067		
Hedges' g (SE)	-0.69 (0.287)		
95%-CI	[-1.27 , -0.11]		
p-value	0.0201		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline Statin Intensity II
Full Analysis Set

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)
Observed data:			
LDL-C at Baseline:			
n		42	21
Mean		144.62	146.33
Standard deviation		38.556	45.286
Percent Change from Baseline:			
n		41	20
Mean (SE)		-32.13 (4.083)	1.23 (6.689)
Standard deviation		26.145	29.913
Median		-38.27	-6.76
Minimum		-83.5	-43.4
Maximum		30.5	75.3
Imputed data:			
n		42	21
LS Mean for Percent Change from Baseline (SE)		-31.35 (4.029)	1.75 (6.531)
95%-CI		[-39.25 , -23.46]	[-11.05 , 14.55]
Difference of LS Means (SE)	-33.11 (7.673)		
95%-CI	[-48.14 , -18.07]		
p-value	<.0001		
Hedges' g (SE)	-1.19 (0.285)		
95%-CI	[-1.76 , -0.62]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline Statin Intensity II
Full Analysis Set

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)
Observed data:			
LDL-C at Baseline:			
n		33	14
Mean		171.35	167.96
Standard deviation		39.863	29.072
Percent Change from Baseline:			
n		33	13
Mean (SE)		-39.00 (4.426)	0.32 (4.341)
Standard deviation		25.428	15.650
Median		-45.26	0.23
Minimum		-67.3	-26.6
Maximum		43.3	24.3
Imputed data:			
n		33	14
LS Mean for Percent Change from Baseline (SE)		-38.74 (4.431)	0.26 (3.990)
95%-CI		[-47.77 , -29.71]	[-8.37 , 8.89]
Difference of LS Means (SE)	-39.00 (5.963)		
95%-CI	[-51.06 , -26.95]		
p-value	<.0001		
Hedges' g (SE)	-1.67 (0.358)		
95%-CI	[-2.39 , -0.95]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline Statin Intensity II
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Baseline Statin Dose Intensity II	Convergence criteria met				0.0519
High Intensity Statin vs. Other Intensity Statin		0.0231	0.1138	0.0646	
None vs. Other Intensity Statin		0.0231	0.1696	0.0224	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol.
[a] Two-sided t-test p-value from ANCOVA including treatment, baseline CVD risk category (ASCVD and/or HeFH vs. multiple cardiovascular risk factors), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Race
Full Analysis Set

Race: White

Statistic	FDC vs. Placebo	FDC (N= 85)	Placebo (N= 48)
Observed data:			
LDL-C at Baseline:			
n		85	48
Mean		151.39	151.29
Standard deviation		38.000	43.632
Percent Change from Baseline:			
n		82	46
Mean (SE)		-32.80 (2.831)	-3.62 (3.311)
Standard deviation		25.634	22.454
Median		-38.76	-6.76
Minimum		-70.3	-44.2
Maximum		43.3	75.3
Imputed data:			
n		85	48
LS Mean for Percent Change from Baseline (SE)		-31.66 (2.738)	-3.08 (3.314)
95%-CI		[-37.02 , -26.29]	[-9.57 , 3.42]
Difference of LS Means (SE)	-28.58 (4.301)		
95%-CI	[-37.01 , -20.15]		
p-value	<.0001		
Hedges' g (SE)	-1.16 (0.193)		
95%-CI	[-1.54 , -0.78]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Race
Full Analysis Set

Race: non-White

Statistic	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)
Observed data:			
LDL-C at Baseline:			
n		23	7
Mean		154.33	161.79
Standard deviation		42.747	33.505
Percent Change from Baseline:			
n		23	7
Mean (SE)		-32.00 (6.075)	0.85 (10.025)
Standard deviation		29.134	26.524
Median		-30.79	-5.70
Minimum		-83.5	-39.0
Maximum		40.1	35.8
Imputed data:			
n		23	7
LS Mean for Percent Change from Baseline (SE)		-30.19 (6.436)	3.18 (7.386)
95%-CI		[-43.64 , -16.74]	[-18.30 , 24.66]
Difference of LS Means (SE)	-33.37 (9.729)		
95%-CI	[-54.80 , -11.94]		
p-value	0.0057		
Hedges' g (SE)	-1.13 (0.444)		
95%-CI	[-2.04 , -0.22]		
p-value	0.0171		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Race
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Race	Convergence criteria met				0.7355
non-White vs. White		<.0001	0.6873	0.7355	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other),subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline LDL-C Category
Full Analysis Set

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Placebo	FDC (N= 39)	Placebo (N= 16)
Observed data:			
LDL-C at Baseline:			
n		39	16
Mean		116.00	106.59
Standard deviation		10.803	12.656
Percent Change from Baseline:			
n		38	16
Mean (SE)		-26.75 (4.124)	-4.24 (4.446)
Standard deviation		25.422	17.783
Median		-30.10	-6.76
Minimum		-63.4	-44.2
Maximum		43.3	35.8
Imputed data:			
n		39	16
LS Mean for Percent Change from Baseline (SE)		-26.45 (4.139)	-3.66 (4.515)
95%-CI		[-34.56 , -18.34]	[-12.50 , 5.19]
Difference of LS Means (SE)	-22.79 (6.296)		
95%-CI	[-35.13 , -10.45]		
p-value	0.0003		
Hedges' g (SE)	-0.94 (0.306)		
95%-CI	[-1.55 , -0.33]		
p-value	0.0034		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline LDL-C Category
Full Analysis Set

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)
Observed data:			
LDL-C at Baseline:			
n		31	16
Mean		142.66	144.34
Standard deviation		7.605	8.650
Percent Change from Baseline:			
n		30	14
Mean (SE)		-34.47 (4.900)	3.25 (7.990)
Standard deviation		26.837	29.895
Median		-43.00	-5.81
Minimum		-83.5	-33.6
Maximum		24.2	75.3
Imputed data:			
n		31	16
LS Mean for Percent Change from Baseline (SE)		-32.94 (5.103)	3.20 (6.969)
95%-CI		[-42.94 , -22.94]	[-10.46 , 16.86]
Difference of LS Means (SE)	-36.14 (8.643)		
95%-CI	[-53.08 , -19.20]		
p-value	<.0001		
Hedges' g (SE)	-1.26 (0.329)		
95%-CI	[-1.92 , -0.60]		
p-value	0.0004		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline LDL-C Category
Full Analysis Set

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)
Observed data:			
LDL-C at Baseline:			
n		38	23
Mean		196.62	190.41
Standard deviation		26.805	34.057
Percent Change from Baseline:			
n		37	23
Mean (SE)		-37.16 (4.327)	-6.00 (4.421)
Standard deviation		26.318	21.201
Median		-41.08	-6.22
Minimum		-70.5	-43.4
Maximum		40.1	44.3
Imputed data:			
n		38	23
LS Mean for Percent Change from Baseline (SE)		-36.53 (4.373)	-6.26 (4.636)
95%-CI		[-45.10 , -27.96]	[-15.34 , 2.83]
Difference of LS Means (SE)	-30.27 (6.403)		
95%-CI	[-42.82 , -17.72]		
p-value	<.0001		
Hedges' g (SE)	-1.18 (0.282)		
95%-CI	[-1.75 , -0.62]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline LDL-C Category
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Baseline LDL-C (mg/dL)	Convergence criteria met				0.4353
130 - < 160 vs. < 130		0.0020	0.6491	0.1993	
>= 160 vs. < 130		0.0020	0.7617	0.5534	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other),subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by History of Diabetes
Full Analysis Set

History of Diabetes: Yes

Statistic	FDC vs. Placebo	FDC (N= 49)	Placebo (N= 24)
Observed data:			
LDL-C at Baseline:			
n		49	24
Mean		145.42	142.13
Standard deviation		34.196	33.642
Percent Change from Baseline:			
n		48	23
Mean (SE)		-31.95 (3.854)	-4.54 (4.980)
Standard deviation		26.702	23.885
Median		-37.70	-7.00
Minimum		-83.5	-39.0
Maximum		43.3	75.3
Imputed data:			
n		49	24
LS Mean for Percent Change from Baseline (SE)		-31.56 (3.780)	-4.46 (4.797)
95%-CI		[-38.97 , -24.15]	[-13.86 , 4.95]
Difference of LS Means (SE)	-27.10 (6.110)		
95%-CI	[-39.08 , -15.13]		
p-value	<.0001		
Hedges' g (SE)	-1.05 (0.261)		
95%-CI	[-1.57 , -0.53]		
p-value	0.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by History of Diabetes
Full Analysis Set

History of Diabetes: No

Statistic	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)
Observed data:			
LDL-C at Baseline:			
n		59	31
Mean		157.50	160.76
Standard deviation		41.857	46.960
Percent Change from Baseline:			
n		57	30
Mean (SE)		-33.19 (3.467)	-1.86 (4.066)
Standard deviation		26.172	22.272
Median		-39.58	-3.90
Minimum		-70.5	-44.2
Maximum		40.1	44.3
Imputed data:			
n		59	31
LS Mean for Percent Change from Baseline (SE)		-31.71 (3.390)	-1.34 (4.042)
95%-CI		[-38.35 , -25.07]	[-9.26 , 6.59]
Difference of LS Means (SE)	-30.38 (5.268)		
95%-CI	[-40.70 , -20.05]		
p-value	<.0001		
Hedges' g (SE)	-1.21 (0.238)		
95%-CI	[-1.68 , -0.74]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by History of Diabetes
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
History of Diabetes	Convergence criteria met				0.6784
No vs. Yes		<.0001	0.3669	0.6784	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other),subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by BMI
Full Analysis Set

BMI (kg/m^2): < 25

Statistic	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)
Observed data:			
LDL-C at Baseline:			
n		13	6
Mean		144.54	161.33
Standard deviation		37.764	46.941
Percent Change from Baseline:			
n		13	6
Mean (SE)		-40.61 (7.334)	-7.51 (5.502)
Standard deviation		26.442	13.476
Median		-45.26	-5.19
Minimum		-83.5	-30.1
Maximum		24.2	7.2
Imputed data:			
n		13	6
LS Mean for Percent Change from Baseline (SE)		-40.71 (7.598)	-6.76 (2.091)
95%-CI		[-57.19 , -24.23]	[-11.13 , -2.39]
Difference of LS Means (SE)	-33.95 (8.598)		
95%-CI	[-52.38 , -15.52]		
p-value	0.0014		
Hedges' g (SE)	-1.40 (0.523)		
95%-CI	[-2.50 , -0.29]		
p-value	0.0160		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by BMI
Full Analysis Set

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)
Observed data:			
LDL-C at Baseline:			
n		27	22
Mean		145.57	147.75
Standard deviation		32.480	43.353
Percent Change from Baseline:			
n		26	21
Mean (SE)		-24.51 (5.546)	-1.45 (6.429)
Standard deviation		28.277	29.462
Median		-29.27	-11.22
Minimum		-59.6	-44.2
Maximum		40.1	75.3
Imputed data:			
n		27	22
LS Mean for Percent Change from Baseline (SE)		-23.79 (5.232)	-0.13 (6.743)
95%-CI		[-34.05 , -13.54]	[-13.34 , 13.09]
Difference of LS Means (SE)	-23.67 (8.551)		
95%-CI	[-40.43 , -6.91]		
p-value	0.0056		
Hedges' g (SE)	-0.80 (0.294)		
95%-CI	[-1.39 , -0.20]		
p-value	0.0094		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by BMI
Full Analysis Set

BMI (kg/m^2): >= 30

Statistic	FDC vs. Placebo	FDC (N= 68)	Placebo (N= 27)
Observed data:			
LDL-C at Baseline:			
n		68	27
Mean		156.01	154.67
Standard deviation		41.282	41.744
Percent Change from Baseline:			
n		66	26
Mean (SE)		-34.25 (3.084)	-3.26 (3.635)
Standard deviation		25.058	18.534
Median		-39.70	-5.81
Minimum		-70.5	-39.0
Maximum		43.3	44.3
Imputed data:			
n		68	27
LS Mean for Percent Change from Baseline (SE)		-32.62 (2.955)	-2.99 (3.209)
95%-CI		[-38.41 , -26.83]	[-9.28 , 3.30]
Difference of LS Means (SE)	-29.63 (4.365)		
95%-CI	[-38.18 , -21.07]		
p-value	<.0001		
Hedges' g (SE)	-1.31 (0.245)		
95%-CI	[-1.79 , -0.82]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by BMI
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
BMI (kg/m^2)	Convergence criteria met				0.6232
25 - < 30 vs. < 25		0.0041	0.7126	0.3753	
>= 30 vs. < 25		0.0041	0.8330	0.6529	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other),subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data)
Full Analysis Set

Statistic	FDC vs. Placebo	FDC (N= 108)	Placebo (N= 55)
LDL-C at Baseline:			
n		105	53
Mean		152.06	153.15
Standard deviation		38.962	43.075
Percent Change from Baseline:			
n		105	53
Mean (SE)		-32.62 (2.566)	-3.03 (3.132)
Standard deviation		26.295	22.799
Median		-38.27	-6.22
Minimum		-83.5	-44.2
Maximum		43.3	75.3
LS Mean for Percent Change from Baseline (SE)		-32.47 (2.500)	-2.49 (3.198)
95%-CI		[-37.43 , -27.51]	[-8.91 , 3.93]
Difference of LS Means (SE)	-29.98 (4.058)		
95%-CI	[-38.02 , -21.94]		
p-value	<.0001		
Hedges' g (SE)	-1.20 (0.181)		
95%-CI	[-1.56 , -0.84]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Gender
Full Analysis Set

Gender: Male

Statistic	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)
LDL-C at Baseline:			
n		48	32
Mean		147.53	139.94
Standard deviation		33.170	38.884
Percent Change from Baseline:			
n		48	32
Mean (SE)		-34.37 (3.395)	-2.79 (4.269)
Standard deviation		23.521	24.150
Median		-38.42	-7.67
Minimum		-70.3	-44.2
Maximum		30.5	75.3
LS Mean for Percent Change from Baseline (SE)		-34.00 (3.361)	-2.85 (4.467)
95%-CI		[-40.76 , -27.23]	[-11.99 , 6.28]
Difference of LS Means (SE)	-31.14 (5.587)		
95%-CI	[-42.32 , -19.96]		
p-value	<.0001		
Hedges' g (SE)	-1.28 (0.248)		
95%-CI	[-1.77 , -0.79]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Gender
Full Analysis Set

Gender: Female

Statistic	FDC vs. Placebo	FDC (N= 58)	Placebo (N= 22)
LDL-C at Baseline:			
n		57	21
Mean		155.87	173.29
Standard deviation		43.168	42.138
Percent Change from Baseline:			
n		57	21
Mean (SE)		-31.15 (3.781)	-3.38 (4.615)
Standard deviation		28.547	21.149
Median		-38.27	-4.95
Minimum		-83.5	-43.4
Maximum		43.3	44.3
LS Mean for Percent Change from Baseline (SE)		-31.55 (3.715)	-0.96 (4.566)
95%-CI		[-38.99 , -24.10]	[-10.46 , 8.55]
Difference of LS Means (SE)	-30.59 (5.905)		
95%-CI	[-42.45 , -18.72]		
p-value	<.0001		
Hedges' g (SE)	-1.15 (0.269)		
95%-CI	[-1.68 , -0.61]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Gender
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Gender	Convergence criteria met				0.8551
Female vs. Male		<.0001	0.8694	0.8551	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CV=cardio-vascular, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high intensity statin vs. other statin), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] Type 3 F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Age
Full Analysis Set

Age (years): < 65

Statistic	FDC vs. Placebo	FDC (N= 58)	Placebo (N= 27)
LDL-C at Baseline:			
n		55	25
Mean		155.60	154.98
Standard deviation		41.977	44.946
Percent Change from Baseline:			
n		55	25
Mean (SE)		-31.14 (3.295)	-0.69 (4.969)
Standard deviation		24.436	24.845
Median		-35.31	-4.95
Minimum		-70.5	-44.2
Maximum		30.5	75.3
LS Mean for Percent Change from Baseline (SE)		-30.52 (3.132)	-0.89 (4.796)
95%-CI		[-36.80 , -24.24]	[-10.79 , 9.02]
Difference of LS Means (SE)	-29.64 (5.744)		
95%-CI	[-41.20 , -18.07]		
p-value	<.0001		
Hedges' g (SE)	-1.25 (0.259)		
95%-CI	[-1.77 , -0.74]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Age
Full Analysis Set

Age (years): >= 65

Statistic	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)
LDL-C at Baseline:			
n		50	28
Mean		148.16	151.52
Standard deviation		35.363	42.094
Percent Change from Baseline:			
n		50	28
Mean (SE)		-34.26 (4.011)	-5.11 (3.977)
Standard deviation		28.360	21.046
Median		-43.27	-7.91
Minimum		-83.5	-43.4
Maximum		43.3	44.3
LS Mean for Percent Change from Baseline (SE)		-33.62 (4.058)	-4.55 (4.073)
95%-CI		[-41.78 , -25.46]	[-12.94 , 3.83]
Difference of LS Means (SE)	-29.06 (5.743)		
95%-CI	[-40.52 , -17.60]		
p-value	<.0001		
Hedges' g (SE)	-1.09 (0.249)		
95%-CI	[-1.59 , -0.59]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Age
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Age (years)	Convergence criteria met				0.9965
>= 65 vs. < 65		<.0001	0.5789	0.9965	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CV=cardio-vascular, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high intensity statin vs. other statin), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] Type 3 F-test p-value from ANCOVA model defined as above.

Table 1002FDC.053.102.2.3
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by CVD Risk Category
Full Analysis Set

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Placebo	FDC (N= 60)	Placebo (N= 31)
LDL-C at Baseline:			
n		57	30
Mean		148.09	138.22
Standard deviation		44.465	42.776
Percent Change from Baseline:			
n		57	30
Mean (SE)		-38.48 (2.777)	-0.31 (4.431)
Standard deviation		20.963	24.267
Median		-42.86	-4.28
Minimum		-70.5	-44.2
Maximum		24.2	75.3
LS Mean for Percent Change from Baseline (SE)		-37.80 (2.720)	-0.53 (4.576)
95%-CI		[-43.25 , -32.35]	[-9.90 , 8.83]
Difference of LS Means (SE)	-37.27 (5.326)		
95%-CI	[-47.97 , -26.57]		
p-value	<.0001		
Hedges' g (SE)	-1.67 (0.257)		
95%-CI	[-2.18 , -1.15]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline statin dose intensity (high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by CVD Risk Category
Full Analysis Set

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)
LDL-C at Baseline:			
n		48	23
Mean		156.77	172.63
Standard deviation		31.009	35.676
Percent Change from Baseline:			
n		48	23
Mean (SE)		-25.67 (4.367)	-6.57 (4.320)
Standard deviation		30.256	20.717
Median		-37.36	-8.33
Minimum		-83.5	-43.4
Maximum		43.3	44.3
LS Mean for Percent Change from Baseline (SE)		-26.20 (4.356)	-5.00 (4.292)
95%-CI		[-34.97 , -17.44]	[-13.89 , 3.88]
Difference of LS Means (SE)	-21.20 (6.141)		
95%-CI	[-33.48 , -8.93]		
p-value	0.0010		
Hedges' g (SE)	-0.76 (0.259)		
95%-CI	[-1.28 , -0.25]		
p-value	0.0044		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline statin dose intensity (high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by CVD Risk Category
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
CVD Risk Category	Convergence criteria met				0.0421
Multiple CV risk factors vs. ASCVD and/or HeFH		<.0001	0.6404	0.0421	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CV=cardio-vascular, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy.
[a] Two-sided t-test p-value from ANCOVA including treatment, baseline statin dose intensity (high intensity statin vs. other statin), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] Type 3 F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline Statin Intensity I
Full Analysis Set

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Placebo	FDC (N= 66)	Placebo (N= 34)
LDL-C at Baseline:			
n		64	33
Mean		157.70	157.03
Standard deviation		38.815	41.164
Percent Change from Baseline:			
n		64	33
Mean (SE)		-32.94 (3.324)	-5.61 (2.991)
Standard deviation		26.592	17.182
Median		-38.34	-5.92
Minimum		-70.3	-44.2
Maximum		43.3	35.8
LS Mean for Percent Change from Baseline (SE)		-32.57 (3.239)	-5.32 (3.027)
95%-CI		[-39.04 , -26.09]	[-11.50 , 0.85]
Difference of LS Means (SE)	-27.24 (4.429)		
95%-CI	[-36.04 , -18.44]		
p-value	<.0001		
Hedges' g (SE)	-1.16 (0.228)		
95%-CI	[-1.61 , -0.70]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline CV risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline Statin Intensity I
Full Analysis Set

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)
LDL-C at Baseline:			
n		41	20
Mean		143.26	146.75
Standard deviation		37.997	46.421
Percent Change from Baseline:			
n		41	20
Mean (SE)		-32.13 (4.083)	1.23 (6.689)
Standard deviation		26.145	29.913
Median		-38.27	-6.76
Minimum		-83.5	-43.4
Maximum		30.5	75.3
LS Mean for Percent Change from Baseline (SE)		-32.30 (4.010)	2.18 (6.880)
95%-CI		[-40.40 , -24.19]	[-12.22 , 16.59]
Difference of LS Means (SE)	-34.48 (7.968)		
95%-CI	[-50.70 , -18.25]		
p-value	0.0001		
Hedges' g (SE)	-1.24 (0.292)		
95%-CI	[-1.83 , -0.66]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline CV risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline Statin Intensity I
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Baseline Statin Dose Intensity I	Convergence criteria met				0.3917
High Intensity Statin vs. Other		<.0001	0.2658	0.3917	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CV=cardio-vascular, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy.
[a] Two-sided t-test p-value from ANCOVA including treatment, baseline CV risk category (ASCVD and/or HeFH vs. multiple cardiovascular risk factors), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] Type 3 F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline Statin Intensity II
Full Analysis Set

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 20)
LDL-C at Baseline:			
n		31	20
Mean		143.16	148.50
Standard deviation		32.335	46.120
Percent Change from Baseline:			
n		31	20
Mean (SE)		-26.49 (4.792)	-9.45 (3.892)
Standard deviation		26.682	17.406
Median		-28.06	-11.97
Minimum		-70.3	-44.2
Maximum		40.1	35.8
LS Mean for Percent Change from Baseline (SE)		-26.24 (4.647)	-8.56 (3.916)
95%-CI		[-35.77 , -16.71]	[-16.77 , -0.34]
Difference of LS Means (SE)	-17.68 (6.066)		
95%-CI	[-29.88 , -5.49]		
p-value	0.0054		
Hedges' g (SE)	-0.76 (0.292)		
95%-CI	[-1.34 , -0.17]		
p-value	0.0126		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline CV risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline Statin Intensity II
Full Analysis Set

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)
LDL-C at Baseline:			
n		41	20
Mean		143.26	146.75
Standard deviation		37.997	46.421
Percent Change from Baseline:			
n		41	20
Mean (SE)		-32.13 (4.083)	1.23 (6.689)
Standard deviation		26.145	29.913
Median		-38.27	-6.76
Minimum		-83.5	-43.4
Maximum		30.5	75.3
LS Mean for Percent Change from Baseline (SE)		-32.30 (4.010)	2.18 (6.880)
95%-CI		[-40.40 , -24.19]	[-12.22 , 16.59]
Difference of LS Means (SE)	-34.48 (7.968)		
95%-CI	[-50.70 , -18.25]		
p-value	0.0001		
Hedges' g (SE)	-1.24 (0.292)		
95%-CI	[-1.83 , -0.66]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline CV risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline Statin Intensity II
Full Analysis Set

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)
LDL-C at Baseline:			
n		33	13
Mean		171.35	170.15
Standard deviation		39.863	29.033
Percent Change from Baseline:			
n		33	13
Mean (SE)		-39.00 (4.426)	0.32 (4.341)
Standard deviation		25.428	15.650
Median		-45.26	0.23
Minimum		-67.3	-26.6
Maximum		43.3	24.3
LS Mean for Percent Change from Baseline (SE)		-38.82 (4.415)	0.43 (4.326)
95%-CI		[-47.82 , -29.83]	[-9.01 , 9.87]
Difference of LS Means (SE)	-39.25 (6.179)		
95%-CI	[-51.79 , -26.71]		
p-value	<.0001		
Hedges' g (SE)	-1.67 (0.366)		
95%-CI	[-2.41 , -0.93]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline CV risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline Statin Intensity II
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Baseline Statin Dose Intensity II	Convergence criteria met				0.0837
High Intensity Statin vs. Other Intensity Statin		0.0138	0.1103	0.0779	
None vs. Other Intensity Statin		0.0138	0.1876	0.0411	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CV=cardio-vascular, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy.
[a] Two-sided t-test p-value from ANCOVA including treatment, baseline CV risk category (ASCVD and/or HeFH vs. multiple cardiovascular risk factors), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] Type 3 F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Race
Full Analysis Set

Race: White

Statistic	FDC vs. Placebo	FDC (N= 85)	Placebo (N= 48)
LDL-C at Baseline:			
n		82	46
Mean		151.42	151.84
Standard deviation		38.091	44.509
Percent Change from Baseline:			
n		82	46
Mean (SE)		-32.80 (2.831)	-3.62 (3.311)
Standard deviation		25.634	22.454
Median		-38.76	-6.76
Minimum		-70.3	-44.2
Maximum		43.3	75.3
LS Mean for Percent Change from Baseline (SE)		-32.89 (2.738)	-3.07 (3.468)
95%-CI		[-38.34 , -27.44]	[-10.06 , 3.93]
Difference of LS Means (SE)	-29.82 (4.423)		
95%-CI	[-38.60 , -21.05]		
p-value	<.0001		
Hedges' g (SE)	-1.22 (0.198)		
95%-CI	[-1.61 , -0.83]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Race
Full Analysis Set

Race: non-White

Statistic	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)
LDL-C at Baseline:			
n		23	7
Mean		154.33	161.79
Standard deviation		42.747	33.505
Percent Change from Baseline:			
n		23	7
Mean (SE)		-32.00 (6.075)	0.85 (10.025)
Standard deviation		29.134	26.524
Median		-30.79	-5.70
Minimum		-83.5	-39.0
Maximum		40.1	35.8
LS Mean for Percent Change from Baseline (SE)		-30.56 (6.386)	2.88 (7.608)
95%-CI		[-43.92 , -17.21]	[-19.46 , 25.22]
Difference of LS Means (SE)	-33.44 (9.889)		
95%-CI	[-55.42 , -11.47]		
p-value	0.0068		
Hedges' g (SE)	-1.13 (0.445)		
95%-CI	[-2.04 , -0.22]		
p-value	0.0166		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Race
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Race	Convergence criteria met				0.8411
non-White vs. White		<.0001	0.7117	0.8411	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CV=cardio-vascular, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high intensity statin vs. other statin), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] Type 3 F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline LDL-C Category
Full Analysis Set

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Placebo	FDC (N= 39)	Placebo (N= 16)
LDL-C at Baseline:			
n		38	16
Mean		115.87	106.59
Standard deviation		10.917	12.656
Percent Change from Baseline:			
n		38	16
Mean (SE)		-26.75 (4.124)	-4.24 (4.446)
Standard deviation		25.422	17.783
Median		-30.10	-6.76
Minimum		-63.4	-44.2
Maximum		43.3	35.8
LS Mean for Percent Change from Baseline (SE)		-27.26 (4.178)	-3.60 (4.536)
95%-CI		[-35.73 , -18.78]	[-13.15 , 5.96]
Difference of LS Means (SE)	-23.66 (6.342)		
95%-CI	[-36.43 , -10.90]		
p-value	0.0005		
Hedges' g (SE)	-0.98 (0.308)		
95%-CI	[-1.60 , -0.36]		
p-value	0.0025		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline LDL-C Category
Full Analysis Set

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)
LDL-C at Baseline:			
n		30	14
Mean		143.07	145.14
Standard deviation		7.387	8.986
Percent Change from Baseline:			
n		30	14
Mean (SE)		-34.47 (4.900)	3.25 (7.990)
Standard deviation		26.837	29.895
Median		-43.00	-5.81
Minimum		-83.5	-33.6
Maximum		24.2	75.3
LS Mean for Percent Change from Baseline (SE)		-34.23 (5.080)	3.50 (8.002)
95%-CI		[-44.63 , -23.82]	[-13.95 , 20.95]
Difference of LS Means (SE)	-37.72 (9.487)		
95%-CI	[-57.38 , -18.07]		
p-value	0.0006		
Hedges' g (SE)	-1.30 (0.347)		
95%-CI	[-2.00 , -0.60]		
p-value	0.0005		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline LDL-C Category
Full Analysis Set

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)
LDL-C at Baseline:			
n		37	23
Mean		196.51	190.41
Standard deviation		27.167	34.057
Percent Change from Baseline:			
n		37	23
Mean (SE)		-37.16 (4.327)	-6.00 (4.421)
Standard deviation		26.318	21.201
Median		-41.08	-6.22
Minimum		-70.5	-43.4
Maximum		40.1	44.3
LS Mean for Percent Change from Baseline (SE)		-37.47 (4.338)	-6.33 (4.616)
95%-CI		[-46.29 , -28.65]	[-15.92 , 3.25]
Difference of LS Means (SE)	-31.14 (6.363)		
95%-CI	[-43.90 , -18.37]		
p-value	<.0001		
Hedges' g (SE)	-1.24 (0.285)		
95%-CI	[-1.81 , -0.66]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline LDL-C Category
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Baseline LDL-C (mg/dL)	Convergence criteria met				0.4253
130 - < 160 vs. < 130		0.0014	0.7246	0.1957	
>= 160 vs. < 130		0.0014	0.6648	0.6007	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CV=cardio-vascular, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high intensity statin vs. other statin), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] Type 3 F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by History of Diabetes
Full Analysis Set

History of Diabetes: Yes

Statistic	FDC vs. Placebo	FDC (N= 49)	Placebo (N= 24)
LDL-C at Baseline:			
n		48	23
Mean		145.93	142.30
Standard deviation		34.370	34.386
Percent Change from Baseline:			
n		48	23
Mean (SE)		-31.95 (3.854)	-4.54 (4.980)
Standard deviation		26.702	23.885
Median		-37.70	-7.00
Minimum		-83.5	-39.0
Maximum		43.3	75.3
LS Mean for Percent Change from Baseline (SE)		-32.28 (3.797)	-4.56 (5.007)
95%-CI		[-39.92 , -24.64]	[-14.95 , 5.83]
Difference of LS Means (SE)	-27.72 (6.291)		
95%-CI	[-40.37 , -15.06]		
p-value	<.0001		
Hedges' g (SE)	-1.07 (0.266)		
95%-CI	[-1.60 , -0.54]		
p-value	0.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by History of Diabetes
Full Analysis Set

History of Diabetes: No

Statistic	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)
LDL-C at Baseline:			
n		57	30
Mean		157.22	161.47
Standard deviation		42.053	47.593
Percent Change from Baseline:			
n		57	30
Mean (SE)		-33.19 (3.467)	-1.86 (4.066)
Standard deviation		26.172	22.272
Median		-39.58	-3.90
Minimum		-70.5	-44.2
Maximum		40.1	44.3
LS Mean for Percent Change from Baseline (SE)		-32.89 (3.396)	-1.36 (4.188)
95%-CI		[-39.70 , -26.08]	[-9.94 , 7.21]
Difference of LS Means (SE)	-31.53 (5.383)		
95%-CI	[-42.28 , -20.77]		
p-value	<.0001		
Hedges' g (SE)	-1.26 (0.243)		
95%-CI	[-1.75 , -0.78]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by History of Diabetes
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
History of Diabetes	Convergence criteria met				0.6721
No vs. Yes		<.0001	0.3788	0.6721	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CV=cardio-vascular, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high intensity statin vs. other statin), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] Type 3 F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by BMI
Full Analysis Set

BMI (kg/m^2): < 25

Statistic	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)
LDL-C at Baseline:			
n		13	6
Mean		144.54	161.33
Standard deviation		37.764	46.941
Percent Change from Baseline:			
n		13	6
Mean (SE)		-40.61 (7.334)	-7.51 (5.502)
Standard deviation		26.442	13.476
Median		-45.26	-5.19
Minimum		-83.5	-30.1
Maximum		24.2	7.2
LS Mean for Percent Change from Baseline (SE)		-40.71 (7.598)	-6.76 (2.091)
95%-CI		[-57.19 , -24.23]	[-11.13 , -2.39]
Difference of LS Means (SE)	-33.95 (8.598)		
95%-CI	[-52.38 , -15.52]		
p-value	0.0014		
Hedges' g (SE)	-1.40 (0.523)		
95%-CI	[-2.50 , -0.29]		
p-value	0.0160		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by BMI
Full Analysis Set

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)
LDL-C at Baseline:			
n		26	21
Mean		143.46	148.14
Standard deviation		31.174	44.383
Percent Change from Baseline:			
n		26	21
Mean (SE)		-24.51 (5.546)	-1.45 (6.429)
Standard deviation		28.277	29.462
Median		-29.27	-11.22
Minimum		-59.6	-44.2
Maximum		40.1	75.3
LS Mean for Percent Change from Baseline (SE)		-25.11 (5.247)	-0.22 (7.096)
95%-CI		[-35.97 , -14.25]	[-15.11 , 14.66]
Difference of LS Means (SE)	-24.88 (8.869)		
95%-CI	[-42.84 , -6.93]		
p-value	0.0079		
Hedges' g (SE)	-0.83 (0.301)		
95%-CI	[-1.44 , -0.22]		
p-value	0.0083		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by BMI
Full Analysis Set

BMI (kg/m^2): >= 30

Statistic	FDC vs. Placebo	FDC (N= 68)	Placebo (N= 27)
LDL-C at Baseline:			
n		66	26
Mean		156.92	155.31
Standard deviation		41.556	42.435
Percent Change from Baseline:			
n		66	26
Mean (SE)		-34.25 (3.084)	-3.26 (3.635)
Standard deviation		25.058	18.534
Median		-39.70	-5.81
Minimum		-70.5	-39.0
Maximum		43.3	44.3
LS Mean for Percent Change from Baseline (SE)		-33.66 (2.961)	-2.66 (3.345)
95%-CI		[-39.57 , -27.75]	[-9.57 , 4.25]
Difference of LS Means (SE)	-31.00 (4.470)		
95%-CI	[-39.94 , -22.06]		
p-value	<.0001		
Hedges' g (SE)	-1.38 (0.251)		
95%-CI	[-1.88 , -0.88]		
p-value	<.0001		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by BMI
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
BMI (kg/m^2)	Convergence criteria met				0.6576
25 - < 30 vs. < 25		0.0040	0.7664	0.4061	
>= 30 vs. < 25		0.0040	0.8675	0.6853	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CV=cardio-vascular, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high intensity statin vs. other statin), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] Type 3 F-test p-value from ANCOVA model defined as above.

Table 1002FDC.053.200.1	Frequency Summary of TEAEs	1
Table 1002FDC.053.200.2	Frequency Summary of TESAEs	4
Table 1002FDC.053.200.3	Frequency Summary of Severe TEAEs	5
Table 1002FDC.053.200.4	Frequency Summary of TEAEs Resulting in Discontinuation of Investigational Medicinal Product	6

MedDRA SOC and PT	FDC (N= 107)	Placebo (N= 55)
Any TEAE	63(58.9%)	24(43.6%)
Infections and infestations	27(25.2%)	3(5.5%)
Urinary tract infection	8(7.5%)	2(3.6%)
Nasopharyngitis	4(3.7%)	1(1.8%)
Bronchitis	3(2.8%)	0
Influenza	3(2.8%)	1(1.8%)
Upper respiratory tract infection	3(2.8%)	0
Gastroenteritis viral	2(1.9%)	0
Otitis media acute	2(1.9%)	0
Acarodermatitis	1(0.9%)	0
Acute sinusitis	1(0.9%)	0
Conjunctivitis	1(0.9%)	0
Rhinovirus infection	1(0.9%)	0
Investigations	14(13.1%)	2(3.6%)
Blood creatinine increased	3(2.8%)	0
Blood uric acid increased	3(2.8%)	0
Blood albumin decreased	1(0.9%)	0
Blood glucose increased	1(0.9%)	0
Blood testosterone decreased	1(0.9%)	0
Blood triglycerides increased	1(0.9%)	0
Electrocardiogram QRS complex prolonged	1(0.9%)	0
Electrocardiogram change	1(0.9%)	0
Eosinophil count increased	1(0.9%)	0
Haemoglobin decreased	1(0.9%)	0
Liver function test abnormal	1(0.9%)	0
Liver function test increased	1(0.9%)	0
Protein total decreased	1(0.9%)	0
Protein urine present	1(0.9%)	0
Blood potassium decreased	0	1(1.8%)
Weight increased	0	1(1.8%)
Musculoskeletal and connective tissue disorders	13(12.1%)	7(12.7%)
Back pain	3(2.8%)	2(3.6%)
Muscle spasms	2(1.9%)	0
Myalgia	2(1.9%)	1(1.8%)
Pain in extremity	2(1.9%)	1(1.8%)
Spinal osteoarthritis	2(1.9%)	0
Arthralgia	1(0.9%)	2(3.6%)
Intervertebral disc degeneration	1(0.9%)	0
Neck mass	1(0.9%)	0
Osteoarthritis	1(0.9%)	0
Rheumatoid arthritis	1(0.9%)	0
Joint swelling	0	1(1.8%)
Muscular weakness	0	1(1.8%)
Gastrointestinal disorders	11(10.3%)	1(1.8%)
Constipation	4(3.7%)	0
Diarrhoea	3(2.8%)	0
Abdominal pain	2(1.9%)	0
Nausea	2(1.9%)	0
Oral discomfort	2(1.9%)	0
Anorectal discomfort	1(0.9%)	0
Dry mouth	1(0.9%)	0

Abbreviations: N=number of patients, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

MedDRA SOC and PT	FDC (N= 107)	Placebo (N= 55)
Dysphagia	1(0.9%)	0
Flatulence	1(0.9%)	0
Gastritis	1(0.9%)	0
Gastrointestinal pain	1(0.9%)	0
Oesophagitis	1(0.9%)	0
Vomiting	1(0.9%)	0
Gastrooesophageal reflux disease	0	1(1.8%)
Nervous system disorders	8(7.5%)	3(5.5%)
Dizziness	2(1.9%)	0
Headache	2(1.9%)	1(1.8%)
Syncope	2(1.9%)	0
Dysgeusia	1(0.9%)	0
Hemiparesis	1(0.9%)	0
Horner's syndrome	1(0.9%)	0
Restless legs syndrome	1(0.9%)	0
Sinus headache	1(0.9%)	0
Transient ischaemic attack	1(0.9%)	0
Hypersomnia	0	1(1.8%)
Neuropathy peripheral	0	1(1.8%)
Metabolism and nutrition disorders	7(6.5%)	0
Diabetes mellitus inadequate control	2(1.9%)	0
Hypokalaemia	2(1.9%)	0
Decreased appetite	1(0.9%)	0
Dehydration	1(0.9%)	0
Hyperuricaemia	1(0.9%)	0
Hypoglycaemia	1(0.9%)	0
Cardiac disorders	6(5.6%)	2(3.6%)
Acute myocardial infarction	1(0.9%)	0
Angina pectoris	1(0.9%)	0
Atrial fibrillation	1(0.9%)	0
Coronary artery disease	1(0.9%)	1(1.8%)
Myocardial ischaemia	1(0.9%)	0
Palpitations	1(0.9%)	1(1.8%)
Myocardial infarction	0	1(1.8%)
General disorders and administration site conditions	6(5.6%)	2(3.6%)
Fatigue	3(2.8%)	0
Asthenia	1(0.9%)	0
Chest discomfort	1(0.9%)	0
Feeling jittery	1(0.9%)	0
Non-cardiac chest pain	1(0.9%)	1(1.8%)
Cyst	0	1(1.8%)
Respiratory, thoracic and mediastinal disorders	6(5.6%)	3(5.5%)
Cough	3(2.8%)	0
Asthma	1(0.9%)	0
Oropharyngeal pain	1(0.9%)	0
Sinus congestion	1(0.9%)	0
Dyspnoea	0	2(3.6%)
Epistaxis	0	1(1.8%)
Vascular disorders	4(3.7%)	0

Abbreviations: N=number of patients, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

MedDRA SOC and PT	FDC (N= 107)	Placebo (N= 55)
Hypertension	3(2.8%)	0
Raynaud's phenomenon	1(0.9%)	0
Psychiatric disorders	3(2.8%)	0
Anxiety	2(1.9%)	0
Agitation	1(0.9%)	0
Renal and urinary disorders	3(2.8%)	0
Acute kidney injury	1(0.9%)	0
Chromaturia	1(0.9%)	0
Glycosuria	1(0.9%)	0
Proteinuria	1(0.9%)	0
Injury, poisoning and procedural complications	2(1.9%)	0
Arthropod bite	1(0.9%)	0
Skin abrasion	1(0.9%)	0
Reproductive system and breast disorders	2(1.9%)	1(1.8%)
Prostatitis	2(1.9%)	0
Benign prostatic hyperplasia	0	1(1.8%)
Blood and lymphatic system disorders	1(0.9%)	2(3.6%)
Anaemia	1(0.9%)	2(3.6%)
Ear and labyrinth disorders	1(0.9%)	0
Hypoacusis	1(0.9%)	0
Endocrine disorders	1(0.9%)	0
Hypothyroidism	1(0.9%)	0
Eye disorders	1(0.9%)	0
Eyelids pruritus	1(0.9%)	0
Hepatobiliary disorders	1(0.9%)	0
Non-alcoholic fatty liver	1(0.9%)	0
Skin and subcutaneous tissue disorders	1(0.9%)	2(3.6%)
Dermatitis contact	1(0.9%)	1(1.8%)
Rash	0	1(1.8%)

Abbreviations: N=number of patients, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Frequency Summary of TESAEs

MedDRA SOC and PT	FDC (N= 107)	Placebo (N= 55)
Any TESAE	8(7.5%)	1(1.8%)
Cardiac disorders	5(4.7%)	1(1.8%)
Acute myocardial infarction	1(0.9%)	0
Angina pectoris	1(0.9%)	0
Atrial fibrillation	1(0.9%)	0
Coronary artery disease	1(0.9%)	1(1.8%)
Myocardial ischaemia	1(0.9%)	0
Myocardial infarction	0	1(1.8%)
General disorders and administration site conditions	1(0.9%)	0
Non-cardiac chest pain	1(0.9%)	0
Infections and infestations	1(0.9%)	0
Rhinovirus infection	1(0.9%)	0
Nervous system disorders	1(0.9%)	0
Hemiparesis	1(0.9%)	0

Abbreviations: N=number of patients, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Frequency Summary of Severe TEAEs

MedDRA SOC and PT	FDC (N= 107)	Placebo (N= 55)
Any TEAE	9(8.4%)	1(1.8%)
Cardiac disorders	5(4.7%)	1(1.8%)
Acute myocardial infarction	1(0.9%)	0
Angina pectoris	1(0.9%)	0
Atrial fibrillation	1(0.9%)	0
Coronary artery disease	1(0.9%)	1(1.8%)
Myocardial ischaemia	1(0.9%)	0
Myocardial infarction	0	1(1.8%)
Gastrointestinal disorders	1(0.9%)	0
Constipation	1(0.9%)	0
General disorders and administration site conditions	1(0.9%)	0
Non-cardiac chest pain	1(0.9%)	0
Metabolism and nutrition disorders	1(0.9%)	0
Hypokalaemia	1(0.9%)	0
Nervous system disorders	1(0.9%)	0
Hemiparesis	1(0.9%)	0
Horner's syndrome	1(0.9%)	0
Transient ischaemic attack	1(0.9%)	0

Abbreviations: N=number of patients, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Frequency Summary of TEAEs Resulting in Discontinuation of Investigational Medicinal Product

MedDRA SOC and PT	FDC (N= 107)	Placebo (N= 55)
Any TEAE	7(6.5%)	2(3.6%)
Gastrointestinal disorders	2(1.9%)	0
Oral discomfort	2(1.9%)	0
Gastrointestinal pain	1(0.9%)	0
General disorders and administration site conditions	2(1.9%)	0
Asthenia	1(0.9%)	0
Fatigue	1(0.9%)	0
Investigations	1(0.9%)	1(1.8%)
Blood glucose increased	1(0.9%)	0
Weight increased	0	1(1.8%)
Metabolism and nutrition disorders	1(0.9%)	0
Hypoglycaemia	1(0.9%)	0
Musculoskeletal and connective tissue disorders	1(0.9%)	1(1.8%)
Pain in extremity	1(0.9%)	0
Muscular weakness	0	1(1.8%)
Nervous system disorders	1(0.9%)	0
Dysgeusia	1(0.9%)	0
Psychiatric disorders	1(0.9%)	0
Agitation	1(0.9%)	0

Abbreviations: N=number of patients, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

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Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		63 (58.9%)	24 (43.6%)	87 (53.7%)
Number of patients without events		44 (41.1%)	31 (56.4%)	75 (46.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.849 [0.958, 3.569]			
Stratified OR, 95% CI	1.861 [0.959, 3.613]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.349 [0.961, 1.895]			
Stratified RR, 95% CI	1.328 [0.950, 1.857]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.152 [-0.008, 0.313]			
Stratified ARR, 95% CI (CMH method)	0.154 [-0.007, 0.314]			
Test on Differences [c]				
Unstratified p-value	0.0654			
Stratified p-value	0.0659			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender
Safety Population

Gender: Male

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)	Total (N= 83)
Number of patients at risk		50 (100.0%)	33 (100.0%)	83 (100.0%)
Number of patients with events		28 (56.0%)	13 (39.4%)	41 (49.4%)
Number of patients without events		22 (44.0%)	20 (60.6%)	42 (50.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.958 [0.801, 4.788]			
Stratified OR, 95% CI	2.055 [0.815, 5.185]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.422 [0.871, 2.319]			
Stratified RR, 95% CI	1.350 [0.833, 2.188]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.166 [-0.050, 0.382]			
Stratified ARR, 95% CI (CMH method)	0.175 [-0.040, 0.389]			
Test on Differences [c]				
Unstratified p-value	0.1386			
Stratified p-value	0.1260			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender
Safety Population

Gender: Female

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 22)	Total (N= 79)
Number of patients at risk		57 (100.0%)	22 (100.0%)	79 (100.0%)
Number of patients with events		35 (61.4%)	11 (50.0%)	46 (58.2%)
Number of patients without events		22 (38.6%)	11 (50.0%)	33 (41.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.591 [0.590, 4.287]			
Stratified OR, 95% CI	1.648 [0.579, 4.686]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.228 [0.771, 1.957]			
Stratified RR, 95% CI	1.119 [0.721, 1.736]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.114 [-0.130, 0.358]			
Stratified ARR, 95% CI (CMH method)	0.117 [-0.126, 0.360]			
Test on Differences [c]				
Unstratified p-value	0.3569			
Stratified p-value	0.3545			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Gender
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.6725
Female vs. Male		0.1589	0.4320	0.6713	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Table 1002FDC.053.202.1.2
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age
Safety Population

Age (years): < 65

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 27)	Total (N= 84)
Number of patients at risk		57 (100.0%)	27 (100.0%)	84 (100.0%)
Number of patients with events		35 (61.4%)	11 (40.7%)	46 (54.8%)
Number of patients without events		22 (38.6%)	16 (59.3%)	38 (45.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.314 [0.909, 5.893]			
Stratified OR, 95% CI	2.230 [0.866, 5.744]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.507 [0.915, 2.483]			
Stratified RR, 95% CI	1.457 [0.882, 2.408]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.207 [-0.018, 0.431]			
Stratified ARR, 95% CI (CMH method)	0.199 [-0.028, 0.426]			
Test on Differences [c]				
Unstratified p-value	0.0756			
Stratified p-value	0.0960			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age
Safety Population

Age (years): >= 65

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)	Total (N= 78)
Number of patients at risk		50 (100.0%)	28 (100.0%)	78 (100.0%)
Number of patients with events		28 (56.0%)	13 (46.4%)	41 (52.6%)
Number of patients without events		22 (44.0%)	15 (53.6%)	37 (47.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.469 [0.580, 3.719]			
Stratified OR, 95% CI	1.514 [0.577, 3.972]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.206 [0.756, 1.925]			
Stratified RR, 95% CI	1.141 [0.709, 1.836]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.096 [-0.135, 0.326]			
Stratified ARR, 95% CI (CMH method)	0.109 [-0.124, 0.342]			
Test on Differences [c]				
Unstratified p-value	0.4167			
Stratified p-value	0.3674			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Age
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.5216
>= 65 vs. < 65		0.1073	0.6717	0.5233	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category
Safety Population

CVD Risk Category: ASCVD and/or HeFH

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		36 (61.0%)	15 (48.4%)	51 (56.7%)
Number of patients without events		23 (39.0%)	16 (51.6%)	39 (43.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.670 [0.694, 4.015]			
Stratified OR, 95% CI	1.669 [0.691, 4.026]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.261 [0.831, 1.913]			
Stratified RR, 95% CI	1.252 [0.828, 1.893]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.126 [-0.089, 0.342]			
Stratified ARR, 95% CI (CMH method)	0.125 [-0.089, 0.340]			
Test on Differences [c]				
Unstratified p-value	0.2506			
Stratified p-value	0.2577			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category
Safety Population

CVD Risk Category: Multiple CV risk factors

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		27 (56.3%)	9 (37.5%)	36 (50.0%)
Number of patients without events		21 (43.8%)	15 (62.5%)	36 (50.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.143 [0.785, 5.849]			
Stratified OR, 95% CI	2.147 [0.784, 5.882]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.500 [0.845, 2.662]			
Stratified RR, 95% CI	1.486 [0.838, 2.637]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.188 [-0.052, 0.427]			
Stratified ARR, 95% CI (CMH method)	0.189 [-0.051, 0.429]			
Test on Differences [c]				
Unstratified p-value	0.1336			
Stratified p-value	0.1358			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by CVD Risk Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.6280
Multiple CV risk factors vs. ASCVD and/or HeFH		0.2755	0.4290	0.6314	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: Other

	FDC vs. Placebo	FDC (N= 65)	Placebo (N= 34)	Total (N= 99)
Number of patients at risk		65 (100.0%)	34 (100.0%)	99 (100.0%)
Number of patients with events		40 (61.5%)	15 (44.1%)	55 (55.6%)
Number of patients without events		25 (38.5%)	19 (55.9%)	44 (44.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.027 [0.874, 4.701]			
Stratified OR, 95% CI	2.027 [0.866, 4.746]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.395 [0.913, 2.132]			
Stratified RR, 95% CI	1.352 [0.891, 2.051]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.174 [-0.030, 0.379]			
Stratified ARR, 95% CI (CMH method)	0.174 [-0.030, 0.377]			
Test on Differences [c]				
Unstratified p-value	0.0976			
Stratified p-value	0.1011			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		23 (54.8%)	9 (42.9%)	32 (50.8%)
Number of patients without events		19 (45.2%)	12 (57.1%)	31 (49.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.614 [0.561, 4.642]			
Stratified OR, 95% CI	1.631 [0.566, 4.703]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.278 [0.726, 2.249]			
Stratified RR, 95% CI	1.284 [0.730, 2.259]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.119 [-0.141, 0.379]			
Stratified ARR, 95% CI (CMH method)	0.122 [-0.138, 0.381]			
Test on Differences [c]				
Unstratified p-value	0.3729			
Stratified p-value	0.3707			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity I
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.8089
High Intensity Statin vs. Other		0.1242	0.9272	0.8079	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

	FDC vs. Placebo	FDC (N= 32)	Placebo (N= 20)	Total (N= 52)
Number of patients at risk		32 (100.0%)	20 (100.0%)	52 (100.0%)
Number of patients with events		15 (46.9%)	9 (45.0%)	24 (46.2%)
Number of patients without events		17 (53.1%)	11 (55.0%)	28 (53.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.078 [0.351, 3.311]			
Stratified OR, 95% CI	1.083 [0.351, 3.339]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.042 [0.567, 1.915]			
Stratified RR, 95% CI	1.036 [0.562, 1.907]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.019 [-0.260, 0.297]			
Stratified ARR, 95% CI (CMH method)	0.020 [-0.259, 0.298]			
Test on Differences [c]				
Unstratified p-value	0.8950			
Stratified p-value	0.8909			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		23 (54.8%)	9 (42.9%)	32 (50.8%)
Number of patients without events		19 (45.2%)	12 (57.1%)	31 (49.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.614 [0.561, 4.642]			
Stratified OR, 95% CI	1.631 [0.566, 4.703]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.278 [0.726, 2.249]			
Stratified RR, 95% CI	1.284 [0.730, 2.259]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.119 [-0.141, 0.379]			
Stratified ARR, 95% CI (CMH method)	0.122 [-0.138, 0.381]			
Test on Differences [c]				
Unstratified p-value	0.3729			
Stratified p-value	0.3707			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: None

	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)	Total (N= 47)
Number of patients at risk		33 (100.0%)	14 (100.0%)	47 (100.0%)
Number of patients with events		25 (75.8%)	6 (42.9%)	31 (66.0%)
Number of patients without events		8 (24.2%)	8 (57.1%)	16 (34.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.167 [1.108, 15.668]			
Stratified OR, 95% CI	4.341 [0.918, 20.539]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.768 [0.937, 3.335]			
Stratified RR, 95% CI	1.270 [0.767, 2.103]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.329 [0.031, 0.627]			
Stratified ARR, 95% CI (CMH method)	0.333 [0.046, 0.619]			
Test on Differences [c]				
Unstratified p-value	0.0295			
Stratified p-value	0.0258			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity II
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.4681
High Intensity Statin vs. Other Intensity Statin		0.8955	0.8901	0.6298	
None vs. Other Intensity Statin		0.8955	0.9018	0.2387	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race
Safety Population

Race: White

	FDC vs. Placebo	FDC (N= 84)	Placebo (N= 48)	Total (N= 132)
Number of patients at risk		84 (100.0%)	48 (100.0%)	132 (100.0%)
Number of patients with events		52 (61.9%)	21 (43.8%)	73 (55.3%)
Number of patients without events		32 (38.1%)	27 (56.3%)	59 (44.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.089 [1.016, 4.294]			
Stratified OR, 95% CI	2.112 [1.015, 4.399]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.415 [0.985, 2.032]			
Stratified RR, 95% CI	1.370 [0.962, 1.953]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.182 [0.007, 0.356]			
Stratified ARR, 95% CI (CMH method)	0.183 [0.009, 0.357]			
Test on Differences [c]				
Unstratified p-value	0.0436			
Stratified p-value	0.0442			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race
Safety Population

Race: non-White

	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)	Total (N= 30)
Number of patients at risk		23 (100.0%)	7 (100.0%)	30 (100.0%)
Number of patients with events		11 (47.8%)	3 (42.9%)	14 (46.7%)
Number of patients without events		12 (52.2%)	4 (57.1%)	16 (53.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.222 [0.222, 6.730]			
Stratified OR, 95% CI	1.091 [0.204, 5.839]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.116 [0.429, 2.903]			
Stratified RR, 95% CI	1.025 [0.412, 2.550]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.050 [-0.370, 0.469]			
Stratified ARR, 95% CI (CMH method)	0.043 [-0.378, 0.464]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8531			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Table 1002FDC.053.202.1.6.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Race
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.6635
non-White vs. White		0.0602	0.9647	0.6490	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): < 130

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 16)	Total (N= 54)
Number of patients at risk		38 (100.0%)	16 (100.0%)	54 (100.0%)
Number of patients with events		19 (50.0%)	8 (50.0%)	27 (50.0%)
Number of patients without events		19 (50.0%)	8 (50.0%)	27 (50.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.000 [0.311, 3.216]			
Stratified OR, 95% CI	0.863 [0.251, 2.972]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.000 [0.558, 1.793]			
Stratified RR, 95% CI	0.927 [0.491, 1.750]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.000 [-0.292, 0.292]			
Stratified ARR, 95% CI (CMH method)	-0.037 [-0.345, 0.272]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8194			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)	Total (N= 47)
Number of patients at risk		31 (100.0%)	16 (100.0%)	47 (100.0%)
Number of patients with events		17 (54.8%)	6 (37.5%)	23 (48.9%)
Number of patients without events		14 (45.2%)	10 (62.5%)	24 (51.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.024 [0.589, 6.957]			
Stratified OR, 95% CI	2.231 [0.554, 8.977]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.462 [0.720, 2.970]			
Stratified RR, 95% CI	1.397 [0.656, 2.976]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.173 [-0.122, 0.468]			
Stratified ARR, 95% CI (CMH method)	0.187 [-0.119, 0.494]			
Test on Differences [c]				
Unstratified p-value	0.2598			
Stratified p-value	0.2358			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): >= 160

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)	Total (N= 61)
Number of patients at risk		38 (100.0%)	23 (100.0%)	61 (100.0%)
Number of patients with events		27 (71.1%)	10 (43.5%)	37 (60.7%)
Number of patients without events		11 (28.9%)	13 (56.5%)	24 (39.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.191 [1.081, 9.417]			
Stratified OR, 95% CI	2.670 [0.858, 8.312]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.634 [0.983, 2.717]			
Stratified RR, 95% CI	1.421 [0.848, 2.380]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.276 [0.027, 0.524]			
Stratified ARR, 95% CI (CMH method)	0.250 [-0.011, 0.512]			
Test on Differences [c]				
Unstratified p-value	0.0326			
Stratified p-value	0.0644			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline LDL-C Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.4718
130 - < 160 vs. < 130		1.0000	0.4810	0.4173	
>= 160 vs. < 130		1.0000	0.6854	0.2138	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes
Safety Population

History of Diabetes: Yes

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		26 (54.2%)	10 (41.7%)	36 (50.0%)
Number of patients without events		22 (45.8%)	14 (58.3%)	36 (50.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.655 [0.615, 4.455]			
Stratified OR, 95% CI	1.613 [0.575, 4.527]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.300 [0.757, 2.231]			
Stratified RR, 95% CI	1.172 [0.684, 2.006]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.125 [-0.117, 0.367]			
Stratified ARR, 95% CI (CMH method)	0.129 [-0.124, 0.381]			
Test on Differences [c]				
Unstratified p-value	0.3173			
Stratified p-value	0.3185			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes
Safety Population

History of Diabetes: No

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		37 (62.7%)	14 (45.2%)	51 (56.7%)
Number of patients without events		22 (37.3%)	17 (54.8%)	39 (43.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.042 [0.845, 4.936]			
Stratified OR, 95% CI	2.026 [0.807, 5.084]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.389 [0.899, 2.145]			
Stratified RR, 95% CI	1.238 [0.825, 1.859]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.176 [-0.039, 0.390]			
Stratified ARR, 95% CI (CMH method)	0.176 [-0.040, 0.393]			
Test on Differences [c]				
Unstratified p-value	0.1104			
Stratified p-value	0.1127			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by History of Diabetes
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.8526
No vs. Yes		0.3411	0.7965	0.8522	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI
Safety Population

BMI (kg/m^2): < 25

	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)	Total (N= 19)
Number of patients at risk		13 (100.0%)	6 (100.0%)	19 (100.0%)
Number of patients with events		8 (61.5%)	4 (66.7%)	12 (63.2%)
Number of patients without events		5 (38.5%)	2 (33.3%)	7 (36.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.800 [0.105, 6.104]			
Stratified OR, 95% CI	0.882 [0.096, 8.150]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.923 [0.454, 1.878]			
Stratified RR, 95% CI	1.211 [0.591, 2.482]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.051 [-0.512, 0.409]			
Stratified ARR, 95% CI (CMH method)	-0.038 [-0.561, 0.486]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8894			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI
Safety Population

BMI (kg/m^2): 25 - < 30

	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)	Total (N= 49)
Number of patients at risk		27 (100.0%)	22 (100.0%)	49 (100.0%)
Number of patients with events		14 (51.9%)	10 (45.5%)	24 (49.0%)
Number of patients without events		13 (48.1%)	12 (54.5%)	25 (51.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.292 [0.418, 3.996]			
Stratified OR, 95% CI	1.124 [0.329, 3.844]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.141 [0.636, 2.047]			
Stratified RR, 95% CI	0.994 [0.527, 1.873]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.064 [-0.217, 0.345]			
Stratified ARR, 95% CI (CMH method)	0.034 [-0.261, 0.329]			
Test on Differences [c]				
Unstratified p-value	0.6559			
Stratified p-value	0.8245			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI
Safety Population

BMI (kg/m^2): >= 30

	FDC vs. Placebo	FDC (N= 67)	Placebo (N= 27)	Total (N= 94)
Number of patients at risk		67 (100.0%)	27 (100.0%)	94 (100.0%)
Number of patients with events		41 (61.2%)	10 (37.0%)	51 (54.3%)
Number of patients without events		26 (38.8%)	17 (63.0%)	43 (45.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.681 [1.065, 6.746]			
Stratified OR, 95% CI	2.607 [1.023, 6.642]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.652 [0.975, 2.800]			
Stratified RR, 95% CI	1.610 [0.947, 2.736]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.242 [0.025, 0.458]			
Stratified ARR, 95% CI (CMH method)	0.233 [0.015, 0.450]			
Test on Differences [c]				
Unstratified p-value	0.0334			
Stratified p-value	0.0450			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by BMI
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.4053
25 - < 30 vs. < 25		0.8252	0.3023	0.6520	
>= 30 vs. < 25		0.8252	0.1244	0.1972	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		8 (7.5%)	1 (1.8%)	9 (5.6%)
Number of patients without events		99 (92.5%)	54 (98.2%)	153 (94.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.364 [0.532, 35.818]			
Stratified OR, 95% CI	2.063 [0.396, 10.741]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.112 [0.528, 32.047]			
Stratified RR, 95% CI	1.910 [0.404, 9.028]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.057 [-0.004, 0.118]			
Stratified ARR, 95% CI (CMH method)	0.057 [-0.004, 0.119]			
Test on Differences [c]				
Unstratified p-value	0.1691			
Stratified p-value	0.1301			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Gender
Safety Population

Gender: Male

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)	Total (N= 83)
Number of patients at risk		50 (100.0%)	33 (100.0%)	83 (100.0%)
Number of patients with events		3 (6.0%)	1 (3.0%)	4 (4.8%)
Number of patients without events		47 (94.0%)	32 (97.0%)	79 (95.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.043 [0.203, 20.522]			
Stratified OR, 95% CI	1.521 [0.182, 12.693]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.980 [0.215, 18.232]			
Stratified RR, 95% CI	1.452 [0.201, 10.473]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.030 [-0.058, 0.118]			
Stratified ARR, 95% CI (CMH method)	0.032 [-0.056, 0.119]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5151			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Gender
Safety Population

Gender: Female

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 22)	Total (N= 79)
Number of patients at risk		57 (100.0%)	22 (100.0%)	79 (100.0%)
Number of patients with events		5 (8.8%)	0	5 (6.3%)
Number of patients without events		52 (91.2%)	22 (100.0%)	74 (93.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.714 [0.250, 88.897]			
Stratified OR, 95% CI	1.758 [0.262, 11.815]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.362 [0.251, 75.750]			
Stratified RR, 95% CI	1.619 [0.296, 8.864]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.088 [0.014, 0.161]			
Stratified ARR, 95% CI (CMH method)	0.085 [0.011, 0.158]			
Test on Differences [c]				
Unstratified p-value	0.3145			
Stratified p-value	0.1552			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TESAE by Gender
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.2598
Female vs. Male		0.5465	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Table 1002FDC.053.202.2.2
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Age
Safety Population

Age (years): < 65

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 27)	Total (N= 84)
Number of patients at risk		57 (100.0%)	27 (100.0%)	84 (100.0%)
Number of patients with events		6 (10.5%)	1 (3.7%)	7 (8.3%)
Number of patients without events		51 (89.5%)	26 (96.3%)	77 (91.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.059 [0.350, 26.765]			
Stratified OR, 95% CI	1.569 [0.282, 8.739]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.842 [0.360, 22.453]			
Stratified RR, 95% CI	1.422 [0.313, 6.472]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.068 [-0.039, 0.175]			
Stratified ARR, 95% CI (CMH method)	0.065 [-0.046, 0.177]			
Test on Differences [c]				
Unstratified p-value	0.4204			
Stratified p-value	0.3075			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Age
Safety Population

Age (years): >= 65

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)	Total (N= 78)
Number of patients at risk		50 (100.0%)	28 (100.0%)	78 (100.0%)
Number of patients with events		2 (4.0%)	0	2 (2.6%)
Number of patients without events		48 (96.0%)	28 (100.0%)	76 (97.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.938 [0.136, 63.382]			
Stratified OR, 95% CI	2.931 [0.125, 68.549]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.843 [0.141, 57.218]			
Stratified RR, 95% CI	2.647 [0.142, 49.419]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.040 [-0.014, 0.094]			
Stratified ARR, 95% CI (CMH method)	0.038 [-0.016, 0.091]			
Test on Differences [c]				
Unstratified p-value	0.5338			
Stratified p-value	0.3066			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Table 1002FDC.053.202.2.2.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TESAE by Age
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.4299
>= 65 vs. < 65		0.3219	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by CVD Risk Category
Safety Population

CVD Risk Category: ASCVD and/or HeFH

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		7 (11.9%)	1 (3.2%)	8 (8.9%)
Number of patients without events		52 (88.1%)	30 (96.8%)	82 (91.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.038 [0.474, 34.425]			
Stratified OR, 95% CI	2.021 [0.261, 15.631]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.678 [0.474, 28.561]			
Stratified RR, 95% CI	1.841 [0.262, 12.932]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.086 [-0.017, 0.190]			
Stratified ARR, 95% CI (CMH method)	0.088 [-0.019, 0.194]			
Test on Differences [c]				
Unstratified p-value	0.2547			
Stratified p-value	0.1632			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by CVD Risk Category
Safety Population

CVD Risk Category: Multiple CV risk factors

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		1 (2.1%)	0	1 (1.4%)
Number of patients without events		47 (97.9%)	24 (100.0%)	71 (98.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.547 [0.061, 39.412]			
Stratified OR, 95% CI	1.452 [0.053, 40.040]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.531 [0.065, 36.227]			
Stratified RR, 95% CI	1.412 [0.064, 30.974]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.021 [-0.020, 0.061]			
Stratified ARR, 95% CI (CMH method)	0.019 [-0.020, 0.058]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5083			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TESAE by CVD Risk Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.6234
Multiple CV risk factors vs. ASCVD and/or HeFH		0.2130	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: Other

	FDC vs. Placebo	FDC (N= 65)	Placebo (N= 34)	Total (N= 99)
Number of patients at risk		65 (100.0%)	34 (100.0%)	99 (100.0%)
Number of patients with events		1 (1.5%)	1 (2.9%)	2 (2.0%)
Number of patients without events		64 (98.5%)	33 (97.1%)	97 (98.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.516 [0.031, 8.509]			
Stratified OR, 95% CI	0.500 [0.029, 8.524]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.523 [0.034, 8.106]			
Stratified RR, 95% CI	0.515 [0.034, 7.737]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.014 [-0.078, 0.050]			
Stratified ARR, 95% CI (CMH method)	-0.014 [-0.078, 0.049]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.6294			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		7 (16.7%)	0	7 (11.1%)
Number of patients without events		35 (83.3%)	21 (100.0%)	56 (88.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	9.085 [0.494, 167.16]			
Stratified OR, 95% CI	4.064 [0.448, 36.904]			
Relative Risk [a]				
Unstratified RR, 95% CI	7.674 [0.459, 128.27]			
Stratified RR, 95% CI	3.452 [0.433, 27.546]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.167 [0.054, 0.279]			
Stratified ARR, 95% CI (CMH method)	0.172 [0.058, 0.286]			
Test on Differences [c]				
Unstratified p-value	0.0848			
Stratified p-value	0.0423			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TESAE by Baseline Statin Intensity I
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.0611
High Intensity Statin vs. Other		0.6430	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

	FDC vs. Placebo	FDC (N= 32)	Placebo (N= 20)	Total (N= 52)
Number of patients at risk		32 (100.0%)	20 (100.0%)	52 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		32 (100.0%)	20 (100.0%)	52 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		7 (16.7%)	0	7 (11.1%)
Number of patients without events		35 (83.3%)	21 (100.0%)	56 (88.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	9.085 [0.494, 167.16]			
Stratified OR, 95% CI	4.064 [0.448, 36.904]			
Relative Risk [a]				
Unstratified RR, 95% CI	7.674 [0.459, 128.27]			
Stratified RR, 95% CI	3.452 [0.433, 27.546]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.167 [0.054, 0.279]			
Stratified ARR, 95% CI (CMH method)	0.172 [0.058, 0.286]			
Test on Differences [c]				
Unstratified p-value	0.0848			
Stratified p-value	0.0423			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: None

	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)	Total (N= 47)
Number of patients at risk		33 (100.0%)	14 (100.0%)	47 (100.0%)
Number of patients with events		1 (3.0%)	1 (7.1%)	2 (4.3%)
Number of patients without events		32 (97.0%)	13 (92.9%)	45 (95.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.406 [0.024, 6.994]			
Stratified OR, 95% CI	0.400 [0.021, 7.484]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.424 [0.029, 6.315]			
Stratified RR, 95% CI	0.438 [0.032, 6.043]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.041 [-0.188, 0.106]			
Stratified ARR, 95% CI (CMH method)	-0.040 [-0.184, 0.104]			
Test on Differences [c]				
Unstratified p-value	0.5116			
Stratified p-value	0.5382			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TESAE by Baseline Statin Intensity II
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	WARNING: Negative of Hessian not positive definite				-
High Intensity Statin vs. Other Intensity Statin		0.9999	1.0000	-	
None vs. Other Intensity Statin		0.9999	-	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Race
Safety Population

Race: White

	FDC vs. Placebo	FDC (N= 84)	Placebo (N= 48)	Total (N= 132)
Number of patients at risk		84 (100.0%)	48 (100.0%)	132 (100.0%)
Number of patients with events		5 (6.0%)	1 (2.1%)	6 (4.5%)
Number of patients without events		79 (94.0%)	47 (97.9%)	126 (95.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.975 [0.337, 26.241]			
Stratified OR, 95% CI	1.684 [0.313, 9.055]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.857 [0.344, 23.745]			
Stratified RR, 95% CI	1.605 [0.335, 7.686]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.039 [-0.026, 0.103]			
Stratified ARR, 95% CI (CMH method)	0.038 [-0.026, 0.103]			
Test on Differences [c]				
Unstratified p-value	0.4159			
Stratified p-value	0.3101			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Race
Safety Population

Race: non-White

	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)	Total (N= 30)
Number of patients at risk		23 (100.0%)	7 (100.0%)	30 (100.0%)
Number of patients with events		3 (13.0%)	0	3 (10.0%)
Number of patients without events		20 (87.0%)	7 (100.0%)	27 (90.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.561 [0.118, 55.665]			
Stratified OR, 95% CI	3.182 [0.115, 87.919]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.333 [0.135, 40.464]			
Stratified RR, 95% CI	2.333 [0.163, 33.343]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.130 [-0.007, 0.268]			
Stratified ARR, 95% CI (CMH method)	0.116 [-0.023, 0.254]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3261			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TESAE by Race
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.4638
non-White vs. White		0.3312	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): < 130

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 16)	Total (N= 54)
Number of patients at risk		38 (100.0%)	16 (100.0%)	54 (100.0%)
Number of patients with events		3 (7.9%)	0	3 (5.6%)
Number of patients without events		35 (92.1%)	16 (100.0%)	51 (94.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.254 [0.159, 66.681]			
Stratified OR, 95% CI	4.103 [0.188, 89.443]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.051 [0.167, 55.895]			
Stratified RR, 95% CI	3.500 [0.202, 60.696]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.079 [-0.007, 0.165]			
Stratified ARR, 95% CI (CMH method)	0.095 [-0.015, 0.206]			
Test on Differences [c]				
Unstratified p-value	0.5465			
Stratified p-value	0.2146			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)	Total (N= 47)
Number of patients at risk		31 (100.0%)	16 (100.0%)	47 (100.0%)
Number of patients with events		2 (6.5%)	1 (6.3%)	3 (6.4%)
Number of patients without events		29 (93.5%)	15 (93.8%)	44 (93.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.034 [0.087, 12.354]			
Stratified OR, 95% CI	1.091 [0.106, 11.195]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.032 [0.101, 10.540]			
Stratified RR, 95% CI	1.045 [0.158, 6.927]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.002 [-0.145, 0.149]			
Stratified ARR, 95% CI (CMH method)	0.015 [-0.130, 0.160]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8480			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): >= 160

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)	Total (N= 61)
Number of patients at risk		38 (100.0%)	23 (100.0%)	61 (100.0%)
Number of patients with events		3 (7.9%)	0	3 (4.9%)
Number of patients without events		35 (92.1%)	23 (100.0%)	58 (95.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.634 [0.229, 93.884]			
Stratified OR, 95% CI	1.749 [0.243, 12.584]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.308 [0.233, 79.809]			
Stratified RR, 95% CI	1.628 [0.288, 9.195]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.079 [-0.007, 0.165]			
Stratified ARR, 95% CI (CMH method)	0.072 [-0.014, 0.158]			
Test on Differences [c]				
Unstratified p-value	0.2836			
Stratified p-value	0.2213			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TESAE by Baseline LDL-C Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.2850
130 - < 160 vs. < 130		<.0001	<.0001	-	
>= 160 vs. < 130		<.0001	1.0000	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by History of Diabetes
Safety Population

History of Diabetes: Yes

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		3 (6.3%)	0	3 (4.2%)
Number of patients without events		45 (93.8%)	24 (100.0%)	69 (95.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.769 [0.187, 75.981]			
Stratified OR, 95% CI	2.665 [0.261, 27.237]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.571 [0.192, 66.469]			
Stratified RR, 95% CI	2.355 [0.291, 19.029]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.063 [-0.006, 0.131]			
Stratified ARR, 95% CI (CMH method)	0.065 [-0.006, 0.135]			
Test on Differences [c]				
Unstratified p-value	0.5461			
Stratified p-value	0.1983			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by History of Diabetes
Safety Population

History of Diabetes: No

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		5 (8.5%)	1 (3.2%)	6 (6.7%)
Number of patients without events		54 (91.5%)	30 (96.8%)	84 (93.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.778 [0.310, 24.893]			
Stratified OR, 95% CI	1.248 [0.187, 8.343]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.627 [0.321, 21.508]			
Stratified RR, 95% CI	1.232 [0.229, 6.633]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.052 [-0.042, 0.147]			
Stratified ARR, 95% CI (CMH method)	0.039 [-0.054, 0.132]			
Test on Differences [c]				
Unstratified p-value	0.6601			
Stratified p-value	0.4606			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TESAE by History of Diabetes
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.3561
No vs. Yes		<.0001	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by BMI
Safety Population

BMI (kg/m^2): < 25

	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)	Total (N= 19)
Number of patients at risk		13 (100.0%)	6 (100.0%)	19 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		13 (100.0%)	6 (100.0%)	19 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by BMI
Safety Population

BMI (kg/m^2): 25 - < 30

	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)	Total (N= 49)
Number of patients at risk		27 (100.0%)	22 (100.0%)	49 (100.0%)
Number of patients with events		3 (11.1%)	1 (4.5%)	4 (8.2%)
Number of patients without events		24 (88.9%)	21 (95.5%)	45 (91.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.625 [0.253, 27.189]			
Stratified OR, 95% CI	1.510 [0.179, 12.706]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.444 [0.273, 21.886]			
Stratified RR, 95% CI	1.391 [0.246, 7.867]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.066 [-0.081, 0.213]			
Stratified ARR, 95% CI (CMH method)	0.042 [-0.099, 0.183]			
Test on Differences [c]				
Unstratified p-value	0.6173			
Stratified p-value	0.5920			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by BMI
Safety Population

BMI (kg/m^2): >= 30

	FDC vs. Placebo	FDC (N= 67)	Placebo (N= 27)	Total (N= 94)
Number of patients at risk		67 (100.0%)	27 (100.0%)	94 (100.0%)
Number of patients with events		5 (7.5%)	0	5 (5.3%)
Number of patients without events		62 (92.5%)	27 (100.0%)	89 (94.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.840 [0.259, 90.605]			
Stratified OR, 95% CI	4.172 [0.196, 88.713]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.529 [0.259, 79.202]			
Stratified RR, 95% CI	3.300 [0.211, 51.495]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.075 [0.012, 0.138]			
Stratified ARR, 95% CI (CMH method)	0.055 [-0.001, 0.111]			
Test on Differences [c]				
Unstratified p-value	0.3167			
Stratified p-value	0.2069			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TESAE by BMI
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	WARNING: Negative of Hessian not positive definite				-
25 - < 30 vs. < 25		0.9987	<.0001	-	
>= 30 vs. < 25		0.9987	-	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		9 (8.4%)	1 (1.8%)	10 (6.2%)
Number of patients without events		98 (91.6%)	54 (98.2%)	152 (93.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.959 [0.612, 40.196]			
Stratified OR, 95% CI	1.803 [0.388, 8.372]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.626 [0.601, 35.586]			
Stratified RR, 95% CI	1.692 [0.393, 7.287]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.066 [0.003, 0.129]			
Stratified ARR, 95% CI (CMH method)	0.067 [0.003, 0.131]			
Test on Differences [c]				
Unstratified p-value	0.1663			
Stratified p-value	0.0909			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Gender
Safety Population

Gender: Male

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)	Total (N= 83)
Number of patients at risk		50 (100.0%)	33 (100.0%)	83 (100.0%)
Number of patients with events		3 (6.0%)	1 (3.0%)	4 (4.8%)
Number of patients without events		47 (94.0%)	32 (97.0%)	79 (95.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.043 [0.203, 20.522]			
Stratified OR, 95% CI	1.252 [0.133, 11.814]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.980 [0.215, 18.232]			
Stratified RR, 95% CI	1.214 [0.147, 10.005]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.030 [-0.058, 0.118]			
Stratified ARR, 95% CI (CMH method)	0.029 [-0.059, 0.118]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5388			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Gender
Safety Population

Gender: Female

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 22)	Total (N= 79)
Number of patients at risk		57 (100.0%)	22 (100.0%)	79 (100.0%)
Number of patients with events		6 (10.5%)	0	6 (7.6%)
Number of patients without events		51 (89.5%)	22 (100.0%)	73 (92.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.680 [0.307, 105.18]			
Stratified OR, 95% CI	1.725 [0.331, 8.976]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.155 [0.303, 87.848]			
Stratified RR, 95% CI	1.610 [0.362, 7.153]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.105 [0.026, 0.185]			
Stratified ARR, 95% CI (CMH method)	0.106 [0.025, 0.187]			
Test on Differences [c]				
Unstratified p-value	0.1782			
Stratified p-value	0.1124			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Severe TEAE by Gender
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.2286
Female vs. Male		0.5465	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Age
Safety Population

Age (years): < 65

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 27)	Total (N= 84)
Number of patients at risk		57 (100.0%)	27 (100.0%)	84 (100.0%)
Number of patients with events		6 (10.5%)	1 (3.7%)	7 (8.3%)
Number of patients without events		51 (89.5%)	26 (96.3%)	77 (91.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.059 [0.350, 26.765]			
Stratified OR, 95% CI	1.425 [0.292, 6.961]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.842 [0.360, 22.453]			
Stratified RR, 95% CI	1.332 [0.316, 5.606]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.068 [-0.039, 0.175]			
Stratified ARR, 95% CI (CMH method)	0.072 [-0.043, 0.187]			
Test on Differences [c]				
Unstratified p-value	0.4204			
Stratified p-value	0.2736			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Age
Safety Population

Age (years): >= 65

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)	Total (N= 78)
Number of patients at risk		50 (100.0%)	28 (100.0%)	78 (100.0%)
Number of patients with events		3 (6.0%)	0	3 (3.8%)
Number of patients without events		47 (94.0%)	28 (100.0%)	75 (96.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.200 [0.209, 84.305]			
Stratified OR, 95% CI	4.407 [0.202, 96.375]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.980 [0.213, 74.388]			
Stratified RR, 95% CI	3.706 [0.214, 64.125]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.060 [-0.006, 0.126]			
Stratified ARR, 95% CI (CMH method)	0.057 [-0.008, 0.122]			
Test on Differences [c]				
Unstratified p-value	0.5491			
Stratified p-value	0.1999			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Severe TEAE by Age
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.3487
>= 65 vs. < 65		0.3219	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by CVD Risk Category
Safety Population

CVD Risk Category: ASCVD and/or HeFH

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		7 (11.9%)	1 (3.2%)	8 (8.9%)
Number of patients without events		52 (88.1%)	30 (96.8%)	82 (91.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.038 [0.474, 34.425]			
Stratified OR, 95% CI	2.021 [0.261, 15.631]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.678 [0.474, 28.561]			
Stratified RR, 95% CI	1.841 [0.262, 12.932]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.086 [-0.017, 0.190]			
Stratified ARR, 95% CI (CMH method)	0.088 [-0.019, 0.194]			
Test on Differences [c]				
Unstratified p-value	0.2547			
Stratified p-value	0.1632			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by CVD Risk Category
Safety Population

CVD Risk Category: Multiple CV risk factors

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		2 (4.2%)	0	2 (2.8%)
Number of patients without events		46 (95.8%)	24 (100.0%)	70 (97.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.634 [0.122, 57.065]			
Stratified OR, 95% CI	1.558 [0.153, 15.893]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.551 [0.127, 51.131]			
Stratified RR, 95% CI	1.518 [0.167, 13.764]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.042 [-0.015, 0.098]			
Stratified ARR, 95% CI (CMH method)	0.041 [-0.015, 0.097]			
Test on Differences [c]				
Unstratified p-value	0.5493			
Stratified p-value	0.3252			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Severe TEAE by CVD Risk Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.4985
Multiple CV risk factors vs. ASCVD and/or HeFH		0.2130	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: Other

	FDC vs. Placebo	FDC (N= 65)	Placebo (N= 34)	Total (N= 99)
Number of patients at risk		65 (100.0%)	34 (100.0%)	99 (100.0%)
Number of patients with events		2 (3.1%)	1 (2.9%)	3 (3.0%)
Number of patients without events		63 (96.9%)	33 (97.1%)	96 (97.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.048 [0.092, 11.985]			
Stratified OR, 95% CI	0.841 [0.099, 7.132]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.046 [0.098, 11.128]			
Stratified RR, 95% CI	0.842 [0.108, 6.567]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.001 [-0.069, 0.072]			
Stratified ARR, 95% CI (CMH method)	0.001 [-0.070, 0.072]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9737			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		7 (16.7%)	0	7 (11.1%)
Number of patients without events		35 (83.3%)	21 (100.0%)	56 (88.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	9.085 [0.494, 167.16]			
Stratified OR, 95% CI	4.064 [0.448, 36.904]			
Relative Risk [a]				
Unstratified RR, 95% CI	7.674 [0.459, 128.27]			
Stratified RR, 95% CI	3.452 [0.433, 27.546]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.167 [0.054, 0.279]			
Stratified ARR, 95% CI (CMH method)	0.172 [0.058, 0.286]			
Test on Differences [c]				
Unstratified p-value	0.0848			
Stratified p-value	0.0423			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Severe TEAE by Baseline Statin Intensity I
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.1018
High Intensity Statin vs. Other		0.9702	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

	FDC vs. Placebo	FDC (N= 32)	Placebo (N= 20)	Total (N= 52)
Number of patients at risk		32 (100.0%)	20 (100.0%)	52 (100.0%)
Number of patients with events		1 (3.1%)	0	1 (1.9%)
Number of patients without events		31 (96.9%)	20 (100.0%)	51 (98.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.952 [0.076, 50.281]			
Stratified OR, 95% CI	2.172 [0.080, 58.763]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.909 [0.082, 44.707]			
Stratified RR, 95% CI	2.063 [0.092, 46.113]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.031 [-0.029, 0.092]			
Stratified ARR, 95% CI (CMH method)	0.033 [-0.029, 0.094]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4142			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		7 (16.7%)	0	7 (11.1%)
Number of patients without events		35 (83.3%)	21 (100.0%)	56 (88.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	9.085 [0.494, 167.16]			
Stratified OR, 95% CI	4.064 [0.448, 36.904]			
Relative Risk [a]				
Unstratified RR, 95% CI	7.674 [0.459, 128.27]			
Stratified RR, 95% CI	3.452 [0.433, 27.546]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.167 [0.054, 0.279]			
Stratified ARR, 95% CI (CMH method)	0.172 [0.058, 0.286]			
Test on Differences [c]				
Unstratified p-value	0.0848			
Stratified p-value	0.0423			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: None

	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)	Total (N= 47)
Number of patients at risk		33 (100.0%)	14 (100.0%)	47 (100.0%)
Number of patients with events		1 (3.0%)	1 (7.1%)	2 (4.3%)
Number of patients without events		32 (97.0%)	13 (92.9%)	45 (95.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.406 [0.024, 6.994]			
Stratified OR, 95% CI	0.400 [0.021, 7.484]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.424 [0.029, 6.315]			
Stratified RR, 95% CI	0.438 [0.032, 6.043]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.041 [-0.188, 0.106]			
Stratified ARR, 95% CI (CMH method)	-0.040 [-0.184, 0.104]			
Test on Differences [c]				
Unstratified p-value	0.5116			
Stratified p-value	0.5382			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Severe TEAE by Baseline Statin Intensity II
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.1252
High Intensity Statin vs. Other Intensity Statin		<.0001	1.0000	-	
None vs. Other Intensity Statin		<.0001	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Race
Safety Population

Race: White

	FDC vs. Placebo	FDC (N= 84)	Placebo (N= 48)	Total (N= 132)
Number of patients at risk		84 (100.0%)	48 (100.0%)	132 (100.0%)
Number of patients with events		5 (6.0%)	1 (2.1%)	6 (4.5%)
Number of patients without events		79 (94.0%)	47 (97.9%)	126 (95.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.975 [0.337, 26.241]			
Stratified OR, 95% CI	1.537 [0.262, 9.007]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.857 [0.344, 23.745]			
Stratified RR, 95% CI	1.466 [0.280, 7.675]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.039 [-0.026, 0.103]			
Stratified ARR, 95% CI (CMH method)	0.040 [-0.026, 0.106]			
Test on Differences [c]				
Unstratified p-value	0.4159			
Stratified p-value	0.2948			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Race
Safety Population

Race: non-White

	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)	Total (N= 30)
Number of patients at risk		23 (100.0%)	7 (100.0%)	30 (100.0%)
Number of patients with events		4 (17.4%)	0	4 (13.3%)
Number of patients without events		19 (82.6%)	7 (100.0%)	26 (86.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.462 [0.165, 72.414]			
Stratified OR, 95% CI	1.973 [0.177, 22.057]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.000 [0.181, 49.832]			
Stratified RR, 95% CI	1.675 [0.235, 11.936]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.174 [0.019, 0.329]			
Stratified ARR, 95% CI (CMH method)	0.158 [0.000, 0.317]			
Test on Differences [c]				
Unstratified p-value	0.5476			
Stratified p-value	0.2659			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Severe TEAE by Race
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.4062
non-White vs. White		0.3312	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): < 130

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 16)	Total (N= 54)
Number of patients at risk		38 (100.0%)	16 (100.0%)	54 (100.0%)
Number of patients with events		4 (10.5%)	0	4 (7.4%)
Number of patients without events		34 (89.5%)	16 (100.0%)	50 (92.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.304 [0.219, 84.748]			
Stratified OR, 95% CI	5.667 [0.270, 119.08]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.923 [0.223, 68.893]			
Stratified RR, 95% CI	4.500 [0.271, 74.748]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.105 [0.008, 0.203]			
Stratified ARR, 95% CI (CMH method)	0.127 [0.001, 0.253]			
Test on Differences [c]				
Unstratified p-value	0.3064			
Stratified p-value	0.1425			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)	Total (N= 47)
Number of patients at risk		31 (100.0%)	16 (100.0%)	47 (100.0%)
Number of patients with events		1 (3.2%)	1 (6.3%)	2 (4.3%)
Number of patients without events		30 (96.8%)	15 (93.8%)	45 (95.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.500 [0.029, 8.560]			
Stratified OR, 95% CI	0.659 [0.056, 7.744]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.516 [0.035, 7.721]			
Stratified RR, 95% CI	0.731 [0.090, 5.921]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.030 [-0.164, 0.104]			
Stratified ARR, 95% CI (CMH method)	-0.020 [-0.160, 0.120]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7634			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): >= 160

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)	Total (N= 61)
Number of patients at risk		38 (100.0%)	23 (100.0%)	61 (100.0%)
Number of patients with events		4 (10.5%)	0	4 (6.6%)
Number of patients without events		34 (89.5%)	23 (100.0%)	57 (93.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.130 [0.315, 119.30]			
Stratified OR, 95% CI	2.064 [0.379, 11.238]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.538 [0.312, 98.383]			
Stratified RR, 95% CI	1.883 [0.415, 8.535]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.105 [0.008, 0.203]			
Stratified ARR, 95% CI (CMH method)	0.109 [0.006, 0.212]			
Test on Differences [c]				
Unstratified p-value	0.2874			
Stratified p-value	0.1173			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Severe TEAE by Baseline LDL-C Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.1492
130 - < 160 vs. < 130		<.0001	<.0001	-	
>= 160 vs. < 130		<.0001	1.0000	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by History of Diabetes
Safety Population

History of Diabetes: Yes

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		4 (8.3%)	0	4 (5.6%)
Number of patients without events		44 (91.7%)	24 (100.0%)	68 (94.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.955 [0.256, 95.915]			
Stratified OR, 95% CI	2.243 [0.335, 15.015]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.592 [0.257, 81.944]			
Stratified RR, 95% CI	2.038 [0.360, 11.534]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.083 [0.005, 0.162]			
Stratified ARR, 95% CI (CMH method)	0.094 [0.011, 0.178]			
Test on Differences [c]				
Unstratified p-value	0.2939			
Stratified p-value	0.1150			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by History of Diabetes
Safety Population

History of Diabetes: No

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		5 (8.5%)	1 (3.2%)	6 (6.7%)
Number of patients without events		54 (91.5%)	30 (96.8%)	84 (93.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.778 [0.310, 24.893]			
Stratified OR, 95% CI	1.248 [0.187, 8.343]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.627 [0.321, 21.508]			
Stratified RR, 95% CI	1.232 [0.229, 6.633]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.052 [-0.042, 0.147]			
Stratified ARR, 95% CI (CMH method)	0.039 [-0.054, 0.132]			
Test on Differences [c]				
Unstratified p-value	0.6601			
Stratified p-value	0.4606			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Severe TEAE by History of Diabetes
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.3002
No vs. Yes		<.0001	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by BMI
Safety Population

BMI (kg/m^2): < 25

	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)	Total (N= 19)
Number of patients at risk		13 (100.0%)	6 (100.0%)	19 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		13 (100.0%)	6 (100.0%)	19 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by BMI
Safety Population

BMI (kg/m^2): 25 - < 30

	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)	Total (N= 49)
Number of patients at risk		27 (100.0%)	22 (100.0%)	49 (100.0%)
Number of patients with events		2 (7.4%)	1 (4.5%)	3 (6.1%)
Number of patients without events		25 (92.6%)	21 (95.5%)	46 (93.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.680 [0.142, 19.853]			
Stratified OR, 95% CI	0.938 [0.095, 9.241]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.630 [0.158, 16.808]			
Stratified RR, 95% CI	0.955 [0.140, 6.511]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.029 [-0.103, 0.160]			
Stratified ARR, 95% CI (CMH method)	0.007 [-0.121, 0.136]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9153			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by BMI
Safety Population

BMI (kg/m^2): >= 30

	FDC vs. Placebo	FDC (N= 67)	Placebo (N= 27)	Total (N= 94)
Number of patients at risk		67 (100.0%)	27 (100.0%)	94 (100.0%)
Number of patients with events		7 (10.4%)	0	7 (7.4%)
Number of patients without events		60 (89.6%)	27 (100.0%)	87 (92.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.818 [0.376, 123.66]			
Stratified OR, 95% CI	3.221 [0.345, 30.073]			
Relative Risk [a]				
Unstratified RR, 95% CI	6.176 [0.365, 104.52]			
Stratified RR, 95% CI	2.745 [0.353, 21.357]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.104 [0.031, 0.178]			
Stratified ARR, 95% CI (CMH method)	0.085 [0.016, 0.153]			
Test on Differences [c]				
Unstratified p-value	0.1866			
Stratified p-value	0.1087			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Severe TEAE by BMI
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	WARNING: Negative of Hessian not positive definite				-
25 - < 30 vs. < 25		0.9986	<.0001	-	
>= 30 vs. < 25		0.9986	-	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		23 (21.5%)	7 (12.7%)	30 (18.5%)
Number of patients without events		84 (78.5%)	48 (87.3%)	132 (81.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.878 [0.750, 4.699]			
Stratified OR, 95% CI	1.880 [0.738, 4.792]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.689 [0.773, 3.688]			
Stratified RR, 95% CI	1.670 [0.767, 3.638]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.088 [-0.030, 0.205]			
Stratified ARR, 95% CI (CMH method)	0.088 [-0.028, 0.204]			
Test on Differences [c]				
Unstratified p-value	0.1737			
Stratified p-value	0.1668			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Gender
Safety Population

Gender: Male

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)	Total (N= 83)
Number of patients at risk		50 (100.0%)	33 (100.0%)	83 (100.0%)
Number of patients with events		10 (20.0%)	4 (12.1%)	14 (16.9%)
Number of patients without events		40 (80.0%)	29 (87.9%)	69 (83.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.813 [0.517, 6.353]			
Stratified OR, 95% CI	1.830 [0.536, 6.244]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.650 [0.564, 4.825]			
Stratified RR, 95% CI	1.596 [0.629, 4.053]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.079 [-0.078, 0.236]			
Stratified ARR, 95% CI (CMH method)	0.093 [-0.055, 0.241]			
Test on Differences [c]				
Unstratified p-value	0.3890			
Stratified p-value	0.2486			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Gender
Safety Population

Gender: Female

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 22)	Total (N= 79)
Number of patients at risk		57 (100.0%)	22 (100.0%)	79 (100.0%)
Number of patients with events		13 (22.8%)	3 (13.6%)	16 (20.3%)
Number of patients without events		44 (77.2%)	19 (86.4%)	63 (79.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.871 [0.477, 7.333]			
Stratified OR, 95% CI	1.294 [0.348, 4.811]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.673 [0.527, 5.308]			
Stratified RR, 95% CI	1.159 [0.395, 3.407]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.092 [-0.088, 0.272]			
Stratified ARR, 95% CI (CMH method)	0.091 [-0.093, 0.275]			
Test on Differences [c]				
Unstratified p-value	0.5348			
Stratified p-value	0.3741			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Moderate TEAE by Gender
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.9866
Female vs. Male		0.3603	0.8687	0.9866	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Age
Safety Population

Age (years): < 65

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 27)	Total (N= 84)
Number of patients at risk		57 (100.0%)	27 (100.0%)	84 (100.0%)
Number of patients with events		15 (26.3%)	4 (14.8%)	19 (22.6%)
Number of patients without events		42 (73.7%)	23 (85.2%)	65 (77.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.054 [0.610, 6.917]			
Stratified OR, 95% CI	1.552 [0.455, 5.293]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.776 [0.651, 4.845]			
Stratified RR, 95% CI	1.354 [0.499, 3.674]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.115 [-0.061, 0.291]			
Stratified ARR, 95% CI (CMH method)	0.091 [-0.083, 0.266]			
Test on Differences [c]				
Unstratified p-value	0.2784			
Stratified p-value	0.3411			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Age
Safety Population

Age (years): >= 65

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)	Total (N= 78)
Number of patients at risk		50 (100.0%)	28 (100.0%)	78 (100.0%)
Number of patients with events		8 (16.0%)	3 (10.7%)	11 (14.1%)
Number of patients without events		42 (84.0%)	25 (89.3%)	67 (85.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.587 [0.385, 6.542]			
Stratified OR, 95% CI	1.736 [0.429, 7.023]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.493 [0.431, 5.179]			
Stratified RR, 95% CI	1.555 [0.500, 4.842]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.053 [-0.100, 0.206]			
Stratified ARR, 95% CI (CMH method)	0.077 [-0.071, 0.226]			
Test on Differences [c]				
Unstratified p-value	0.7371			
Stratified p-value	0.3530			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Moderate TEAE by Age
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.8319
>= 65 vs. < 65		0.2617	0.6502	0.8314	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by CVD Risk Category
Safety Population

CVD Risk Category: ASCVD and/or HeFH

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		16 (27.1%)	4 (12.9%)	20 (22.2%)
Number of patients without events		43 (72.9%)	27 (87.1%)	70 (77.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.512 [0.759, 8.311]			
Stratified OR, 95% CI	2.264 [0.653, 7.851]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.102 [0.769, 5.746]			
Stratified RR, 95% CI	1.889 [0.656, 5.440]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.142 [-0.022, 0.306]			
Stratified ARR, 95% CI (CMH method)	0.140 [-0.024, 0.305]			
Test on Differences [c]				
Unstratified p-value	0.1823			
Stratified p-value	0.1236			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by CVD Risk Category
Safety Population

CVD Risk Category: Multiple CV risk factors

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		7 (14.6%)	3 (12.5%)	10 (13.9%)
Number of patients without events		41 (85.4%)	21 (87.5%)	62 (86.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.195 [0.280, 5.101]			
Stratified OR, 95% CI	1.192 [0.279, 5.098]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.167 [0.331, 4.116]			
Stratified RR, 95% CI	1.162 [0.329, 4.105]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.021 [-0.145, 0.187]			
Stratified ARR, 95% CI (CMH method)	0.021 [-0.145, 0.188]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8075			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Moderate TEAE by CVD Risk Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.4796
Multiple CV risk factors vs. ASCVD and/or HeFH		0.1478	0.9645	0.4744	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: Other

	FDC vs. Placebo	FDC (N= 65)	Placebo (N= 34)	Total (N= 99)
Number of patients at risk		65 (100.0%)	34 (100.0%)	99 (100.0%)
Number of patients with events		18 (27.7%)	4 (11.8%)	22 (22.2%)
Number of patients without events		47 (72.3%)	30 (88.2%)	77 (77.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.872 [0.886, 9.313]			
Stratified OR, 95% CI	2.725 [0.824, 9.010]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.354 [0.865, 6.404]			
Stratified RR, 95% CI	2.220 [0.800, 6.159]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.159 [0.006, 0.313]			
Stratified ARR, 95% CI (CMH method)	0.158 [0.005, 0.312]			
Test on Differences [c]				
Unstratified p-value	0.0803			
Stratified p-value	0.0700			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		5 (11.9%)	3 (14.3%)	8 (12.7%)
Number of patients without events		37 (88.1%)	18 (85.7%)	55 (87.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.811 [0.174, 3.775]			
Stratified OR, 95% CI	0.808 [0.173, 3.776]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.833 [0.220, 3.157]			
Stratified RR, 95% CI	0.831 [0.219, 3.159]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.024 [-0.203, 0.155]			
Stratified ARR, 95% CI (CMH method)	-0.024 [-0.203, 0.155]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7898			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Moderate TEAE by Baseline Statin Intensity I
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.2304
High Intensity Statin vs. Other		0.0937	0.7850	0.2219	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

	FDC vs. Placebo	FDC (N= 32)	Placebo (N= 20)	Total (N= 52)
Number of patients at risk		32 (100.0%)	20 (100.0%)	52 (100.0%)
Number of patients with events		6 (18.8%)	2 (10.0%)	8 (15.4%)
Number of patients without events		26 (81.3%)	18 (90.0%)	44 (84.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.077 [0.376, 11.477]			
Stratified OR, 95% CI	1.886 [0.309, 11.497]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.875 [0.419, 8.400]			
Stratified RR, 95% CI	1.718 [0.348, 8.485]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.088 [-0.101, 0.276]			
Stratified ARR, 95% CI (CMH method)	0.083 [-0.105, 0.271]			
Test on Differences [c]				
Unstratified p-value	0.4634			
Stratified p-value	0.4176			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		5 (11.9%)	3 (14.3%)	8 (12.7%)
Number of patients without events		37 (88.1%)	18 (85.7%)	55 (87.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.811 [0.174, 3.775]			
Stratified OR, 95% CI	0.808 [0.173, 3.776]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.833 [0.220, 3.157]			
Stratified RR, 95% CI	0.831 [0.219, 3.159]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.024 [-0.203, 0.155]			
Stratified ARR, 95% CI (CMH method)	-0.024 [-0.203, 0.155]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7898			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: None

	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)	Total (N= 47)
Number of patients at risk		33 (100.0%)	14 (100.0%)	47 (100.0%)
Number of patients with events		12 (36.4%)	2 (14.3%)	14 (29.8%)
Number of patients without events		21 (63.6%)	12 (85.7%)	33 (70.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.429 [0.654, 17.968]			
Stratified OR, 95% CI	3.380 [0.636, 17.979]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.545 [0.653, 9.919]			
Stratified RR, 95% CI	2.461 [0.624, 9.702]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.221 [-0.025, 0.467]			
Stratified ARR, 95% CI (CMH method)	0.224 [-0.023, 0.470]			
Test on Differences [c]				
Unstratified p-value	0.1746			
Stratified p-value	0.1263			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Moderate TEAE by Baseline Statin Intensity II
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.4967
High Intensity Statin vs. Other Intensity Statin		0.4113	0.6775	0.4281	
None vs. Other Intensity Statin		0.4113	0.7036	0.7673	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Race
Safety Population

Race: White

	FDC vs. Placebo	FDC (N= 84)	Placebo (N= 48)	Total (N= 132)
Number of patients at risk		84 (100.0%)	48 (100.0%)	132 (100.0%)
Number of patients with events		21 (25.0%)	6 (12.5%)	27 (20.5%)
Number of patients without events		63 (75.0%)	42 (87.5%)	105 (79.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.333 [0.869, 6.265]			
Stratified OR, 95% CI	2.310 [0.840, 6.350]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.000 [0.868, 4.610]			
Stratified RR, 95% CI	1.907 [0.835, 4.354]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.125 [-0.007, 0.257]			
Stratified ARR, 95% CI (CMH method)	0.124 [-0.007, 0.255]			
Test on Differences [c]				
Unstratified p-value	0.0868			
Stratified p-value	0.0875			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Race
Safety Population

Race: non-White

	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)	Total (N= 30)
Number of patients at risk		23 (100.0%)	7 (100.0%)	30 (100.0%)
Number of patients with events		2 (8.7%)	1 (14.3%)	3 (10.0%)
Number of patients without events		21 (91.3%)	6 (85.7%)	27 (90.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.571 [0.044, 7.438]			
Stratified OR, 95% CI	0.389 [0.030, 5.027]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.609 [0.064, 5.754]			
Stratified RR, 95% CI	0.534 [0.077, 3.681]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.056 [-0.340, 0.228]			
Stratified ARR, 95% CI (CMH method)	-0.086 [-0.383, 0.212]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4795			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Moderate TEAE by Race
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.3707
non-White vs. White		0.1038	0.8939	0.3306	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): < 130

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 16)	Total (N= 54)
Number of patients at risk		38 (100.0%)	16 (100.0%)	54 (100.0%)
Number of patients with events		8 (21.1%)	3 (18.8%)	11 (20.4%)
Number of patients without events		30 (78.9%)	13 (81.3%)	43 (79.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.156 [0.264, 5.066]			
Stratified OR, 95% CI	1.101 [0.210, 5.777]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.123 [0.341, 3.696]			
Stratified RR, 95% CI	1.126 [0.320, 3.965]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.023 [-0.208, 0.254]			
Stratified ARR, 95% CI (CMH method)	0.017 [-0.217, 0.250]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8910			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)	Total (N= 47)
Number of patients at risk		31 (100.0%)	16 (100.0%)	47 (100.0%)
Number of patients with events		7 (22.6%)	1 (6.3%)	8 (17.0%)
Number of patients without events		24 (77.4%)	15 (93.8%)	39 (83.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.375 [0.488, 39.184]			
Stratified OR, 95% CI	2.128 [0.393, 11.523]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.613 [0.486, 26.871]			
Stratified RR, 95% CI	1.725 [0.414, 7.187]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.163 [-0.026, 0.352]			
Stratified ARR, 95% CI (CMH method)	0.186 [-0.022, 0.394]			
Test on Differences [c]				
Unstratified p-value	0.2343			
Stratified p-value	0.1109			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): >= 160

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)	Total (N= 61)
Number of patients at risk		38 (100.0%)	23 (100.0%)	61 (100.0%)
Number of patients with events		8 (21.1%)	3 (13.0%)	11 (18.0%)
Number of patients without events		30 (78.9%)	20 (87.0%)	50 (82.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.778 [0.420, 7.522]			
Stratified OR, 95% CI	1.356 [0.286, 6.428]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.614 [0.476, 5.476]			
Stratified RR, 95% CI	1.280 [0.353, 4.645]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.080 [-0.109, 0.269]			
Stratified ARR, 95% CI (CMH method)	0.053 [-0.134, 0.240]			
Test on Differences [c]				
Unstratified p-value	0.5105			
Stratified p-value	0.6001			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Moderate TEAE by Baseline LDL-C Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.5752
130 - < 160 vs. < 130		0.8489	0.3176	0.3263	
>= 160 vs. < 130		0.8489	0.6279	0.6768	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by History of Diabetes
Safety Population

History of Diabetes: Yes

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		6 (12.5%)	2 (8.3%)	8 (11.1%)
Number of patients without events		42 (87.5%)	22 (91.7%)	64 (88.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.571 [0.292, 8.443]			
Stratified OR, 95% CI	1.095 [0.212, 5.652]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.500 [0.327, 6.882]			
Stratified RR, 95% CI	1.064 [0.261, 4.340]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.042 [-0.103, 0.187]			
Stratified ARR, 95% CI (CMH method)	0.024 [-0.121, 0.169]			
Test on Differences [c]				
Unstratified p-value	0.7104			
Stratified p-value	0.7580			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by History of Diabetes
Safety Population

History of Diabetes: No

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		17 (28.8%)	5 (16.1%)	22 (24.4%)
Number of patients without events		42 (71.2%)	26 (83.9%)	68 (75.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.105 [0.693, 6.391]			
Stratified OR, 95% CI	2.073 [0.688, 6.245]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.786 [0.728, 4.382]			
Stratified RR, 95% CI	1.724 [0.742, 4.002]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.127 [-0.047, 0.300]			
Stratified ARR, 95% CI (CMH method)	0.131 [-0.039, 0.301]			
Test on Differences [c]				
Unstratified p-value	0.1833			
Stratified p-value	0.1643			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Moderate TEAE by History of Diabetes
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.8477
No vs. Yes		0.6019	0.4040	0.8464	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by BMI
Safety Population

BMI (kg/m^2): < 25

	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)	Total (N= 19)
Number of patients at risk		13 (100.0%)	6 (100.0%)	19 (100.0%)
Number of patients with events		4 (30.8%)	1 (16.7%)	5 (26.3%)
Number of patients without events		9 (69.2%)	5 (83.3%)	14 (73.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.222 [0.192, 25.723]			
Stratified OR, 95% CI	4.393 [0.380, 50.770]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.846 [0.258, 13.188]			
Stratified RR, 95% CI	2.250 [0.525, 9.645]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.141 [-0.249, 0.531]			
Stratified ARR, 95% CI (CMH method)	0.326 [-0.078, 0.730]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.1921			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by BMI
Safety Population

BMI (kg/m^2): 25 - < 30

	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)	Total (N= 49)
Number of patients at risk		27 (100.0%)	22 (100.0%)	49 (100.0%)
Number of patients with events		6 (22.2%)	2 (9.1%)	8 (16.3%)
Number of patients without events		21 (77.8%)	20 (90.9%)	41 (83.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.857 [0.515, 15.852]			
Stratified OR, 95% CI	2.692 [0.495, 14.654]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.444 [0.547, 10.934]			
Stratified RR, 95% CI	2.167 [0.526, 8.936]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.131 [-0.066, 0.329]			
Stratified ARR, 95% CI (CMH method)	0.155 [-0.046, 0.356]			
Test on Differences [c]				
Unstratified p-value	0.2689			
Stratified p-value	0.1676			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by BMI
Safety Population

BMI (kg/m^2): >= 30

	FDC vs. Placebo	FDC (N= 67)	Placebo (N= 27)	Total (N= 94)
Number of patients at risk		67 (100.0%)	27 (100.0%)	94 (100.0%)
Number of patients with events		13 (19.4%)	4 (14.8%)	17 (18.1%)
Number of patients without events		54 (80.6%)	23 (85.2%)	77 (81.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.384 [0.408, 4.700]			
Stratified OR, 95% CI	1.325 [0.397, 4.421]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.310 [0.469, 3.660]			
Stratified RR, 95% CI	1.240 [0.480, 3.202]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.046 [-0.118, 0.210]			
Stratified ARR, 95% CI (CMH method)	0.056 [-0.104, 0.216]			
Test on Differences [c]				
Unstratified p-value	0.7701			
Stratified p-value	0.5237			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Moderate TEAE by BMI
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.7863
25 - < 30 vs. < 25		0.5411	0.5933	0.8239	
>= 30 vs. < 25		0.5411	0.9083	0.7617	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		31 (29.0%)	16 (29.1%)	47 (29.0%)
Number of patients without events		76 (71.0%)	39 (70.9%)	115 (71.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.994 [0.486, 2.035]			
Stratified OR, 95% CI	0.969 [0.468, 2.007]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.996 [0.599, 1.655]			
Stratified RR, 95% CI	0.965 [0.572, 1.627]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.001 [-0.149, 0.146]			
Stratified ARR, 95% CI (CMH method)	-0.001 [-0.150, 0.148]			
Test on Differences [c]				
Unstratified p-value	0.9874			
Stratified p-value	0.9880			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Gender
Safety Population

Gender: Male

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)	Total (N= 83)
Number of patients at risk		50 (100.0%)	33 (100.0%)	83 (100.0%)
Number of patients with events		15 (30.0%)	8 (24.2%)	23 (27.7%)
Number of patients without events		35 (70.0%)	25 (75.8%)	60 (72.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.339 [0.493, 3.640]			
Stratified OR, 95% CI	1.336 [0.467, 3.822]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.238 [0.592, 2.586]			
Stratified RR, 95% CI	1.179 [0.548, 2.539]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.058 [-0.136, 0.251]			
Stratified ARR, 95% CI (CMH method)	0.052 [-0.141, 0.245]			
Test on Differences [c]				
Unstratified p-value	0.5663			
Stratified p-value	0.6077			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Gender
Safety Population

Gender: Female

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 22)	Total (N= 79)
Number of patients at risk		57 (100.0%)	22 (100.0%)	79 (100.0%)
Number of patients with events		16 (28.1%)	8 (36.4%)	24 (30.4%)
Number of patients without events		41 (71.9%)	14 (63.6%)	55 (69.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.683 [0.241, 1.938]			
Stratified OR, 95% CI	0.654 [0.203, 2.108]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.772 [0.387, 1.541]			
Stratified RR, 95% CI	0.628 [0.295, 1.339]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.083 [-0.315, 0.149]			
Stratified ARR, 95% CI (CMH method)	-0.081 [-0.328, 0.166]			
Test on Differences [c]				
Unstratified p-value	0.4725			
Stratified p-value	0.4979			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Mild TEAE by Gender
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.3617
Female vs. Male		0.5709	0.3314	0.3600	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Age
Safety Population

Age (years): < 65

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 27)	Total (N= 84)
Number of patients at risk		57 (100.0%)	27 (100.0%)	84 (100.0%)
Number of patients with events		14 (24.6%)	6 (22.2%)	20 (23.8%)
Number of patients without events		43 (75.4%)	21 (77.8%)	64 (76.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.140 [0.383, 3.387]			
Stratified OR, 95% CI	1.211 [0.398, 3.685]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.105 [0.477, 2.559]			
Stratified RR, 95% CI	1.136 [0.490, 2.634]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.023 [-0.169, 0.216]			
Stratified ARR, 95% CI (CMH method)	0.035 [-0.157, 0.228]			
Test on Differences [c]				
Unstratified p-value	0.8141			
Stratified p-value	0.7300			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Age
Safety Population

Age (years): >= 65

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)	Total (N= 78)
Number of patients at risk		50 (100.0%)	28 (100.0%)	78 (100.0%)
Number of patients with events		17 (34.0%)	10 (35.7%)	27 (34.6%)
Number of patients without events		33 (66.0%)	18 (64.3%)	51 (65.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.927 [0.352, 2.445]			
Stratified OR, 95% CI	0.866 [0.314, 2.387]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.952 [0.507, 1.786]			
Stratified RR, 95% CI	0.904 [0.455, 1.795]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.017 [-0.238, 0.204]			
Stratified ARR, 95% CI (CMH method)	-0.025 [-0.249, 0.200]			
Test on Differences [c]				
Unstratified p-value	0.8787			
Stratified p-value	0.8290			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Mild TEAE by Age
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.7794
>= 65 vs. < 65		0.8153	0.2813	0.7804	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by CVD Risk Category
Safety Population

CVD Risk Category: ASCVD and/or HeFH

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		13 (22.0%)	10 (32.3%)	23 (25.6%)
Number of patients without events		46 (78.0%)	21 (67.7%)	67 (74.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.593 [0.224, 1.570]			
Stratified OR, 95% CI	0.592 [0.224, 1.570]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.683 [0.339, 1.376]			
Stratified RR, 95% CI	0.680 [0.337, 1.372]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.102 [-0.298, 0.093]			
Stratified ARR, 95% CI (CMH method)	-0.102 [-0.298, 0.093]			
Test on Differences [c]				
Unstratified p-value	0.2906			
Stratified p-value	0.2955			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by CVD Risk Category
Safety Population

CVD Risk Category: Multiple CV risk factors

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		18 (37.5%)	6 (25.0%)	24 (33.3%)
Number of patients without events		30 (62.5%)	18 (75.0%)	48 (66.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.800 [0.603, 5.371]			
Stratified OR, 95% CI	1.799 [0.602, 5.382]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.500 [0.685, 3.283]			
Stratified RR, 95% CI	1.489 [0.680, 3.263]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.125 [-0.096, 0.346]			
Stratified ARR, 95% CI (CMH method)	0.127 [-0.095, 0.349]			
Test on Differences [c]				
Unstratified p-value	0.2888			
Stratified p-value	0.2881			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Mild TEAE by CVD Risk Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.1340
Multiple CV risk factors vs. ASCVD and/or HeFH		0.2861	0.5615	0.1423	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: Other

	FDC vs. Placebo	FDC (N= 65)	Placebo (N= 34)	Total (N= 99)
Number of patients at risk		65 (100.0%)	34 (100.0%)	99 (100.0%)
Number of patients with events		20 (30.8%)	10 (29.4%)	30 (30.3%)
Number of patients without events		45 (69.2%)	24 (70.6%)	69 (69.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.067 [0.431, 2.641]			
Stratified OR, 95% CI	1.032 [0.408, 2.609]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.046 [0.554, 1.976]			
Stratified RR, 95% CI	1.000 [0.515, 1.938]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.014 [-0.176, 0.203]			
Stratified ARR, 95% CI (CMH method)	0.014 [-0.178, 0.207]			
Test on Differences [c]				
Unstratified p-value	0.8890			
Stratified p-value	0.8843			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		11 (26.2%)	6 (28.6%)	17 (27.0%)
Number of patients without events		31 (73.8%)	15 (71.4%)	46 (73.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.887 [0.275, 2.859]			
Stratified OR, 95% CI	0.872 [0.269, 2.830]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.917 [0.394, 2.135]			
Stratified RR, 95% CI	0.907 [0.387, 2.128]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.024 [-0.258, 0.211]			
Stratified ARR, 95% CI (CMH method)	-0.026 [-0.261, 0.208]			
Test on Differences [c]				
Unstratified p-value	0.8409			
Stratified p-value	0.8261			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Mild TEAE by Baseline Statin Intensity I
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.8072
High Intensity Statin vs. Other		0.8894	0.9469	0.8066	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

	FDC vs. Placebo	FDC (N= 32)	Placebo (N= 20)	Total (N= 52)
Number of patients at risk		32 (100.0%)	20 (100.0%)	52 (100.0%)
Number of patients with events		8 (25.0%)	7 (35.0%)	15 (28.8%)
Number of patients without events		24 (75.0%)	13 (65.0%)	37 (71.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.619 [0.183, 2.093]			
Stratified OR, 95% CI	0.625 [0.182, 2.144]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.714 [0.306, 1.666]			
Stratified RR, 95% CI	0.736 [0.319, 1.697]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.100 [-0.357, 0.157]			
Stratified ARR, 95% CI (CMH method)	-0.096 [-0.351, 0.160]			
Test on Differences [c]				
Unstratified p-value	0.4387			
Stratified p-value	0.4625			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		11 (26.2%)	6 (28.6%)	17 (27.0%)
Number of patients without events		31 (73.8%)	15 (71.4%)	46 (73.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.887 [0.275, 2.859]			
Stratified OR, 95% CI	0.872 [0.269, 2.830]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.917 [0.394, 2.135]			
Stratified RR, 95% CI	0.907 [0.387, 2.128]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.024 [-0.258, 0.211]			
Stratified ARR, 95% CI (CMH method)	-0.026 [-0.261, 0.208]			
Test on Differences [c]				
Unstratified p-value	0.8409			
Stratified p-value	0.8261			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: None

	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)	Total (N= 47)
Number of patients at risk		33 (100.0%)	14 (100.0%)	47 (100.0%)
Number of patients with events		12 (36.4%)	3 (21.4%)	15 (31.9%)
Number of patients without events		21 (63.6%)	11 (78.6%)	32 (68.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.095 [0.486, 9.026]			
Stratified OR, 95% CI	1.154 [0.235, 5.673]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.697 [0.565, 5.098]			
Stratified RR, 95% CI	0.886 [0.294, 2.668]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.149 [-0.121, 0.420]			
Stratified ARR, 95% CI (CMH method)	0.149 [-0.137, 0.435]			
Test on Differences [c]				
Unstratified p-value	0.4957			
Stratified p-value	0.3267			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Mild TEAE by Baseline Statin Intensity II
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.4300
High Intensity Statin vs. Other Intensity Statin		0.4360	0.6593	0.6828	
None vs. Other Intensity Statin		0.4360	0.4101	0.2218	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Race
Safety Population

Race: White

	FDC vs. Placebo	FDC (N= 84)	Placebo (N= 48)	Total (N= 132)
Number of patients at risk		84 (100.0%)	48 (100.0%)	132 (100.0%)
Number of patients with events		26 (31.0%)	14 (29.2%)	40 (30.3%)
Number of patients without events		58 (69.0%)	34 (70.8%)	92 (69.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.089 [0.501, 2.364]			
Stratified OR, 95% CI	1.075 [0.487, 2.373]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.061 [0.616, 1.829]			
Stratified RR, 95% CI	1.046 [0.596, 1.835]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.018 [-0.144, 0.180]			
Stratified ARR, 95% CI (CMH method)	0.019 [-0.144, 0.182]			
Test on Differences [c]				
Unstratified p-value	0.8300			
Stratified p-value	0.8214			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Race
Safety Population

Race: non-White

	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)	Total (N= 30)
Number of patients at risk		23 (100.0%)	7 (100.0%)	30 (100.0%)
Number of patients with events		5 (21.7%)	2 (28.6%)	7 (23.3%)
Number of patients without events		18 (78.3%)	5 (71.4%)	23 (76.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.694 [0.102, 4.717]			
Stratified OR, 95% CI	0.715 [0.100, 5.093]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.761 [0.187, 3.100]			
Stratified RR, 95% CI	0.723 [0.210, 2.488]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.068 [-0.443, 0.306]			
Stratified ARR, 95% CI (CMH method)	-0.030 [-0.397, 0.337]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8785			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Mild TEAE by Race
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.6751
non-White vs. White		0.8306	0.9742	0.6651	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): < 130

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 16)	Total (N= 54)
Number of patients at risk		38 (100.0%)	16 (100.0%)	54 (100.0%)
Number of patients with events		7 (18.4%)	5 (31.3%)	12 (22.2%)
Number of patients without events		31 (81.6%)	11 (68.8%)	42 (77.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.497 [0.130, 1.893]			
Stratified OR, 95% CI	0.336 [0.072, 1.559]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.589 [0.220, 1.583]			
Stratified RR, 95% CI	0.439 [0.137, 1.400]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.128 [-0.387, 0.130]			
Stratified ARR, 95% CI (CMH method)	-0.180 [-0.440, 0.079]			
Test on Differences [c]				
Unstratified p-value	0.3005			
Stratified p-value	0.1615			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)	Total (N= 47)
Number of patients at risk		31 (100.0%)	16 (100.0%)	47 (100.0%)
Number of patients with events		9 (29.0%)	4 (25.0%)	13 (27.7%)
Number of patients without events		22 (71.0%)	12 (75.0%)	34 (72.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.227 [0.311, 4.839]			
Stratified OR, 95% CI	0.974 [0.221, 4.290]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.161 [0.422, 3.193]			
Stratified RR, 95% CI	0.935 [0.292, 2.987]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.040 [-0.225, 0.306]			
Stratified ARR, 95% CI (CMH method)	0.021 [-0.251, 0.294]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8783			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): >= 160

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)	Total (N= 61)
Number of patients at risk		38 (100.0%)	23 (100.0%)	61 (100.0%)
Number of patients with events		15 (39.5%)	7 (30.4%)	22 (36.1%)
Number of patients without events		23 (60.5%)	16 (69.6%)	39 (63.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.491 [0.496, 4.482]			
Stratified OR, 95% CI	1.458 [0.471, 4.516]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.297 [0.623, 2.698]			
Stratified RR, 95% CI	1.253 [0.601, 2.613]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.090 [-0.154, 0.334]			
Stratified ARR, 95% CI (CMH method)	0.088 [-0.164, 0.340]			
Test on Differences [c]				
Unstratified p-value	0.4761			
Stratified p-value	0.5093			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Mild TEAE by Baseline LDL-C Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.4517
130 - < 160 vs. < 130		0.2944	0.6955	0.3472	
>= 160 vs. < 130		0.2944	0.9567	0.2089	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by History of Diabetes
Safety Population

History of Diabetes: Yes

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		16 (33.3%)	8 (33.3%)	24 (33.3%)
Number of patients without events		32 (66.7%)	16 (66.7%)	48 (66.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.000 [0.354, 2.828]			
Stratified OR, 95% CI	1.053 [0.357, 3.112]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.000 [0.500, 2.000]			
Stratified RR, 95% CI	1.036 [0.501, 2.142]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.000 [-0.231, 0.231]			
Stratified ARR, 95% CI (CMH method)	0.011 [-0.230, 0.252]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9300			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by History of Diabetes
Safety Population

History of Diabetes: No

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		15 (25.4%)	8 (25.8%)	23 (25.6%)
Number of patients without events		44 (74.6%)	23 (74.2%)	67 (74.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.980 [0.362, 2.652]			
Stratified OR, 95% CI	1.059 [0.373, 3.006]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.985 [0.470, 2.064]			
Stratified RR, 95% CI	1.058 [0.478, 2.341]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.004 [-0.194, 0.186]			
Stratified ARR, 95% CI (CMH method)	0.007 [-0.193, 0.206]			
Test on Differences [c]				
Unstratified p-value	0.9684			
Stratified p-value	0.9455			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Mild TEAE by History of Diabetes
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.9770
No vs. Yes		1.0000	0.5419	0.9770	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by BMI
Safety Population

BMI (kg/m^2): < 25

	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)	Total (N= 19)
Number of patients at risk		13 (100.0%)	6 (100.0%)	19 (100.0%)
Number of patients with events		4 (30.8%)	3 (50.0%)	7 (36.8%)
Number of patients without events		9 (69.2%)	3 (50.0%)	12 (63.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.444 [0.061, 3.242]			
Stratified OR, 95% CI	0.262 [0.030, 2.295]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.615 [0.196, 1.929]			
Stratified RR, 95% CI	0.425 [0.098, 1.843]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.192 [-0.665, 0.280]			
Stratified ARR, 95% CI (CMH method)	-0.364 [-0.852, 0.124]			
Test on Differences [c]				
Unstratified p-value	0.6169			
Stratified p-value	0.1897			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by BMI
Safety Population

BMI (kg/m^2): 25 - < 30

	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)	Total (N= 49)
Number of patients at risk		27 (100.0%)	22 (100.0%)	49 (100.0%)
Number of patients with events		6 (22.2%)	7 (31.8%)	13 (26.5%)
Number of patients without events		21 (77.8%)	15 (68.2%)	36 (73.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.612 [0.171, 2.193]			
Stratified OR, 95% CI	0.634 [0.141, 2.849]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.698 [0.274, 1.777]			
Stratified RR, 95% CI	0.777 [0.261, 2.313]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.096 [-0.346, 0.154]			
Stratified ARR, 95% CI (CMH method)	-0.129 [-0.395, 0.137]			
Test on Differences [c]				
Unstratified p-value	0.4492			
Stratified p-value	0.3329			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by BMI
Safety Population

BMI (kg/m^2): >= 30

	FDC vs. Placebo	FDC (N= 67)	Placebo (N= 27)	Total (N= 94)
Number of patients at risk		67 (100.0%)	27 (100.0%)	94 (100.0%)
Number of patients with events		21 (31.3%)	6 (22.2%)	27 (28.7%)
Number of patients without events		46 (68.7%)	21 (77.8%)	67 (71.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.598 [0.563, 4.538]			
Stratified OR, 95% CI	1.426 [0.493, 4.123]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.410 [0.640, 3.107]			
Stratified RR, 95% CI	1.192 [0.563, 2.523]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.091 [-0.101, 0.283]			
Stratified ARR, 95% CI (CMH method)	0.092 [-0.102, 0.285]			
Test on Differences [c]				
Unstratified p-value	0.3765			
Stratified p-value	0.3849			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Mild TEAE by BMI
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.3659
25 - < 30 vs. < 25		0.4049	0.3791	0.8665	
>= 30 vs. < 25		0.4049	0.1363	0.2418	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		7 (6.5%)	2 (3.6%)	9 (5.6%)
Number of patients without events		100 (93.5%)	53 (96.4%)	153 (94.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.855 [0.372, 9.247]			
Stratified OR, 95% CI	1.544 [0.330, 7.213]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.799 [0.387, 8.371]			
Stratified RR, 95% CI	1.492 [0.349, 6.370]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.029 [-0.039, 0.097]			
Stratified ARR, 95% CI (CMH method)	0.030 [-0.038, 0.098]			
Test on Differences [c]				
Unstratified p-value	0.7193			
Stratified p-value	0.4295			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Gender
Safety Population

Gender: Male

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)	Total (N= 83)
Number of patients at risk		50 (100.0%)	33 (100.0%)	83 (100.0%)
Number of patients with events		2 (4.0%)	1 (3.0%)	3 (3.6%)
Number of patients without events		48 (96.0%)	32 (97.0%)	80 (96.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.333 [0.116, 15.325]			
Stratified OR, 95% CI	1.571 [0.126, 19.668]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.320 [0.125, 13.978]			
Stratified RR, 95% CI	1.500 [0.153, 14.677]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.010 [-0.070, 0.090]			
Stratified ARR, 95% CI (CMH method)	0.014 [-0.063, 0.092]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7290			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Gender
Safety Population

Gender: Female

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 22)	Total (N= 79)
Number of patients at risk		57 (100.0%)	22 (100.0%)	79 (100.0%)
Number of patients with events		5 (8.8%)	1 (4.5%)	6 (7.6%)
Number of patients without events		52 (91.2%)	21 (95.5%)	73 (92.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.019 [0.222, 18.334]			
Stratified OR, 95% CI	1.165 [0.191, 7.094]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.930 [0.239, 15.601]			
Stratified RR, 95% CI	1.075 [0.218, 5.299]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.042 [-0.072, 0.156]			
Stratified ARR, 95% CI (CMH method)	0.044 [-0.070, 0.159]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5163			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Gender
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.8132
Female vs. Male		0.8176	0.7701	0.8133	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Age
Safety Population

Age (years): < 65

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 27)	Total (N= 84)
Number of patients at risk		57 (100.0%)	27 (100.0%)	84 (100.0%)
Number of patients with events		5 (8.8%)	1 (3.7%)	6 (7.1%)
Number of patients without events		52 (91.2%)	26 (96.3%)	78 (92.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.500 [0.278, 22.518]			
Stratified OR, 95% CI	1.426 [0.262, 7.756]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.368 [0.291, 19.295]			
Stratified RR, 95% CI	1.351 [0.298, 6.121]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.051 [-0.052, 0.153]			
Stratified ARR, 95% CI (CMH method)	0.041 [-0.061, 0.144]			
Test on Differences [c]				
Unstratified p-value	0.6589			
Stratified p-value	0.4840			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Age
Safety Population

Age (years): >= 65

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)	Total (N= 78)
Number of patients at risk		50 (100.0%)	28 (100.0%)	78 (100.0%)
Number of patients with events		2 (4.0%)	1 (3.6%)	3 (3.8%)
Number of patients without events		48 (96.0%)	27 (96.4%)	75 (96.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.125 [0.097, 12.989]			
Stratified OR, 95% CI	0.864 [0.128, 5.858]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.120 [0.106, 11.808]			
Stratified RR, 95% CI	0.877 [0.147, 5.231]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.004 [-0.083, 0.092]			
Stratified ARR, 95% CI (CMH method)	0.006 [-0.087, 0.099]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8982			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Age
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.6423
>= 65 vs. < 65		0.4205	0.9791	0.6417	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by CVD Risk Category
Safety Population

CVD Risk Category: ASCVD and/or HeFH

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		5 (8.5%)	2 (6.5%)	7 (7.8%)
Number of patients without events		54 (91.5%)	29 (93.5%)	83 (92.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.343 [0.245, 7.355]			
Stratified OR, 95% CI	0.863 [0.127, 5.850]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.314 [0.270, 6.385]			
Stratified RR, 95% CI	0.835 [0.138, 5.048]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.020 [-0.092, 0.132]			
Stratified ARR, 95% CI (CMH method)	0.020 [-0.094, 0.134]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7370			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by CVD Risk Category
Safety Population

CVD Risk Category: Multiple CV risk factors

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		2 (4.2%)	0	2 (2.8%)
Number of patients without events		46 (95.8%)	24 (100.0%)	70 (97.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.634 [0.122, 57.065]			
Stratified OR, 95% CI	2.869 [0.130, 63.221]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.551 [0.127, 51.131]			
Stratified RR, 95% CI	2.727 [0.138, 53.778]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.042 [-0.015, 0.098]			
Stratified ARR, 95% CI (CMH method)	0.043 [-0.014, 0.101]			
Test on Differences [c]				
Unstratified p-value	0.5493			
Stratified p-value	0.2976			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by CVD Risk Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.2863
Multiple CV risk factors vs. ASCVD and/or HeFH		0.7353	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: Other

	FDC vs. Placebo	FDC (N= 65)	Placebo (N= 34)	Total (N= 99)
Number of patients at risk		65 (100.0%)	34 (100.0%)	99 (100.0%)
Number of patients with events		6 (9.2%)	0	6 (6.1%)
Number of patients without events		59 (90.8%)	34 (100.0%)	93 (93.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	7.538 [0.412, 137.94]			
Stratified OR, 95% CI	3.959 [0.463, 33.859]			
Relative Risk [a]				
Unstratified RR, 95% CI	6.894 [0.400, 118.84]			
Stratified RR, 95% CI	3.645 [0.462, 28.770]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.092 [0.022, 0.163]			
Stratified ARR, 95% CI (CMH method)	0.092 [0.022, 0.162]			
Test on Differences [c]				
Unstratified p-value	0.0911			
Stratified p-value	0.0702			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		1 (2.4%)	2 (9.5%)	3 (4.8%)
Number of patients without events		41 (97.6%)	19 (90.5%)	60 (95.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.232 [0.020, 2.716]			
Stratified OR, 95% CI	0.240 [0.020, 2.916]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.250 [0.024, 2.602]			
Stratified RR, 95% CI	0.269 [0.027, 2.715]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.071 [-0.205, 0.062]			
Stratified ARR, 95% CI (CMH method)	-0.068 [-0.200, 0.064]			
Test on Differences [c]				
Unstratified p-value	0.2556			
Stratified p-value	0.2378			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline Statin Intensity I
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.0138
High Intensity Statin vs. Other		<.0001	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

	FDC vs. Placebo	FDC (N= 32)	Placebo (N= 20)	Total (N= 52)
Number of patients at risk		32 (100.0%)	20 (100.0%)	52 (100.0%)
Number of patients with events		3 (9.4%)	0	3 (5.8%)
Number of patients without events		29 (90.6%)	20 (100.0%)	49 (94.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.864 [0.238, 99.310]			
Stratified OR, 95% CI	2.743 [0.283, 26.615]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.455 [0.242, 81.955]			
Stratified RR, 95% CI	2.537 [0.300, 21.489]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.094 [-0.007, 0.195]			
Stratified ARR, 95% CI (CMH method)	0.093 [-0.008, 0.193]			
Test on Differences [c]				
Unstratified p-value	0.2760			
Stratified p-value	0.1692			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		1 (2.4%)	2 (9.5%)	3 (4.8%)
Number of patients without events		41 (97.6%)	19 (90.5%)	60 (95.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.232 [0.020, 2.716]			
Stratified OR, 95% CI	0.240 [0.020, 2.916]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.250 [0.024, 2.602]			
Stratified RR, 95% CI	0.269 [0.027, 2.715]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.071 [-0.205, 0.062]			
Stratified ARR, 95% CI (CMH method)	-0.068 [-0.200, 0.064]			
Test on Differences [c]				
Unstratified p-value	0.2556			
Stratified p-value	0.2378			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: None

	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)	Total (N= 47)
Number of patients at risk		33 (100.0%)	14 (100.0%)	47 (100.0%)
Number of patients with events		3 (9.1%)	0	3 (6.4%)
Number of patients without events		30 (90.9%)	14 (100.0%)	44 (93.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.328 [0.161, 68.769]			
Stratified OR, 95% CI	1.907 [0.193, 18.788]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.088 [0.170, 56.140]			
Stratified RR, 95% CI	1.800 [0.216, 15.022]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.091 [-0.007, 0.189]			
Stratified ARR, 95% CI (CMH method)	0.092 [-0.007, 0.190]			
Test on Differences [c]				
Unstratified p-value	0.5441			
Stratified p-value	0.2493			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline Statin Intensity II
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.0484
High Intensity Statin vs. Other Intensity Statin		<.0001	<.0001	-	
None vs. Other Intensity Statin		<.0001	0.9999	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Race
Safety Population

Race: White

	FDC vs. Placebo	FDC (N= 84)	Placebo (N= 48)	Total (N= 132)
Number of patients at risk		84 (100.0%)	48 (100.0%)	132 (100.0%)
Number of patients with events		6 (7.1%)	2 (4.2%)	8 (6.1%)
Number of patients without events		78 (92.9%)	46 (95.8%)	124 (93.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.769 [0.343, 9.132]			
Stratified OR, 95% CI	1.569 [0.327, 7.526]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.714 [0.360, 8.162]			
Stratified RR, 95% CI	1.509 [0.350, 6.516]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.030 [-0.049, 0.109]			
Stratified ARR, 95% CI (CMH method)	0.033 [-0.046, 0.111]			
Test on Differences [c]				
Unstratified p-value	0.7100			
Stratified p-value	0.4524			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Race
Safety Population

Race: non-White

	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)	Total (N= 30)
Number of patients at risk		23 (100.0%)	7 (100.0%)	30 (100.0%)
Number of patients with events		1 (4.3%)	0	1 (3.3%)
Number of patients without events		22 (95.7%)	7 (100.0%)	29 (96.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.000 [0.037, 27.264]			
Stratified OR, 95% CI	1.154 [0.034, 38.877]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.000 [0.045, 22.175]			
Stratified RR, 95% CI	1.125 [0.061, 20.705]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.043 [-0.040, 0.127]			
Stratified ARR, 95% CI (CMH method)	0.043 [-0.044, 0.130]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5930			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Race
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.5734
non-White vs. White		0.4984	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): < 130

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 16)	Total (N= 54)
Number of patients at risk		38 (100.0%)	16 (100.0%)	54 (100.0%)
Number of patients with events		2 (5.3%)	2 (12.5%)	4 (7.4%)
Number of patients without events		36 (94.7%)	14 (87.5%)	50 (92.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.389 [0.050, 3.036]			
Stratified OR, 95% CI	0.323 [0.036, 2.892]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.421 [0.065, 2.734]			
Stratified RR, 95% CI	0.360 [0.048, 2.675]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.072 [-0.249, 0.105]			
Stratified ARR, 95% CI (CMH method)	-0.093 [-0.268, 0.082]			
Test on Differences [c]				
Unstratified p-value	0.5732			
Stratified p-value	0.2481			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)	Total (N= 47)
Number of patients at risk		31 (100.0%)	16 (100.0%)	47 (100.0%)
Number of patients with events		2 (6.5%)	0	2 (4.3%)
Number of patients without events		29 (93.5%)	16 (100.0%)	45 (95.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.797 [0.127, 61.804]			
Stratified OR, 95% CI	4.091 [0.154, 108.94]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.656 [0.135, 52.235]			
Stratified RR, 95% CI	3.125 [0.186, 52.601]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.065 [-0.022, 0.151]			
Stratified ARR, 95% CI (CMH method)	0.070 [-0.021, 0.160]			
Test on Differences [c]				
Unstratified p-value	0.5412			
Stratified p-value	0.2598			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): >= 160

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)	Total (N= 61)
Number of patients at risk		38 (100.0%)	23 (100.0%)	61 (100.0%)
Number of patients with events		3 (7.9%)	0	3 (4.9%)
Number of patients without events		35 (92.1%)	23 (100.0%)	58 (95.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.634 [0.229, 93.884]			
Stratified OR, 95% CI	2.566 [0.258, 25.534]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.308 [0.233, 79.809]			
Stratified RR, 95% CI	2.333 [0.282, 19.293]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.079 [-0.007, 0.165]			
Stratified ARR, 95% CI (CMH method)	0.073 [-0.013, 0.159]			
Test on Differences [c]				
Unstratified p-value	0.2836			
Stratified p-value	0.1987			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline LDL-C Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.0863
130 - < 160 vs. < 130		0.3648	<.0001	-	
>= 160 vs. < 130		0.3648	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by History of Diabetes
Safety Population

History of Diabetes: Yes

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		3 (6.3%)	1 (4.2%)	4 (5.6%)
Number of patients without events		45 (93.8%)	23 (95.8%)	68 (94.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.533 [0.151, 15.576]			
Stratified OR, 95% CI	0.988 [0.148, 6.606]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.500 [0.165, 13.667]			
Stratified RR, 95% CI	0.992 [0.175, 5.616]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.021 [-0.084, 0.126]			
Stratified ARR, 95% CI (CMH method)	0.022 [-0.081, 0.124]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7140			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by History of Diabetes
Safety Population

History of Diabetes: No

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		4 (6.8%)	1 (3.2%)	5 (5.6%)
Number of patients without events		55 (93.2%)	30 (96.8%)	85 (94.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.182 [0.233, 20.413]			
Stratified OR, 95% CI	1.595 [0.231, 11.020]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.102 [0.245, 18.002]			
Stratified RR, 95% CI	1.527 [0.261, 8.942]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.036 [-0.054, 0.125]			
Stratified ARR, 95% CI (CMH method)	0.036 [-0.052, 0.123]			
Test on Differences [c]				
Unstratified p-value	0.6560			
Stratified p-value	0.4823			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by History of Diabetes
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.8303
No vs. Yes		0.7191	0.8537	0.8301	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by BMI
Safety Population

BMI (kg/m^2): < 25

	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)	Total (N= 19)
Number of patients at risk		13 (100.0%)	6 (100.0%)	19 (100.0%)
Number of patients with events		1 (7.7%)	1 (16.7%)	2 (10.5%)
Number of patients without events		12 (92.3%)	5 (83.3%)	17 (89.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.417 [0.022, 8.054]			
Stratified OR, 95% CI	0.712 [0.055, 9.236]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.462 [0.034, 6.199]			
Stratified RR, 95% CI	0.748 [0.098, 5.701]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.090 [-0.421, 0.242]			
Stratified ARR, 95% CI (CMH method)	-0.050 [-0.463, 0.363]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8055			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by BMI
Safety Population

BMI (kg/m^2): 25 - < 30

	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)	Total (N= 49)
Number of patients at risk		27 (100.0%)	22 (100.0%)	49 (100.0%)
Number of patients with events		1 (3.7%)	0	1 (2.0%)
Number of patients without events		26 (96.3%)	22 (100.0%)	48 (98.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.547 [0.099, 65.663]			
Stratified OR, 95% CI	2.294 [0.080, 66.018]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.464 [0.105, 57.664]			
Stratified RR, 95% CI	2.100 [0.099, 44.404]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.037 [-0.034, 0.108]			
Stratified ARR, 95% CI (CMH method)	0.035 [-0.036, 0.106]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4142			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by BMI
Safety Population

BMI (kg/m^2): >= 30

	FDC vs. Placebo	FDC (N= 67)	Placebo (N= 27)	Total (N= 94)
Number of patients at risk		67 (100.0%)	27 (100.0%)	94 (100.0%)
Number of patients with events		5 (7.5%)	1 (3.7%)	6 (6.4%)
Number of patients without events		62 (92.5%)	26 (96.3%)	88 (93.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.097 [0.233, 18.835]			
Stratified OR, 95% CI	1.222 [0.223, 6.709]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.015 [0.247, 16.455]			
Stratified RR, 95% CI	1.175 [0.250, 5.519]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.038 [-0.057, 0.133]			
Stratified ARR, 95% CI (CMH method)	0.041 [-0.056, 0.138]			
Test on Differences [c]				
Unstratified p-value	0.6696			
Stratified p-value	0.4717			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by BMI
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.4293
25 - < 30 vs. < 25		0.5596	<.0001	-	
>= 30 vs. < 25		0.5596	0.2618	0.3872	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
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Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Gastrointestinal disorders (SOC)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		11 (10.3%)	1 (1.8%)	12 (7.4%)
Number of patients without events		96 (89.7%)	54 (98.2%)	150 (92.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.188 [0.778, 49.236]			
Stratified OR, 95% CI	3.262 [0.683, 15.587]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.654 [0.749, 42.671]			
Stratified RR, 95% CI	2.940 [0.673, 12.840]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.085 [0.017, 0.152]			
Stratified ARR, 95% CI (CMH method)	0.086 [0.019, 0.153]			
Test on Differences [c]				
Unstratified p-value	0.0606			
Stratified p-value	0.0470			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Gastrointestinal disorders (SOC)
Safety Population

Gender: Male

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)	Total (N= 83)
Number of patients at risk		50 (100.0%)	33 (100.0%)	83 (100.0%)
Number of patients with events		4 (8.0%)	1 (3.0%)	5 (6.0%)
Number of patients without events		46 (92.0%)	32 (97.0%)	78 (94.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.783 [0.297, 26.067]			
Stratified OR, 95% CI	2.293 [0.328, 16.027]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.640 [0.309, 22.591]			
Stratified RR, 95% CI	2.094 [0.361, 12.136]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.050 [-0.046, 0.145]			
Stratified ARR, 95% CI (CMH method)	0.054 [-0.038, 0.147]			
Test on Differences [c]				
Unstratified p-value	0.6436			
Stratified p-value	0.3045			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Gastrointestinal disorders (SOC)
Safety Population

Gender: Female

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 22)	Total (N= 79)
Number of patients at risk		57 (100.0%)	22 (100.0%)	79 (100.0%)
Number of patients with events		7 (12.3%)	0	7 (8.9%)
Number of patients without events		50 (87.7%)	22 (100.0%)	72 (91.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.683 [0.366, 122.13]			
Stratified OR, 95% CI	2.590 [0.409, 16.379]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.948 [0.354, 99.961]			
Stratified RR, 95% CI	2.268 [0.423, 12.155]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.123 [0.038, 0.208]			
Stratified ARR, 95% CI (CMH method)	0.132 [0.043, 0.220]			
Test on Differences [c]				
Unstratified p-value	0.1811			
Stratified p-value	0.0716			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Gender - Gastrointestinal disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.2463
Female vs. Male		0.3755	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Gastrointestinal disorders (SOC)
Safety Population

Age (years): < 65

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 27)	Total (N= 84)
Number of patients at risk		57 (100.0%)	27 (100.0%)	84 (100.0%)
Number of patients with events		7 (12.3%)	0	7 (8.3%)
Number of patients without events		50 (87.7%)	27 (100.0%)	77 (91.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	8.168 [0.449, 148.47]			
Stratified OR, 95% CI	4.370 [0.496, 38.515]			
Relative Risk [a]				
Unstratified RR, 95% CI	7.241 [0.429, 122.34]			
Stratified RR, 95% CI	3.602 [0.477, 27.197]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.123 [0.038, 0.208]			
Stratified ARR, 95% CI (CMH method)	0.130 [0.042, 0.219]			
Test on Differences [c]				
Unstratified p-value	0.0907			
Stratified p-value	0.0428			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Gastrointestinal disorders (SOC)
Safety Population

Age (years): >= 65

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)	Total (N= 78)
Number of patients at risk		50 (100.0%)	28 (100.0%)	78 (100.0%)
Number of patients with events		4 (8.0%)	1 (3.6%)	5 (6.4%)
Number of patients without events		46 (92.0%)	27 (96.4%)	73 (93.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.348 [0.249, 22.103]			
Stratified OR, 95% CI	2.426 [0.340, 17.330]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.240 [0.263, 19.075]			
Stratified RR, 95% CI	2.167 [0.381, 12.334]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.044 [-0.058, 0.146]			
Stratified ARR, 95% CI (CMH method)	0.065 [-0.034, 0.164]			
Test on Differences [c]				
Unstratified p-value	0.6491			
Stratified p-value	0.2661			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Age - Gastrointestinal disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.1891
>= 65 vs. < 65		<.0001	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Gastrointestinal disorders (SOC)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		6 (10.2%)	1 (3.2%)	7 (7.8%)
Number of patients without events		53 (89.8%)	30 (96.8%)	83 (92.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.396 [0.390, 29.563]			
Stratified OR, 95% CI	2.424 [0.384, 15.313]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.153 [0.397, 25.030]			
Stratified RR, 95% CI	2.258 [0.402, 12.679]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.069 [-0.030, 0.169]			
Stratified ARR, 95% CI (CMH method)	0.068 [-0.029, 0.166]			
Test on Differences [c]				
Unstratified p-value	0.4146			
Stratified p-value	0.2462			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Gastrointestinal disorders (SOC)
Safety Population

CVD Risk Category: Multiple CV risk factors

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		5 (10.4%)	0	5 (6.9%)
Number of patients without events		43 (89.6%)	24 (100.0%)	67 (93.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.195 [0.328, 116.85]			
Stratified OR, 95% CI	7.000 [0.364, 134.61]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.612 [0.323, 97.480]			
Stratified RR, 95% CI	6.000 [0.351, 102.44]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.104 [0.018, 0.191]			
Stratified ARR, 95% CI (CMH method)	0.109 [0.021, 0.197]			
Test on Differences [c]				
Unstratified p-value	0.1619			
Stratified p-value	0.0887			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by CVD Risk Category - Gastrointestinal disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.2898
Multiple CV risk factors vs. ASCVD and/or HeFH		0.2774	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Gastrointestinal disorders (SOC)
Safety Population

Baseline Statin Dose Intensity I: Other

	FDC vs. Placebo	FDC (N= 65)	Placebo (N= 34)	Total (N= 99)
Number of patients at risk		65 (100.0%)	34 (100.0%)	99 (100.0%)
Number of patients with events		10 (15.4%)	1 (2.9%)	11 (11.1%)
Number of patients without events		55 (84.6%)	33 (97.1%)	88 (88.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.000 [0.734, 49.019]			
Stratified OR, 95% CI	3.956 [0.666, 23.507]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.231 [0.699, 39.169]			
Stratified RR, 95% CI	3.452 [0.650, 18.341]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.124 [0.020, 0.229]			
Stratified ARR, 95% CI (CMH method)	0.124 [0.020, 0.229]			
Test on Differences [c]				
Unstratified p-value	0.0915			
Stratified p-value	0.0642			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Gastrointestinal disorders (SOC)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		1 (2.4%)	0	1 (1.6%)
Number of patients without events		41 (97.6%)	21 (100.0%)	62 (98.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.554 [0.061, 39.792]			
Stratified OR, 95% CI	1.706 [0.065, 44.655]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.535 [0.065, 36.146]			
Stratified RR, 95% CI	1.667 [0.072, 38.420]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.024 [-0.022, 0.070]			
Stratified ARR, 95% CI (CMH method)	0.025 [-0.022, 0.072]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4631			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity I - Gastrointestinal disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.6753
High Intensity Statin vs. Other		0.1072	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Gastrointestinal disorders (SOC)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

	FDC vs. Placebo	FDC (N= 32)	Placebo (N= 20)	Total (N= 52)
Number of patients at risk		32 (100.0%)	20 (100.0%)	52 (100.0%)
Number of patients with events		5 (15.6%)	0	5 (9.6%)
Number of patients without events		27 (84.4%)	20 (100.0%)	47 (90.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	8.200 [0.429, 156.83]			
Stratified OR, 95% CI	4.199 [0.450, 39.178]			
Relative Risk [a]				
Unstratified RR, 95% CI	7.000 [0.408, 120.16]			
Stratified RR, 95% CI	3.576 [0.443, 28.884]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.156 [0.030, 0.282]			
Stratified ARR, 95% CI (CMH method)	0.160 [0.033, 0.287]			
Test on Differences [c]				
Unstratified p-value	0.1431			
Stratified p-value	0.0572			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Gastrointestinal disorders (SOC)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		1 (2.4%)	0	1 (1.6%)
Number of patients without events		41 (97.6%)	21 (100.0%)	62 (98.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.554 [0.061, 39.792]			
Stratified OR, 95% CI	1.706 [0.065, 44.655]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.535 [0.065, 36.146]			
Stratified RR, 95% CI	1.667 [0.072, 38.420]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.024 [-0.022, 0.070]			
Stratified ARR, 95% CI (CMH method)	0.025 [-0.022, 0.072]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4631			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Gastrointestinal disorders (SOC)
Safety Population

Baseline Statin Dose Intensity II: None

	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)	Total (N= 47)
Number of patients at risk		33 (100.0%)	14 (100.0%)	47 (100.0%)
Number of patients with events		5 (15.2%)	1 (7.1%)	6 (12.8%)
Number of patients without events		28 (84.8%)	13 (92.9%)	41 (87.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.321 [0.246, 21.927]			
Stratified OR, 95% CI	1.753 [0.251, 12.251]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.121 [0.272, 16.544]			
Stratified RR, 95% CI	1.615 [0.301, 8.672]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.080 [-0.102, 0.262]			
Stratified ARR, 95% CI (CMH method)	0.083 [-0.092, 0.257]			
Test on Differences [c]				
Unstratified p-value	0.6532			
Stratified p-value	0.4322			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity II - Gastrointestinal disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.3836
High Intensity Statin vs. Other Intensity Statin		<.0001	1.0000	-	
None vs. Other Intensity Statin		<.0001	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Gastrointestinal disorders (SOC)
Safety Population

Race: White

	FDC vs. Placebo	FDC (N= 84)	Placebo (N= 48)	Total (N= 132)
Number of patients at risk		84 (100.0%)	48 (100.0%)	132 (100.0%)
Number of patients with events		8 (9.5%)	1 (2.1%)	9 (6.8%)
Number of patients without events		76 (90.5%)	47 (97.9%)	123 (93.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.947 [0.600, 40.825]			
Stratified OR, 95% CI	2.963 [0.604, 14.537]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.571 [0.589, 35.453]			
Stratified RR, 95% CI	2.700 [0.610, 11.948]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.074 [0.000, 0.149]			
Stratified ARR, 95% CI (CMH method)	0.077 [0.003, 0.151]			
Test on Differences [c]				
Unstratified p-value	0.1545			
Stratified p-value	0.0927			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Gastrointestinal disorders (SOC)
Safety Population

Race: non-White

	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)	Total (N= 30)
Number of patients at risk		23 (100.0%)	7 (100.0%)	30 (100.0%)
Number of patients with events		3 (13.0%)	0	3 (10.0%)
Number of patients without events		20 (87.0%)	7 (100.0%)	27 (90.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.561 [0.118, 55.665]			
Stratified OR, 95% CI	3.889 [0.137, 109.99]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.333 [0.135, 40.464]			
Stratified RR, 95% CI	2.625 [0.186, 37.135]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.130 [-0.007, 0.268]			
Stratified ARR, 95% CI (CMH method)	0.128 [-0.016, 0.273]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.2850			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Race - Gastrointestinal disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.5498
non-White vs. White		0.1459	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Gastrointestinal disorders (SOC)
Safety Population

Baseline LDL-C (mg/dL): < 130

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 16)	Total (N= 54)
Number of patients at risk		38 (100.0%)	16 (100.0%)	54 (100.0%)
Number of patients with events		2 (5.3%)	0	2 (3.7%)
Number of patients without events		36 (94.7%)	16 (100.0%)	52 (96.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.260 [0.103, 49.750]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.179 [0.110, 43.015]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.053 [-0.018, 0.124]			
Stratified ARR, 95% CI (CMH method)	0.000 [0.000, 0.000]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	-			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Gastrointestinal disorders (SOC)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)	Total (N= 47)
Number of patients at risk		31 (100.0%)	16 (100.0%)	47 (100.0%)
Number of patients with events		4 (12.9%)	0	4 (8.5%)
Number of patients without events		27 (87.1%)	16 (100.0%)	43 (91.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.400 [0.273, 106.83]			
Stratified OR, 95% CI	2.607 [0.371, 18.313]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.781 [0.273, 83.648]			
Stratified RR, 95% CI	2.241 [0.412, 12.180]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.129 [0.011, 0.247]			
Stratified ARR, 95% CI (CMH method)	0.139 [0.017, 0.261]			
Test on Differences [c]				
Unstratified p-value	0.2839			
Stratified p-value	0.1189			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Gastrointestinal disorders (SOC)
Safety Population

Baseline LDL-C (mg/dL): >= 160

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)	Total (N= 61)
Number of patients at risk		38 (100.0%)	23 (100.0%)	61 (100.0%)
Number of patients with events		5 (13.2%)	1 (4.3%)	6 (9.8%)
Number of patients without events		33 (86.8%)	22 (95.7%)	55 (90.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.333 [0.364, 30.500]			
Stratified OR, 95% CI	2.023 [0.281, 14.566]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.026 [0.377, 24.313]			
Stratified RR, 95% CI	1.682 [0.318, 8.895]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.088 [-0.048, 0.224]			
Stratified ARR, 95% CI (CMH method)	0.073 [-0.069, 0.215]			
Test on Differences [c]				
Unstratified p-value	0.3946			
Stratified p-value	0.3421			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline LDL-C Category - Gastrointestinal disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.5242
130 - < 160 vs. < 130		<.0001	1.0000	-	
>= 160 vs. < 130		<.0001	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Gastrointestinal disorders (SOC)
Safety Population

History of Diabetes: Yes

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		3 (6.3%)	0	3 (4.2%)
Number of patients without events		45 (93.8%)	24 (100.0%)	69 (95.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.769 [0.187, 75.981]			
Stratified OR, 95% CI	3.889 [0.176, 85.870]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.571 [0.192, 66.469]			
Stratified RR, 95% CI	3.294 [0.192, 56.468]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.063 [-0.006, 0.131]			
Stratified ARR, 95% CI (CMH method)	0.058 [-0.009, 0.126]			
Test on Differences [c]				
Unstratified p-value	0.5461			
Stratified p-value	0.2295			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Gastrointestinal disorders (SOC)
Safety Population

History of Diabetes: No

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		8 (13.6%)	1 (3.2%)	9 (10.0%)
Number of patients without events		51 (86.4%)	30 (96.8%)	81 (90.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.706 [0.561, 39.489]			
Stratified OR, 95% CI	2.713 [0.543, 13.561]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.203 [0.550, 32.097]			
Stratified RR, 95% CI	2.420 [0.556, 10.531]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.103 [-0.004, 0.211]			
Stratified ARR, 95% CI (CMH method)	0.110 [0.003, 0.216]			
Test on Differences [c]				
Unstratified p-value	0.1561			
Stratified p-value	0.1034			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by History of Diabetes - Gastrointestinal disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.4434
No vs. Yes		<.0001	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Gastrointestinal disorders (SOC)
Safety Population

BMI (kg/m^2): < 25

	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)	Total (N= 19)
Number of patients at risk		13 (100.0%)	6 (100.0%)	19 (100.0%)
Number of patients with events		2 (15.4%)	1 (16.7%)	3 (15.8%)
Number of patients without events		11 (84.6%)	5 (83.3%)	16 (84.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.909 [0.066, 12.524]			
Stratified OR, 95% CI	1.311 [0.113, 15.154]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.923 [0.103, 8.305]			
Stratified RR, 95% CI	1.170 [0.193, 7.077]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.013 [-0.370, 0.344]			
Stratified ARR, 95% CI (CMH method)	0.075 [-0.346, 0.496]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7494			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Gastrointestinal disorders (SOC)
Safety Population

BMI (kg/m^2): 25 - < 30

	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)	Total (N= 49)
Number of patients at risk		27 (100.0%)	22 (100.0%)	49 (100.0%)
Number of patients with events		3 (11.1%)	0	3 (6.1%)
Number of patients without events		24 (88.9%)	22 (100.0%)	46 (93.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.429 [0.314, 131.46]			
Stratified OR, 95% CI	3.451 [0.340, 35.026]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.750 [0.313, 105.70]			
Stratified RR, 95% CI	2.949 [0.362, 24.047]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.111 [-0.007, 0.230]			
Stratified ARR, 95% CI (CMH method)	0.111 [-0.011, 0.233]			
Test on Differences [c]				
Unstratified p-value	0.2423			
Stratified p-value	0.1274			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Gastrointestinal disorders (SOC)
Safety Population

BMI (kg/m^2): >= 30

	FDC vs. Placebo	FDC (N= 67)	Placebo (N= 27)	Total (N= 94)
Number of patients at risk		67 (100.0%)	27 (100.0%)	94 (100.0%)
Number of patients with events		6 (9.0%)	0	6 (6.4%)
Number of patients without events		61 (91.0%)	27 (100.0%)	88 (93.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.813 [0.316, 106.85]			
Stratified OR, 95% CI	4.017 [0.458, 35.206]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.353 [0.312, 91.856]			
Stratified RR, 95% CI	3.485 [0.460, 26.398]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.090 [0.021, 0.158]			
Stratified ARR, 95% CI (CMH method)	0.102 [0.028, 0.175]			
Test on Differences [c]				
Unstratified p-value	0.1772			
Stratified p-value	0.0789			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by BMI - Gastrointestinal disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				-
25 - < 30 vs. < 25		0.9431	<.0001	-	
>= 30 vs. < 25		0.9431	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Infections and infestations (SOC)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		27 (25.2%)	3 (5.5%)	30 (18.5%)
Number of patients without events		80 (74.8%)	52 (94.5%)	132 (81.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.850 [1.688, 20.273]			
Stratified OR, 95% CI	4.751 [1.455, 15.513]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.626 [1.468, 14.576]			
Stratified RR, 95% CI	3.661 [1.263, 10.615]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.198 [0.096, 0.300]			
Stratified ARR, 95% CI (CMH method)	0.197 [0.095, 0.299]			
Test on Differences [c]				
Unstratified p-value	0.0023			
Stratified p-value	0.0025			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Infections and infestations (SOC)
Safety Population

Gender: Male

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)	Total (N= 83)
Number of patients at risk		50 (100.0%)	33 (100.0%)	83 (100.0%)
Number of patients with events		11 (22.0%)	1 (3.0%)	12 (14.5%)
Number of patients without events		39 (78.0%)	32 (97.0%)	71 (85.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	9.026 [1.105, 73.691]			
Stratified OR, 95% CI	4.320 [0.922, 20.242]			
Relative Risk [a]				
Unstratified RR, 95% CI	7.260 [0.983, 53.610]			
Stratified RR, 95% CI	2.804 [0.810, 9.708]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.190 [0.061, 0.319]			
Stratified ARR, 95% CI (CMH method)	0.189 [0.067, 0.311]			
Test on Differences [c]				
Unstratified p-value	0.0231			
Stratified p-value	0.0156			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Infections and infestations (SOC)
Safety Population

Gender: Female

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 22)	Total (N= 79)
Number of patients at risk		57 (100.0%)	22 (100.0%)	79 (100.0%)
Number of patients with events		16 (28.1%)	2 (9.1%)	18 (22.8%)
Number of patients without events		41 (71.9%)	20 (90.9%)	61 (77.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.902 [0.817, 18.648]			
Stratified OR, 95% CI	2.689 [0.697, 10.373]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.088 [0.773, 12.338]			
Stratified RR, 95% CI	2.170 [0.703, 6.695]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.190 [0.022, 0.357]			
Stratified ARR, 95% CI (CMH method)	0.181 [0.016, 0.346]			
Test on Differences [c]				
Unstratified p-value	0.0818			
Stratified p-value	0.0863			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Gender - Infections and infestations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.4769
Female vs. Male		0.0520	0.3573	0.4909	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Infections and infestations (SOC)
Safety Population

Age (years): < 65

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 27)	Total (N= 84)
Number of patients at risk		57 (100.0%)	27 (100.0%)	84 (100.0%)
Number of patients with events		11 (19.3%)	2 (7.4%)	13 (15.5%)
Number of patients without events		46 (80.7%)	25 (92.6%)	71 (84.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.989 [0.614, 14.561]			
Stratified OR, 95% CI	1.982 [0.498, 7.884]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.605 [0.620, 10.945]			
Stratified RR, 95% CI	1.781 [0.535, 5.926]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.119 [-0.023, 0.261]			
Stratified ARR, 95% CI (CMH method)	0.102 [-0.039, 0.244]			
Test on Differences [c]				
Unstratified p-value	0.2076			
Stratified p-value	0.2213			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Infections and infestations (SOC)
Safety Population

Age (years): >= 65

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)	Total (N= 78)
Number of patients at risk		50 (100.0%)	28 (100.0%)	78 (100.0%)
Number of patients with events		16 (32.0%)	1 (3.6%)	17 (21.8%)
Number of patients without events		34 (68.0%)	27 (96.4%)	61 (78.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	12.706 [1.583, 101.96]			
Stratified OR, 95% CI	4.568 [1.013, 20.595]			
Relative Risk [a]				
Unstratified RR, 95% CI	8.960 [1.254, 64.031]			
Stratified RR, 95% CI	2.788 [0.798, 9.742]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.284 [0.138, 0.431]			
Stratified ARR, 95% CI (CMH method)	0.274 [0.123, 0.425]			
Test on Differences [c]				
Unstratified p-value	0.0035			
Stratified p-value	0.0058			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Age - Infections and infestations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.3016
>= 65 vs. < 65		0.1910	0.5414	0.3200	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Infections and infestations (SOC)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		15 (25.4%)	1 (3.2%)	16 (17.8%)
Number of patients without events		44 (74.6%)	30 (96.8%)	74 (82.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	10.227 [1.282, 81.599]			
Stratified OR, 95% CI	6.738 [1.174, 38.664]			
Relative Risk [a]				
Unstratified RR, 95% CI	7.881 [1.091, 56.912]			
Stratified RR, 95% CI	5.228 [1.031, 26.502]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.222 [0.095, 0.349]			
Stratified ARR, 95% CI (CMH method)	0.222 [0.094, 0.350]			
Test on Differences [c]				
Unstratified p-value	0.0086			
Stratified p-value	0.0097			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Infections and infestations (SOC)
Safety Population

CVD Risk Category: Multiple CV risk factors

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		12 (25.0%)	2 (8.3%)	14 (19.4%)
Number of patients without events		36 (75.0%)	22 (91.7%)	58 (80.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.667 [0.749, 17.947]			
Stratified OR, 95% CI	3.429 [0.685, 17.170]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.000 [0.729, 12.343]			
Stratified RR, 95% CI	2.733 [0.665, 11.229]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.167 [0.002, 0.332]			
Stratified ARR, 95% CI (CMH method)	0.166 [0.000, 0.331]			
Test on Differences [c]				
Unstratified p-value	0.1206			
Stratified p-value	0.0988			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by CVD Risk Category - Infections and infestations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.4201
Multiple CV risk factors vs. ASCVD and/or HeFH		0.0407	0.4268	0.4361	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Infections and infestations (SOC)
Safety Population

Baseline Statin Dose Intensity I: Other

	FDC vs. Placebo	FDC (N= 65)	Placebo (N= 34)	Total (N= 99)
Number of patients at risk		65 (100.0%)	34 (100.0%)	99 (100.0%)
Number of patients with events		16 (24.6%)	2 (5.9%)	18 (18.2%)
Number of patients without events		49 (75.4%)	32 (94.1%)	81 (81.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.224 [1.125, 24.273]			
Stratified OR, 95% CI	5.226 [1.125, 24.278]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.185 [1.021, 17.144]			
Stratified RR, 95% CI	4.185 [1.022, 17.146]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.187 [0.056, 0.319]			
Stratified ARR, 95% CI (CMH method)	0.187 [0.056, 0.319]			
Test on Differences [c]				
Unstratified p-value	0.0273			
Stratified p-value	0.0231			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Infections and infestations (SOC)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		11 (26.2%)	1 (4.8%)	12 (19.0%)
Number of patients without events		31 (73.8%)	20 (95.2%)	51 (81.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	7.097 [0.849, 59.295]			
Stratified OR, 95% CI	3.975 [0.619, 25.532]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.500 [0.760, 39.794]			
Stratified RR, 95% CI	2.974 [0.584, 15.144]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.214 [0.053, 0.375]			
Stratified ARR, 95% CI (CMH method)	0.213 [0.049, 0.376]			
Test on Differences [c]				
Unstratified p-value	0.0478			
Stratified p-value	0.0458			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity I - Infections and infestations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.8232
High Intensity Statin vs. Other		0.0467	0.8594	0.8255	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Infections and infestations (SOC)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

	FDC vs. Placebo	FDC (N= 32)	Placebo (N= 20)	Total (N= 52)
Number of patients at risk		32 (100.0%)	20 (100.0%)	52 (100.0%)
Number of patients with events		5 (15.6%)	2 (10.0%)	7 (13.5%)
Number of patients without events		27 (84.4%)	18 (90.0%)	45 (86.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.667 [0.291, 9.542]			
Stratified OR, 95% CI	1.649 [0.286, 9.503]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.563 [0.334, 7.301]			
Stratified RR, 95% CI	1.548 [0.329, 7.283]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.056 [-0.126, 0.238]			
Stratified ARR, 95% CI (CMH method)	0.055 [-0.126, 0.237]			
Test on Differences [c]				
Unstratified p-value	0.6936			
Stratified p-value	0.5760			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Infections and infestations (SOC)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		11 (26.2%)	1 (4.8%)	12 (19.0%)
Number of patients without events		31 (73.8%)	20 (95.2%)	51 (81.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	7.097 [0.849, 59.295]			
Stratified OR, 95% CI	3.975 [0.619, 25.532]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.500 [0.760, 39.794]			
Stratified RR, 95% CI	2.974 [0.584, 15.144]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.214 [0.053, 0.375]			
Stratified ARR, 95% CI (CMH method)	0.213 [0.049, 0.376]			
Test on Differences [c]				
Unstratified p-value	0.0478			
Stratified p-value	0.0458			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Infections and infestations (SOC)
Safety Population

Baseline Statin Dose Intensity II: None

	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)	Total (N= 47)
Number of patients at risk		33 (100.0%)	14 (100.0%)	47 (100.0%)
Number of patients with events		11 (33.3%)	0	11 (23.4%)
Number of patients without events		22 (66.7%)	14 (100.0%)	36 (76.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	14.822 [0.810, 271.37]			
Stratified OR, 95% CI	7.803 [0.916, 66.430]			
Relative Risk [a]				
Unstratified RR, 95% CI	10.147 [0.639, 161.20]			
Stratified RR, 95% CI	5.471 [0.776, 38.563]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.333 [0.172, 0.494]			
Stratified ARR, 95% CI (CMH method)	0.333 [0.172, 0.494]			
Test on Differences [c]				
Unstratified p-value	0.0202			
Stratified p-value	0.0158			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity II - Infections and infestations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.1671
High Intensity Statin vs. Other Intensity Statin		0.5705	0.5310	0.3255	
None vs. Other Intensity Statin		0.5705	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Infections and infestations (SOC)
Safety Population

Race: White

	FDC vs. Placebo	FDC (N= 84)	Placebo (N= 48)	Total (N= 132)
Number of patients at risk		84 (100.0%)	48 (100.0%)	132 (100.0%)
Number of patients with events		24 (28.6%)	2 (4.2%)	26 (19.7%)
Number of patients without events		60 (71.4%)	46 (95.8%)	106 (80.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	9.200 [2.068, 40.934]			
Stratified OR, 95% CI	5.215 [1.422, 19.131]			
Relative Risk [a]				
Unstratified RR, 95% CI	6.857 [1.694, 27.758]			
Stratified RR, 95% CI	3.655 [1.157, 11.545]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.244 [0.132, 0.356]			
Stratified ARR, 95% CI (CMH method)	0.243 [0.129, 0.358]			
Test on Differences [c]				
Unstratified p-value	0.0005			
Stratified p-value	0.0009			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Infections and infestations (SOC)
Safety Population

Race: non-White

	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)	Total (N= 30)
Number of patients at risk		23 (100.0%)	7 (100.0%)	30 (100.0%)
Number of patients with events		3 (13.0%)	1 (14.3%)	4 (13.3%)
Number of patients without events		20 (87.0%)	6 (85.7%)	26 (86.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.900 [0.078, 10.327]			
Stratified OR, 95% CI	0.673 [0.110, 4.116]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.913 [0.112, 7.449]			
Stratified RR, 95% CI	0.746 [0.179, 3.111]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.012 [-0.306, 0.281]			
Stratified ARR, 95% CI (CMH method)	-0.002 [-0.334, 0.330]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9895			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Race - Infections and infestations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.1674
non-White vs. White		0.0070	0.2865	0.1172	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Infections and infestations (SOC)
Safety Population

Baseline LDL-C (mg/dL): < 130

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 16)	Total (N= 54)
Number of patients at risk		38 (100.0%)	16 (100.0%)	54 (100.0%)
Number of patients with events		9 (23.7%)	0	9 (16.7%)
Number of patients without events		29 (76.3%)	16 (100.0%)	45 (83.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	10.627 [0.581, 194.48]			
Stratified OR, 95% CI	6.284 [0.713, 55.393]			
Relative Risk [a]				
Unstratified RR, 95% CI	8.282 [0.511, 134.33]			
Stratified RR, 95% CI	4.857 [0.660, 35.731]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.237 [0.102, 0.372]			
Stratified ARR, 95% CI (CMH method)	0.253 [0.090, 0.415]			
Test on Differences [c]				
Unstratified p-value	0.0450			
Stratified p-value	0.0323			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Infections and infestations (SOC)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)	Total (N= 47)
Number of patients at risk		31 (100.0%)	16 (100.0%)	47 (100.0%)
Number of patients with events		9 (29.0%)	1 (6.3%)	10 (21.3%)
Number of patients without events		22 (71.0%)	15 (93.8%)	37 (78.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.136 [0.702, 53.621]			
Stratified OR, 95% CI	4.049 [0.702, 23.364]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.645 [0.644, 33.507]			
Stratified RR, 95% CI	2.621 [0.672, 10.223]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.228 [0.029, 0.427]			
Stratified ARR, 95% CI (CMH method)	0.240 [0.048, 0.432]			
Test on Differences [c]				
Unstratified p-value	0.1307			
Stratified p-value	0.0586			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Infections and infestations (SOC)
Safety Population

Baseline LDL-C (mg/dL): >= 160

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)	Total (N= 61)
Number of patients at risk		38 (100.0%)	23 (100.0%)	61 (100.0%)
Number of patients with events		9 (23.7%)	2 (8.7%)	11 (18.0%)
Number of patients without events		29 (76.3%)	21 (91.3%)	50 (82.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.259 [0.637, 16.662]			
Stratified OR, 95% CI	3.007 [0.625, 14.470]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.724 [0.644, 11.519]			
Stratified RR, 95% CI	2.283 [0.647, 8.054]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.150 [-0.028, 0.327]			
Stratified ARR, 95% CI (CMH method)	0.161 [-0.013, 0.335]			
Test on Differences [c]				
Unstratified p-value	0.1822			
Stratified p-value	0.1198			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline LDL-C Category - Infections and infestations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.3552
130 - < 160 vs. < 130		<.0001	<.0001	<.0001	
>= 160 vs. < 130		<.0001	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Infections and infestations (SOC)
Safety Population

History of Diabetes: Yes

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		12 (25.0%)	2 (8.3%)	14 (19.4%)
Number of patients without events		36 (75.0%)	22 (91.7%)	58 (80.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.667 [0.749, 17.947]			
Stratified OR, 95% CI	2.288 [0.563, 9.298]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.000 [0.729, 12.343]			
Stratified RR, 95% CI	1.847 [0.561, 6.082]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.167 [0.002, 0.332]			
Stratified ARR, 95% CI (CMH method)	0.174 [-0.002, 0.350]			
Test on Differences [c]				
Unstratified p-value	0.1206			
Stratified p-value	0.0904			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Infections and infestations (SOC)
Safety Population

History of Diabetes: No

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		15 (25.4%)	1 (3.2%)	16 (17.8%)
Number of patients without events		44 (74.6%)	30 (96.8%)	74 (82.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	10.227 [1.282, 81.599]			
Stratified OR, 95% CI	4.647 [1.113, 19.402]			
Relative Risk [a]				
Unstratified RR, 95% CI	7.881 [1.091, 56.912]			
Stratified RR, 95% CI	3.493 [0.996, 12.255]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.222 [0.095, 0.349]			
Stratified ARR, 95% CI (CMH method)	0.231 [0.103, 0.360]			
Test on Differences [c]				
Unstratified p-value	0.0086			
Stratified p-value	0.0077			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by History of Diabetes - Infections and infestations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.4201
No vs. Yes		0.1279	0.4268	0.4361	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Infections and infestations (SOC)
Safety Population

BMI (kg/m^2): < 25

	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)	Total (N= 19)
Number of patients at risk		13 (100.0%)	6 (100.0%)	19 (100.0%)
Number of patients with events		6 (46.2%)	1 (16.7%)	7 (36.8%)
Number of patients without events		7 (53.8%)	5 (83.3%)	12 (63.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.286 [0.386, 47.625]			
Stratified OR, 95% CI	2.659 [0.291, 24.300]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.769 [0.421, 18.204]			
Stratified RR, 95% CI	1.509 [0.324, 7.023]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.295 [-0.108, 0.698]			
Stratified ARR, 95% CI (CMH method)	0.347 [-0.182, 0.876]			
Test on Differences [c]				
Unstratified p-value	0.3331			
Stratified p-value	0.2310			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Infections and infestations (SOC)
Safety Population

BMI (kg/m^2): 25 - < 30

	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)	Total (N= 49)
Number of patients at risk		27 (100.0%)	22 (100.0%)	49 (100.0%)
Number of patients with events		6 (22.2%)	1 (4.5%)	7 (14.3%)
Number of patients without events		21 (77.8%)	21 (95.5%)	42 (85.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.000 [0.664, 54.243]			
Stratified OR, 95% CI	2.903 [0.512, 16.457]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.889 [0.635, 37.628]			
Stratified RR, 95% CI	2.313 [0.548, 9.767]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.177 [-0.003, 0.356]			
Stratified ARR, 95% CI (CMH method)	0.159 [-0.019, 0.338]			
Test on Differences [c]				
Unstratified p-value	0.1116			
Stratified p-value	0.1257			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Infections and infestations (SOC)
Safety Population

BMI (kg/m^2): >= 30

	FDC vs. Placebo	FDC (N= 67)	Placebo (N= 27)	Total (N= 94)
Number of patients at risk		67 (100.0%)	27 (100.0%)	94 (100.0%)
Number of patients with events		15 (22.4%)	1 (3.7%)	16 (17.0%)
Number of patients without events		52 (77.6%)	26 (96.3%)	78 (83.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	7.500 [0.939, 59.929]			
Stratified OR, 95% CI	3.130 [0.751, 13.043]			
Relative Risk [a]				
Unstratified RR, 95% CI	6.045 [0.839, 43.533]			
Stratified RR, 95% CI	2.576 [0.728, 9.113]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.187 [0.064, 0.309]			
Stratified ARR, 95% CI (CMH method)	0.179 [0.055, 0.304]			
Test on Differences [c]				
Unstratified p-value	0.0338			
Stratified p-value	0.0388			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by BMI - Infections and infestations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.8539
25 - < 30 vs. < 25		0.2891	0.3312	0.6883	
>= 30 vs. < 25		0.2891	0.2618	0.5750	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Investigations (SOC)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		14 (13.1%)	2 (3.6%)	16 (9.9%)
Number of patients without events		93 (86.9%)	53 (96.4%)	146 (90.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.989 [0.873, 18.231]			
Stratified OR, 95% CI	2.153 [0.601, 7.712]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.598 [0.848, 15.270]			
Stratified RR, 95% CI	1.882 [0.597, 5.937]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.094 [0.014, 0.175]			
Stratified ARR, 95% CI (CMH method)	0.096 [0.016, 0.177]			
Test on Differences [c]				
Unstratified p-value	0.0920			
Stratified p-value	0.0535			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Investigations (SOC)
Safety Population

Gender: Male

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)	Total (N= 83)
Number of patients at risk		50 (100.0%)	33 (100.0%)	83 (100.0%)
Number of patients with events		7 (14.0%)	0	7 (8.4%)
Number of patients without events		43 (86.0%)	33 (100.0%)	76 (91.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	11.552 [0.637, 209.51]			
Stratified OR, 95% CI	4.214 [0.687, 25.862]			
Relative Risk [a]				
Unstratified RR, 95% CI	10.000 [0.590, 169.39]			
Stratified RR, 95% CI	3.637 [0.667, 19.833]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.140 [0.044, 0.236]			
Stratified ARR, 95% CI (CMH method)	0.141 [0.045, 0.238]			
Test on Differences [c]				
Unstratified p-value	0.0384			
Stratified p-value	0.0250			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Investigations (SOC)
Safety Population

Gender: Female

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 22)	Total (N= 79)
Number of patients at risk		57 (100.0%)	22 (100.0%)	79 (100.0%)
Number of patients with events		7 (12.3%)	2 (9.1%)	9 (11.4%)
Number of patients without events		50 (87.7%)	20 (90.9%)	70 (88.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.400 [0.268, 7.325]			
Stratified OR, 95% CI	0.855 [0.179, 4.083]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.351 [0.304, 6.009]			
Stratified RR, 95% CI	0.764 [0.202, 2.880]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.032 [-0.115, 0.179]			
Stratified ARR, 95% CI (CMH method)	0.042 [-0.110, 0.195]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.6051			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Gender - Investigations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.0534
Female vs. Male		<.0001	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Investigations (SOC)
Safety Population

Age (years): < 65

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 27)	Total (N= 84)
Number of patients at risk		57 (100.0%)	27 (100.0%)	84 (100.0%)
Number of patients with events		6 (10.5%)	1 (3.7%)	7 (8.3%)
Number of patients without events		51 (89.5%)	26 (96.3%)	77 (91.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.059 [0.350, 26.765]			
Stratified OR, 95% CI	1.477 [0.302, 7.225]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.842 [0.360, 22.453]			
Stratified RR, 95% CI	1.372 [0.327, 5.758]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.068 [-0.039, 0.175]			
Stratified ARR, 95% CI (CMH method)	0.079 [-0.030, 0.187]			
Test on Differences [c]				
Unstratified p-value	0.4204			
Stratified p-value	0.2441			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Investigations (SOC)
Safety Population

Age (years): >= 65

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)	Total (N= 78)
Number of patients at risk		50 (100.0%)	28 (100.0%)	78 (100.0%)
Number of patients with events		8 (16.0%)	1 (3.6%)	9 (11.5%)
Number of patients without events		42 (84.0%)	27 (96.4%)	69 (88.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.143 [0.609, 43.464]			
Stratified OR, 95% CI	2.903 [0.564, 14.953]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.480 [0.590, 34.000]			
Stratified RR, 95% CI	2.447 [0.567, 10.559]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.124 [0.002, 0.247]			
Stratified ARR, 95% CI (CMH method)	0.132 [0.006, 0.258]			
Test on Differences [c]				
Unstratified p-value	0.1455			
Stratified p-value	0.0870			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Age - Investigations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.7587
>= 65 vs. < 65		0.3219	0.9791	0.7580	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Investigations (SOC)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		8 (13.6%)	2 (6.5%)	10 (11.1%)
Number of patients without events		51 (86.4%)	29 (93.5%)	80 (88.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.275 [0.452, 11.438]			
Stratified OR, 95% CI	1.689 [0.353, 8.071]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.102 [0.475, 9.300]			
Stratified RR, 95% CI	1.517 [0.383, 6.004]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.071 [-0.052, 0.194]			
Stratified ARR, 95% CI (CMH method)	0.072 [-0.050, 0.194]			
Test on Differences [c]				
Unstratified p-value	0.4841			
Stratified p-value	0.3058			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Investigations (SOC)
Safety Population

CVD Risk Category: Multiple CV risk factors

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		6 (12.5%)	0	6 (8.3%)
Number of patients without events		42 (87.5%)	24 (100.0%)	66 (91.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	7.494 [0.405, 138.82]			
Stratified OR, 95% CI	3.488 [0.384, 31.708]			
Relative Risk [a]				
Unstratified RR, 95% CI	6.633 [0.389, 113.05]			
Stratified RR, 95% CI	3.094 [0.383, 25.001]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.125 [0.031, 0.219]			
Stratified ARR, 95% CI (CMH method)	0.128 [0.033, 0.222]			
Test on Differences [c]				
Unstratified p-value	0.1692			
Stratified p-value	0.0682			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by CVD Risk Category - Investigations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.1535
Multiple CV risk factors vs. ASCVD and/or HeFH		0.3277	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Investigations (SOC)
Safety Population

Baseline Statin Dose Intensity I: Other

	FDC vs. Placebo	FDC (N= 65)	Placebo (N= 34)	Total (N= 99)
Number of patients at risk		65 (100.0%)	34 (100.0%)	99 (100.0%)
Number of patients with events		9 (13.8%)	0	9 (9.1%)
Number of patients without events		56 (86.2%)	34 (100.0%)	90 (90.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	11.602 [0.654, 205.68]			
Stratified OR, 95% CI	6.120 [0.750, 49.936]			
Relative Risk [a]				
Unstratified RR, 95% CI	10.076 [0.604, 168.05]			
Stratified RR, 95% CI	5.353 [0.713, 40.198]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.138 [0.054, 0.222]			
Stratified ARR, 95% CI (CMH method)	0.139 [0.055, 0.223]			
Test on Differences [c]				
Unstratified p-value	0.0256			
Stratified p-value	0.0240			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Investigations (SOC)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		5 (11.9%)	2 (9.5%)	7 (11.1%)
Number of patients without events		37 (88.1%)	19 (90.5%)	56 (88.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.284 [0.227, 7.246]			
Stratified OR, 95% CI	1.167 [0.234, 5.820]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.250 [0.264, 5.912]			
Stratified RR, 95% CI	1.138 [0.281, 4.608]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.024 [-0.135, 0.183]			
Stratified ARR, 95% CI (CMH method)	0.029 [-0.127, 0.185]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7327			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity I - Investigations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.0470
High Intensity Statin vs. Other		<.0001	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Investigations (SOC)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

	FDC vs. Placebo	FDC (N= 32)	Placebo (N= 20)	Total (N= 52)
Number of patients at risk		32 (100.0%)	20 (100.0%)	52 (100.0%)
Number of patients with events		4 (12.5%)	0	4 (7.7%)
Number of patients without events		28 (87.5%)	20 (100.0%)	48 (92.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.474 [0.330, 126.99]			
Stratified OR, 95% CI	3.629 [0.394, 33.392]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.727 [0.325, 101.02]			
Stratified RR, 95% CI	3.241 [0.405, 25.915]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.125 [0.010, 0.240]			
Stratified ARR, 95% CI (CMH method)	0.125 [0.011, 0.240]			
Test on Differences [c]				
Unstratified p-value	0.1507			
Stratified p-value	0.1060			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Investigations (SOC)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		5 (11.9%)	2 (9.5%)	7 (11.1%)
Number of patients without events		37 (88.1%)	19 (90.5%)	56 (88.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.284 [0.227, 7.246]			
Stratified OR, 95% CI	1.167 [0.234, 5.820]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.250 [0.264, 5.912]			
Stratified RR, 95% CI	1.138 [0.281, 4.608]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.024 [-0.135, 0.183]			
Stratified ARR, 95% CI (CMH method)	0.029 [-0.127, 0.185]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7327			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Investigations (SOC)
Safety Population

Baseline Statin Dose Intensity II: None

	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)	Total (N= 47)
Number of patients at risk		33 (100.0%)	14 (100.0%)	47 (100.0%)
Number of patients with events		5 (15.2%)	0	5 (10.6%)
Number of patients without events		28 (84.8%)	14 (100.0%)	42 (89.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.596 [0.289, 108.36]			
Stratified OR, 95% CI	3.072 [0.337, 28.013]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.853 [0.286, 82.284]			
Stratified RR, 95% CI	2.715 [0.354, 20.809]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.152 [0.029, 0.274]			
Stratified ARR, 95% CI (CMH method)	0.151 [0.029, 0.273]			
Test on Differences [c]				
Unstratified p-value	0.3029			
Stratified p-value	0.1320			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity II - Investigations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	WARNING: Negative of Hessian not positive definite				-
High Intensity Statin vs. Other Intensity Statin		<.0001	<.0001	-	
None vs. Other Intensity Statin		<.0001	0.9988	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Investigations (SOC)
Safety Population

Race: White

	FDC vs. Placebo	FDC (N= 84)	Placebo (N= 48)	Total (N= 132)
Number of patients at risk		84 (100.0%)	48 (100.0%)	132 (100.0%)
Number of patients with events		11 (13.1%)	2 (4.2%)	13 (9.8%)
Number of patients without events		73 (86.9%)	46 (95.8%)	119 (90.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.466 [0.735, 16.348]			
Stratified OR, 95% CI	1.850 [0.472, 7.246]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.143 [0.727, 13.591]			
Stratified RR, 95% CI	1.625 [0.472, 5.594]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.089 [-0.002, 0.181]			
Stratified ARR, 95% CI (CMH method)	0.093 [0.001, 0.185]			
Test on Differences [c]				
Unstratified p-value	0.1322			
Stratified p-value	0.0898			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Investigations (SOC)
Safety Population

Race: non-White

	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)	Total (N= 30)
Number of patients at risk		23 (100.0%)	7 (100.0%)	30 (100.0%)
Number of patients with events		3 (13.0%)	0	3 (10.0%)
Number of patients without events		20 (87.0%)	7 (100.0%)	27 (90.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.561 [0.118, 55.665]			
Stratified OR, 95% CI	1.506 [0.132, 17.156]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.333 [0.135, 40.464]			
Stratified RR, 95% CI	1.386 [0.188, 10.199]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.130 [-0.007, 0.268]			
Stratified ARR, 95% CI (CMH method)	0.120 [-0.021, 0.260]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3575			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Race - Investigations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.4669
non-White vs. White		0.1253	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Investigations (SOC)
Safety Population

Baseline LDL-C (mg/dL): < 130

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 16)	Total (N= 54)
Number of patients at risk		38 (100.0%)	16 (100.0%)	54 (100.0%)
Number of patients with events		5 (13.2%)	1 (6.3%)	6 (11.1%)
Number of patients without events		33 (86.8%)	15 (93.8%)	48 (88.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.273 [0.244, 21.180]			
Stratified OR, 95% CI	0.920 [0.103, 8.224]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.105 [0.267, 16.618]			
Stratified RR, 95% CI	0.913 [0.123, 6.783]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.069 [-0.091, 0.229]			
Stratified ARR, 95% CI (CMH method)	0.006 [-0.152, 0.165]			
Test on Differences [c]				
Unstratified p-value	0.6570			
Stratified p-value	0.9401			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Investigations (SOC)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)	Total (N= 47)
Number of patients at risk		31 (100.0%)	16 (100.0%)	47 (100.0%)
Number of patients with events		2 (6.5%)	1 (6.3%)	3 (6.4%)
Number of patients without events		29 (93.5%)	15 (93.8%)	44 (93.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.034 [0.087, 12.354]			
Stratified OR, 95% CI	1.153 [0.107, 12.385]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.032 [0.101, 10.540]			
Stratified RR, 95% CI	1.059 [0.168, 6.680]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.002 [-0.145, 0.149]			
Stratified ARR, 95% CI (CMH method)	0.021 [-0.112, 0.154]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7825			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Investigations (SOC)
Safety Population

Baseline LDL-C (mg/dL): >= 160

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)	Total (N= 61)
Number of patients at risk		38 (100.0%)	23 (100.0%)	61 (100.0%)
Number of patients with events		7 (18.4%)	0	7 (11.5%)
Number of patients without events		31 (81.6%)	23 (100.0%)	54 (88.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	11.190 [0.608, 205.86]			
Stratified OR, 95% CI	3.394 [0.658, 17.504]			
Relative Risk [a]				
Unstratified RR, 95% CI	9.231 [0.552, 154.43]			
Stratified RR, 95% CI	2.787 [0.657, 11.823]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.184 [0.061, 0.307]			
Stratified ARR, 95% CI (CMH method)	0.191 [0.062, 0.321]			
Test on Differences [c]				
Unstratified p-value	0.0383			
Stratified p-value	0.0308			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline LDL-C Category - Investigations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.1842
130 - < 160 vs. < 130		0.4801	1.0000	0.6532	
>= 160 vs. < 130		0.4801	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Investigations (SOC)
Safety Population

History of Diabetes: Yes

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		5 (10.4%)	1 (4.2%)	6 (8.3%)
Number of patients without events		43 (89.6%)	23 (95.8%)	66 (91.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.674 [0.295, 24.280]			
Stratified OR, 95% CI	1.599 [0.264, 9.673]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.500 [0.309, 20.220]			
Stratified RR, 95% CI	1.487 [0.292, 7.563]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.063 [-0.055, 0.180]			
Stratified ARR, 95% CI (CMH method)	0.070 [-0.045, 0.185]			
Test on Differences [c]				
Unstratified p-value	0.6563			
Stratified p-value	0.3269			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Investigations (SOC)
Safety Population

History of Diabetes: No

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		9 (15.3%)	1 (3.2%)	10 (11.1%)
Number of patients without events		50 (84.7%)	30 (96.8%)	80 (88.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.400 [0.651, 44.763]			
Stratified OR, 95% CI	2.594 [0.506, 13.308]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.729 [0.627, 35.637]			
Stratified RR, 95% CI	2.172 [0.509, 9.269]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.120 [0.009, 0.231]			
Stratified ARR, 95% CI (CMH method)	0.114 [0.002, 0.227]			
Test on Differences [c]				
Unstratified p-value	0.1552			
Stratified p-value	0.1013			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by History of Diabetes - Investigations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.6691
No vs. Yes		0.3903	0.8537	0.6674	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Investigations (SOC)
Safety Population

BMI (kg/m^2): < 25

	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)	Total (N= 19)
Number of patients at risk		13 (100.0%)	6 (100.0%)	19 (100.0%)
Number of patients with events		2 (15.4%)	1 (16.7%)	3 (15.8%)
Number of patients without events		11 (84.6%)	5 (83.3%)	16 (84.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.909 [0.066, 12.524]			
Stratified OR, 95% CI	1.268 [0.100, 16.110]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.923 [0.103, 8.305]			
Stratified RR, 95% CI	1.037 [0.187, 5.753]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.013 [-0.370, 0.344]			
Stratified ARR, 95% CI (CMH method)	0.067 [-0.339, 0.473]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7688			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Investigations (SOC)
Safety Population

BMI (kg/m^2): 25 - < 30

	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)	Total (N= 49)
Number of patients at risk		27 (100.0%)	22 (100.0%)	49 (100.0%)
Number of patients with events		1 (3.7%)	1 (4.5%)	2 (4.1%)
Number of patients without events		26 (96.3%)	21 (95.5%)	47 (95.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.808 [0.048, 13.698]			
Stratified OR, 95% CI	1.149 [0.105, 12.568]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.815 [0.054, 12.296]			
Stratified RR, 95% CI	1.114 [0.131, 9.493]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.008 [-0.121, 0.104]			
Stratified ARR, 95% CI (CMH method)	0.006 [-0.101, 0.114]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9149			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Investigations (SOC)
Safety Population

BMI (kg/m^2): >= 30

	FDC vs. Placebo	FDC (N= 67)	Placebo (N= 27)	Total (N= 94)
Number of patients at risk		67 (100.0%)	27 (100.0%)	94 (100.0%)
Number of patients with events		11 (16.4%)	0	11 (11.7%)
Number of patients without events		56 (83.6%)	27 (100.0%)	83 (88.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	11.195 [0.636, 197.02]			
Stratified OR, 95% CI	3.053 [0.634, 14.698]			
Relative Risk [a]				
Unstratified RR, 95% CI	9.471 [0.578, 155.28]			
Stratified RR, 95% CI	2.638 [0.626, 11.121]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.164 [0.075, 0.253]			
Stratified ARR, 95% CI (CMH method)	0.169 [0.078, 0.260]			
Test on Differences [c]				
Unstratified p-value	0.0302			
Stratified p-value	0.0252			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by BMI - Investigations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.1023
25 - < 30 vs. < 25		0.9431	0.3312	0.9442	
>= 30 vs. < 25		0.9431	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		13 (12.1%)	7 (12.7%)	20 (12.3%)
Number of patients without events		94 (87.9%)	48 (87.3%)	142 (87.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.948 [0.355, 2.533]			
Stratified OR, 95% CI	0.932 [0.335, 2.592]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.955 [0.404, 2.254]			
Stratified RR, 95% CI	0.936 [0.387, 2.263]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.006 [-0.113, 0.102]			
Stratified ARR, 95% CI (CMH method)	-0.003 [-0.110, 0.104]			
Test on Differences [c]				
Unstratified p-value	0.9157			
Stratified p-value	0.9564			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Gender: Male

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)	Total (N= 83)
Number of patients at risk		50 (100.0%)	33 (100.0%)	83 (100.0%)
Number of patients with events		8 (16.0%)	3 (9.1%)	11 (13.3%)
Number of patients without events		42 (84.0%)	30 (90.9%)	72 (86.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.905 [0.466, 7.780]			
Stratified OR, 95% CI	1.736 [0.383, 7.878]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.760 [0.503, 6.155]			
Stratified RR, 95% CI	1.595 [0.416, 6.110]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.069 [-0.072, 0.210]			
Stratified ARR, 95% CI (CMH method)	0.077 [-0.067, 0.220]			
Test on Differences [c]				
Unstratified p-value	0.5131			
Stratified p-value	0.3082			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Gender: Female

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 22)	Total (N= 79)
Number of patients at risk		57 (100.0%)	22 (100.0%)	79 (100.0%)
Number of patients with events		5 (8.8%)	4 (18.2%)	9 (11.4%)
Number of patients without events		52 (91.2%)	18 (81.8%)	70 (88.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.433 [0.105, 1.790]			
Stratified OR, 95% CI	0.462 [0.107, 1.990]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.482 [0.143, 1.633]			
Stratified RR, 95% CI	0.532 [0.161, 1.763]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.094 [-0.271, 0.083]			
Stratified ARR, 95% CI (CMH method)	-0.083 [-0.259, 0.092]			
Test on Differences [c]				
Unstratified p-value	0.2551			
Stratified p-value	0.3090			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Gender - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.1429
Female vs. Male		0.3762	0.3306	0.1467	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Age (years): < 65

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 27)	Total (N= 84)
Number of patients at risk		57 (100.0%)	27 (100.0%)	84 (100.0%)
Number of patients with events		6 (10.5%)	3 (11.1%)	9 (10.7%)
Number of patients without events		51 (89.5%)	24 (88.9%)	75 (89.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.941 [0.217, 4.087]			
Stratified OR, 95% CI	0.757 [0.153, 3.751]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.947 [0.256, 3.504]			
Stratified RR, 95% CI	0.806 [0.198, 3.286]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.006 [-0.149, 0.137]			
Stratified ARR, 95% CI (CMH method)	-0.021 [-0.160, 0.118]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7613			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Age (years): >= 65

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)	Total (N= 78)
Number of patients at risk		50 (100.0%)	28 (100.0%)	78 (100.0%)
Number of patients with events		7 (14.0%)	4 (14.3%)	11 (14.1%)
Number of patients without events		43 (86.0%)	24 (85.7%)	67 (85.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.977 [0.259, 3.679]			
Stratified OR, 95% CI	0.953 [0.239, 3.797]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.980 [0.314, 3.058]			
Stratified RR, 95% CI	0.926 [0.293, 2.929]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.003 [-0.164, 0.159]			
Stratified ARR, 95% CI (CMH method)	-0.002 [-0.165, 0.162]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9837			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Age - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.9695
>= 65 vs. < 65		0.9354	0.7251	0.9695	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		10 (16.9%)	4 (12.9%)	14 (15.6%)
Number of patients without events		49 (83.1%)	27 (87.1%)	76 (84.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.378 [0.394, 4.813]			
Stratified OR, 95% CI	1.131 [0.288, 4.444]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.314 [0.448, 3.848]			
Stratified RR, 95% CI	1.039 [0.318, 3.392]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.040 [-0.111, 0.192]			
Stratified ARR, 95% CI (CMH method)	0.040 [-0.114, 0.194]			
Test on Differences [c]				
Unstratified p-value	0.7638			
Stratified p-value	0.6196			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

CVD Risk Category: Multiple CV risk factors

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		3 (6.3%)	3 (12.5%)	6 (8.3%)
Number of patients without events		45 (93.8%)	21 (87.5%)	66 (91.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.467 [0.087, 2.509]			
Stratified OR, 95% CI	0.483 [0.086, 2.703]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.500 [0.109, 2.294]			
Stratified RR, 95% CI	0.531 [0.120, 2.353]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.063 [-0.211, 0.086]			
Stratified ARR, 95% CI (CMH method)	-0.058 [-0.204, 0.089]			
Test on Differences [c]				
Unstratified p-value	0.3932			
Stratified p-value	0.4053			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by CVD Risk Category - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.3096
Multiple CV risk factors vs. ASCVD and/or HeFH		0.6190	0.9645	0.3099	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Baseline Statin Dose Intensity I: Other

	FDC vs. Placebo	FDC (N= 65)	Placebo (N= 34)	Total (N= 99)
Number of patients at risk		65 (100.0%)	34 (100.0%)	99 (100.0%)
Number of patients with events		10 (15.4%)	4 (11.8%)	14 (14.1%)
Number of patients without events		55 (84.6%)	30 (88.2%)	85 (85.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.364 [0.394, 4.721]			
Stratified OR, 95% CI	1.117 [0.289, 4.321]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.308 [0.443, 3.861]			
Stratified RR, 95% CI	1.046 [0.316, 3.460]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.036 [-0.103, 0.176]			
Stratified ARR, 95% CI (CMH method)	0.036 [-0.105, 0.177]			
Test on Differences [c]				
Unstratified p-value	0.7659			
Stratified p-value	0.6292			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		3 (7.1%)	3 (14.3%)	6 (9.5%)
Number of patients without events		39 (92.9%)	18 (85.7%)	57 (90.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.462 [0.085, 2.514]			
Stratified OR, 95% CI	0.478 [0.083, 2.764]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.500 [0.110, 2.268]			
Stratified RR, 95% CI	0.538 [0.125, 2.324]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.071 [-0.240, 0.097]			
Stratified ARR, 95% CI (CMH method)	-0.064 [-0.228, 0.100]			
Test on Differences [c]				
Unstratified p-value	0.3911			
Stratified p-value	0.4094			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity I - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.3106
High Intensity Statin vs. Other		0.6273	0.7850	0.3110	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

	FDC vs. Placebo	FDC (N= 32)	Placebo (N= 20)	Total (N= 52)
Number of patients at risk		32 (100.0%)	20 (100.0%)	52 (100.0%)
Number of patients with events		3 (9.4%)	3 (15.0%)	6 (11.5%)
Number of patients without events		29 (90.6%)	17 (85.0%)	46 (88.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.586 [0.106, 3.237]			
Stratified OR, 95% CI	0.518 [0.076, 3.553]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.625 [0.140, 2.800]			
Stratified RR, 95% CI	0.543 [0.097, 3.030]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.056 [-0.242, 0.130]			
Stratified ARR, 95% CI (CMH method)	-0.054 [-0.242, 0.134]			
Test on Differences [c]				
Unstratified p-value	0.6644			
Stratified p-value	0.5614			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		3 (7.1%)	3 (14.3%)	6 (9.5%)
Number of patients without events		39 (92.9%)	18 (85.7%)	57 (90.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.462 [0.085, 2.514]			
Stratified OR, 95% CI	0.478 [0.083, 2.764]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.500 [0.110, 2.268]			
Stratified RR, 95% CI	0.538 [0.125, 2.324]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.071 [-0.240, 0.097]			
Stratified ARR, 95% CI (CMH method)	-0.064 [-0.228, 0.100]			
Test on Differences [c]				
Unstratified p-value	0.3911			
Stratified p-value	0.4094			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Baseline Statin Dose Intensity II: None

	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)	Total (N= 47)
Number of patients at risk		33 (100.0%)	14 (100.0%)	47 (100.0%)
Number of patients with events		7 (21.2%)	1 (7.1%)	8 (17.0%)
Number of patients without events		26 (78.8%)	13 (92.9%)	39 (83.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.500 [0.388, 31.541]			
Stratified OR, 95% CI	2.612 [0.393, 17.359]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.970 [0.402, 21.940]			
Stratified RR, 95% CI	2.198 [0.433, 11.156]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.141 [-0.053, 0.335]			
Stratified ARR, 95% CI (CMH method)	0.143 [-0.043, 0.330]			
Test on Differences [c]				
Unstratified p-value	0.4048			
Stratified p-value	0.2297			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity II - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.2562
High Intensity Statin vs. Other Intensity Statin		0.5390	0.9484	0.8373	
None vs. Other Intensity Statin		0.5390	0.5003	0.2217	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Race: White

	FDC vs. Placebo	FDC (N= 84)	Placebo (N= 48)	Total (N= 132)
Number of patients at risk		84 (100.0%)	48 (100.0%)	132 (100.0%)
Number of patients with events		9 (10.7%)	6 (12.5%)	15 (11.4%)
Number of patients without events		75 (89.3%)	42 (87.5%)	117 (88.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.840 [0.280, 2.523]			
Stratified OR, 95% CI	0.872 [0.275, 2.773]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.857 [0.325, 2.262]			
Stratified RR, 95% CI	0.886 [0.323, 2.430]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.018 [-0.132, 0.097]			
Stratified ARR, 95% CI (CMH method)	-0.012 [-0.127, 0.102]			
Test on Differences [c]				
Unstratified p-value	0.7558			
Stratified p-value	0.8298			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Race: non-White

	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)	Total (N= 30)
Number of patients at risk		23 (100.0%)	7 (100.0%)	30 (100.0%)
Number of patients with events		4 (17.4%)	1 (14.3%)	5 (16.7%)
Number of patients without events		19 (82.6%)	6 (85.7%)	25 (83.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.263 [0.117, 13.591]			
Stratified OR, 95% CI	0.687 [0.090, 5.264]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.217 [0.161, 9.190]			
Stratified RR, 95% CI	0.687 [0.157, 3.013]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.031 [-0.271, 0.333]			
Stratified ARR, 95% CI (CMH method)	-0.009 [-0.321, 0.304]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9570			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Race - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.7521
non-White vs. White		0.7555	0.8939	0.7591	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Baseline LDL-C (mg/dL): < 130

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 16)	Total (N= 54)
Number of patients at risk		38 (100.0%)	16 (100.0%)	54 (100.0%)
Number of patients with events		6 (15.8%)	2 (12.5%)	8 (14.8%)
Number of patients without events		32 (84.2%)	14 (87.5%)	46 (85.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.313 [0.235, 7.323]			
Stratified OR, 95% CI	1.592 [0.268, 9.460]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.263 [0.285, 5.604]			
Stratified RR, 95% CI	1.483 [0.323, 6.806]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.033 [-0.166, 0.232]			
Stratified ARR, 95% CI (CMH method)	0.064 [-0.155, 0.282]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5876			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)	Total (N= 47)
Number of patients at risk		31 (100.0%)	16 (100.0%)	47 (100.0%)
Number of patients with events		3 (9.7%)	0	3 (6.4%)
Number of patients without events		28 (90.3%)	16 (100.0%)	44 (93.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.053 [0.197, 83.425]			
Stratified OR, 95% CI	2.052 [0.284, 14.815]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.719 [0.204, 67.871]			
Stratified RR, 95% CI	1.864 [0.331, 10.503]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.097 [-0.007, 0.201]			
Stratified ARR, 95% CI (CMH method)	0.104 [-0.004, 0.212]			
Test on Differences [c]				
Unstratified p-value	0.5412			
Stratified p-value	0.1874			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Baseline LDL-C (mg/dL): >= 160

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)	Total (N= 61)
Number of patients at risk		38 (100.0%)	23 (100.0%)	61 (100.0%)
Number of patients with events		4 (10.5%)	5 (21.7%)	9 (14.8%)
Number of patients without events		34 (89.5%)	18 (78.3%)	52 (85.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.424 [0.101, 1.776]			
Stratified OR, 95% CI	0.398 [0.082, 1.920]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.484 [0.145, 1.621]			
Stratified RR, 95% CI	0.486 [0.132, 1.796]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.112 [-0.307, 0.083]			
Stratified ARR, 95% CI (CMH method)	-0.119 [-0.312, 0.074]			
Test on Differences [c]				
Unstratified p-value	0.2777			
Stratified p-value	0.2157			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline LDL-C Category - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.1311
130 - < 160 vs. < 130		0.7586	<.0001	-	
>= 160 vs. < 130		0.7586	0.4728	0.3273	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

History of Diabetes: Yes

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		5 (10.4%)	2 (8.3%)	7 (9.7%)
Number of patients without events		43 (89.6%)	22 (91.7%)	65 (90.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.279 [0.229, 7.132]			
Stratified OR, 95% CI	1.162 [0.223, 6.049]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.250 [0.261, 5.978]			
Stratified RR, 95% CI	1.140 [0.272, 4.780]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.021 [-0.120, 0.161]			
Stratified ARR, 95% CI (CMH method)	0.025 [-0.112, 0.162]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7404			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

History of Diabetes: No

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		8 (13.6%)	5 (16.1%)	13 (14.4%)
Number of patients without events		51 (86.4%)	26 (83.9%)	77 (85.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.816 [0.242, 2.744]			
Stratified OR, 95% CI	0.888 [0.235, 3.351]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.841 [0.300, 2.353]			
Stratified RR, 95% CI	0.946 [0.309, 2.901]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.026 [-0.182, 0.130]			
Stratified ARR, 95% CI (CMH method)	-0.026 [-0.183, 0.131]			
Test on Differences [c]				
Unstratified p-value	0.7418			
Stratified p-value	0.7389			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by History of Diabetes - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.6741
No vs. Yes		0.7799	0.4040	0.6781	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

BMI (kg/m^2): < 25

	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)	Total (N= 19)
Number of patients at risk		13 (100.0%)	6 (100.0%)	19 (100.0%)
Number of patients with events		3 (23.1%)	0	3 (15.8%)
Number of patients without events		10 (76.9%)	6 (100.0%)	16 (84.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.333 [0.191, 98.180]			
Stratified OR, 95% CI	4.697 [0.384, 57.465]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.500 [0.208, 58.770]			
Stratified RR, 95% CI	3.029 [0.424, 21.653]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.231 [0.002, 0.460]			
Stratified ARR, 95% CI (CMH method)	0.368 [0.031, 0.705]			
Test on Differences [c]				
Unstratified p-value	0.5170			
Stratified p-value	0.1184			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

BMI (kg/m^2): 25 - < 30

	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)	Total (N= 49)
Number of patients at risk		27 (100.0%)	22 (100.0%)	49 (100.0%)
Number of patients with events		1 (3.7%)	3 (13.6%)	4 (8.2%)
Number of patients without events		26 (96.3%)	19 (86.4%)	45 (91.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.244 [0.023, 2.527]			
Stratified OR, 95% CI	0.423 [0.065, 2.738]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.272 [0.030, 2.432]			
Stratified RR, 95% CI	0.478 [0.092, 2.482]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.099 [-0.259, 0.061]			
Stratified ARR, 95% CI (CMH method)	-0.098 [-0.258, 0.063]			
Test on Differences [c]				
Unstratified p-value	0.3136			
Stratified p-value	0.2412			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

BMI (kg/m^2): >= 30

	FDC vs. Placebo	FDC (N= 67)	Placebo (N= 27)	Total (N= 94)
Number of patients at risk		67 (100.0%)	27 (100.0%)	94 (100.0%)
Number of patients with events		9 (13.4%)	4 (14.8%)	13 (13.8%)
Number of patients without events		58 (86.6%)	23 (85.2%)	81 (86.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.892 [0.250, 3.187]			
Stratified OR, 95% CI	0.893 [0.239, 3.333]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.907 [0.305, 2.696]			
Stratified RR, 95% CI	0.898 [0.300, 2.682]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.014 [-0.171, 0.143]			
Stratified ARR, 95% CI (CMH method)	-0.008 [-0.165, 0.148]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9156			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by BMI - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.1262
25 - < 30 vs. < 25		<.0001	<.0001	<.0001	
>= 30 vs. < 25		<.0001	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

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Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Creatine Kinase Elevations (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE - Creatine Kinase Elevations (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE - Creatine Kinase Elevations (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE - Creatine Kinase Elevations (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Hepatic Disorders (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		2 (1.9%)	0	2 (1.2%)
Number of patients without events		105 (98.1%)	55 (100.0%)	160 (98.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.630 [0.124, 55.747]			
Stratified OR, 95% CI	2.778 [0.126, 61.175]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.593 [0.127, 53.081]			
Stratified RR, 95% CI	2.647 [0.134, 52.226]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.019 [-0.007, 0.044]			
Stratified ARR, 95% CI (CMH method)	0.019 [-0.007, 0.044]			
Test on Differences [c]				
Unstratified p-value	0.5487			
Stratified p-value	0.3051			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Hepatic Disorders (AESI)
Safety Population

Gender: Male

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)	Total (N= 83)
Number of patients at risk		50 (100.0%)	33 (100.0%)	83 (100.0%)
Number of patients with events		1 (2.0%)	0	1 (1.2%)
Number of patients without events		49 (98.0%)	33 (100.0%)	82 (98.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.030 [0.080, 51.351]			
Stratified OR, 95% CI	2.419 [0.090, 64.695]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.000 [0.084, 47.665]			
Stratified RR, 95% CI	2.294 [0.101, 51.854]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.020 [-0.019, 0.059]			
Stratified ARR, 95% CI (CMH method)	0.022 [-0.019, 0.062]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3865			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Hepatic Disorders (AESI)
Safety Population

Gender: Female

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 22)	Total (N= 79)
Number of patients at risk		57 (100.0%)	22 (100.0%)	79 (100.0%)
Number of patients with events		1 (1.8%)	0	1 (1.3%)
Number of patients without events		56 (98.2%)	22 (100.0%)	78 (98.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.195 [0.047, 30.434]			
Stratified OR, 95% CI	1.000 [0.035, 28.302]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.190 [0.050, 28.152]			
Stratified RR, 95% CI	1.000 [0.047, 21.421]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.018 [-0.017, 0.052]			
Stratified ARR, 95% CI (CMH method)	0.014 [-0.017, 0.046]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5876			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Gender - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				1.0000
Female vs. Male		-	0.9999	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Hepatic Disorders (AESI)
Safety Population

Age (years): < 65

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 27)	Total (N= 84)
Number of patients at risk		57 (100.0%)	27 (100.0%)	84 (100.0%)
Number of patients with events		1 (1.8%)	0	1 (1.2%)
Number of patients without events		56 (98.2%)	27 (100.0%)	83 (98.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.460 [0.058, 37.020]			
Stratified OR, 95% CI	1.098 [0.040, 30.000]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.448 [0.061, 34.434]			
Stratified RR, 95% CI	1.091 [0.049, 24.134]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.018 [-0.017, 0.052]			
Stratified ARR, 95% CI (CMH method)	0.014 [-0.017, 0.045]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5637			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Hepatic Disorders (AESI)
Safety Population

Age (years): >= 65

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)	Total (N= 78)
Number of patients at risk		50 (100.0%)	28 (100.0%)	78 (100.0%)
Number of patients with events		1 (2.0%)	0	1 (1.3%)
Number of patients without events		49 (98.0%)	28 (100.0%)	77 (98.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.727 [0.068, 43.823]			
Stratified OR, 95% CI	2.739 [0.100, 74.872]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.706 [0.072, 40.531]			
Stratified RR, 95% CI	2.538 [0.115, 56.250]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.020 [-0.019, 0.059]			
Stratified ARR, 95% CI (CMH method)	0.026 [-0.019, 0.070]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3613			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Age - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				1.0000
>= 65 vs. < 65		-	1.0000	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Hepatic Disorders (AESI)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		2 (3.4%)	0	2 (2.2%)
Number of patients without events		57 (96.6%)	31 (100.0%)	88 (97.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.739 [0.127, 58.846]			
Stratified OR, 95% CI	2.778 [0.126, 61.175]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.667 [0.132, 53.878]			
Stratified RR, 95% CI	2.647 [0.134, 52.226]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.034 [-0.012, 0.080]			
Stratified ARR, 95% CI (CMH method)	0.033 [-0.012, 0.079]			
Test on Differences [c]				
Unstratified p-value	0.5433			
Stratified p-value	0.3051			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Hepatic Disorders (AESI)
Safety Population

CVD Risk Category: Multiple CV risk factors

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		48 (100.0%)	24 (100.0%)	72 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by CVD Risk Category - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	WARNING: Negative of Hessian not positive definite				-
Multiple CV risk factors vs. ASCVD and/or HeFH		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Hepatic Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: Other

	FDC vs. Placebo	FDC (N= 65)	Placebo (N= 34)	Total (N= 99)
Number of patients at risk		65 (100.0%)	34 (100.0%)	99 (100.0%)
Number of patients with events		2 (3.1%)	0	2 (2.0%)
Number of patients without events		63 (96.9%)	34 (100.0%)	97 (98.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.717 [0.127, 58.200]			
Stratified OR, 95% CI	2.778 [0.126, 61.175]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.652 [0.131, 53.716]			
Stratified RR, 95% CI	2.647 [0.134, 52.226]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.031 [-0.011, 0.073]			
Stratified ARR, 95% CI (CMH method)	0.030 [-0.011, 0.072]			
Test on Differences [c]				
Unstratified p-value	0.5444			
Stratified p-value	0.3051			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Hepatic Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		42 (100.0%)	21 (100.0%)	63 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity I - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	WARNING: Negative of Hessian not positive definite				-
High Intensity Statin vs. Other		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Hepatic Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

	FDC vs. Placebo	FDC (N= 32)	Placebo (N= 20)	Total (N= 52)
Number of patients at risk		32 (100.0%)	20 (100.0%)	52 (100.0%)
Number of patients with events		2 (6.3%)	0	2 (3.8%)
Number of patients without events		30 (93.8%)	20 (100.0%)	50 (96.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.361 [0.153, 73.675]			
Stratified OR, 95% CI	3.387 [0.147, 77.926]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.182 [0.161, 63.062]			
Stratified RR, 95% CI	3.056 [0.161, 57.929]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.063 [-0.021, 0.146]			
Stratified ARR, 95% CI (CMH method)	0.060 [-0.022, 0.143]			
Test on Differences [c]				
Unstratified p-value	0.5173			
Stratified p-value	0.2687			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Hepatic Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		42 (100.0%)	21 (100.0%)	63 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Hepatic Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: None

	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)	Total (N= 47)
Number of patients at risk		33 (100.0%)	14 (100.0%)	47 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		33 (100.0%)	14 (100.0%)	47 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity II - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	WARNING: Negative of Hessian not positive definite				-
High Intensity Statin vs. Other Intensity Statin		-	1.0000	1.0000	
None vs. Other Intensity Statin		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Hepatic Disorders (AESI)
Safety Population

Race: White

	FDC vs. Placebo	FDC (N= 84)	Placebo (N= 48)	Total (N= 132)
Number of patients at risk		84 (100.0%)	48 (100.0%)	132 (100.0%)
Number of patients with events		2 (2.4%)	0	2 (1.5%)
Number of patients without events		82 (97.6%)	48 (100.0%)	130 (98.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.939 [0.138, 62.503]			
Stratified OR, 95% CI	3.113 [0.141, 68.965]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.882 [0.141, 58.824]			
Stratified RR, 95% CI	2.931 [0.149, 57.519]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.024 [-0.009, 0.056]			
Stratified ARR, 95% CI (CMH method)	0.024 [-0.009, 0.057]			
Test on Differences [c]				
Unstratified p-value	0.5337			
Stratified p-value	0.2794			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Hepatic Disorders (AESI)
Safety Population

Race: non-White

	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)	Total (N= 30)
Number of patients at risk		23 (100.0%)	7 (100.0%)	30 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		23 (100.0%)	7 (100.0%)	30 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Race - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	WARNING: Negative of Hessian not positive definite				-
non-White vs. White		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Hepatic Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): < 130

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 16)	Total (N= 54)
Number of patients at risk		38 (100.0%)	16 (100.0%)	54 (100.0%)
Number of patients with events		1 (2.6%)	0	1 (1.9%)
Number of patients without events		37 (97.4%)	16 (100.0%)	53 (98.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.320 [0.051, 34.131]			
Stratified OR, 95% CI	2.429 [0.087, 67.573]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.308 [0.056, 30.501]			
Stratified RR, 95% CI	2.250 [0.103, 49.040]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.026 [-0.025, 0.077]			
Stratified ARR, 95% CI (CMH method)	0.042 [-0.033, 0.116]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3938			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Hepatic Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)	Total (N= 47)
Number of patients at risk		31 (100.0%)	16 (100.0%)	47 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		31 (100.0%)	16 (100.0%)	47 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Hepatic Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): >= 160

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)	Total (N= 61)
Number of patients at risk		38 (100.0%)	23 (100.0%)	61 (100.0%)
Number of patients with events		1 (2.6%)	0	1 (1.6%)
Number of patients without events		37 (97.4%)	23 (100.0%)	60 (98.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.880 [0.073, 48.094]			
Stratified OR, 95% CI	1.138 [0.040, 32.360]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.846 [0.078, 43.513]			
Stratified RR, 95% CI	1.125 [0.053, 23.993]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.026 [-0.025, 0.077]			
Stratified ARR, 95% CI (CMH method)	0.018 [-0.026, 0.063]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5637			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline LDL-C Category - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	WARNING: Negative of Hessian not positive definite				-
130 - < 160 vs. < 130		-	1.0000	1.0000	
>= 160 vs. < 130		-	0.9997	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Hepatic Disorders (AESI)
Safety Population

History of Diabetes: Yes

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		48 (100.0%)	24 (100.0%)	72 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Hepatic Disorders (AESI)
Safety Population

History of Diabetes: No

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		2 (3.4%)	0	2 (2.2%)
Number of patients without events		57 (96.6%)	31 (100.0%)	88 (97.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.739 [0.127, 58.846]			
Stratified OR, 95% CI	3.140 [0.140, 70.512]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.667 [0.132, 53.878]			
Stratified RR, 95% CI	2.917 [0.151, 56.509]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.034 [-0.012, 0.080]			
Stratified ARR, 95% CI (CMH method)	0.036 [-0.012, 0.084]			
Test on Differences [c]				
Unstratified p-value	0.5433			
Stratified p-value	0.2807			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by History of Diabetes - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	WARNING: Negative of Hessian not positive definite				-
No vs. Yes		-	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Hepatic Disorders (AESI)
Safety Population

BMI (kg/m^2): < 25

	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)	Total (N= 19)
Number of patients at risk		13 (100.0%)	6 (100.0%)	19 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		13 (100.0%)	6 (100.0%)	19 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Hepatic Disorders (AESI)
Safety Population

BMI (kg/m^2): 25 - < 30

	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)	Total (N= 49)
Number of patients at risk		27 (100.0%)	22 (100.0%)	49 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		27 (100.0%)	22 (100.0%)	49 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Hepatic Disorders (AESI)
Safety Population

BMI (kg/m^2): >= 30

	FDC vs. Placebo	FDC (N= 67)	Placebo (N= 27)	Total (N= 94)
Number of patients at risk		67 (100.0%)	27 (100.0%)	94 (100.0%)
Number of patients with events		2 (3.0%)	0	2 (2.1%)
Number of patients without events		65 (97.0%)	27 (100.0%)	92 (97.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.099 [0.098, 45.170]			
Stratified OR, 95% CI	2.297 [0.099, 53.241]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.059 [0.102, 41.531]			
Stratified RR, 95% CI	2.143 [0.114, 40.301]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.030 [-0.011, 0.071]			
Stratified ARR, 95% CI (CMH method)	0.030 [-0.012, 0.072]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3621			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by BMI - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	WARNING: Negative of Hessian not positive definite				-
25 - < 30 vs. < 25		-	1.0000	1.0000	
>= 30 vs. < 25		-	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE - Hepatic Disorders (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE - Hepatic Disorders (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE - Hepatic Disorders (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		2 (1.9%)	0	2 (1.2%)
Number of patients without events		105 (98.1%)	55 (100.0%)	160 (98.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.630 [0.124, 55.747]			
Stratified OR, 95% CI	2.778 [0.126, 61.175]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.593 [0.127, 53.081]			
Stratified RR, 95% CI	2.647 [0.134, 52.226]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.019 [-0.007, 0.044]			
Stratified ARR, 95% CI (CMH method)	0.019 [-0.007, 0.044]			
Test on Differences [c]				
Unstratified p-value	0.5487			
Stratified p-value	0.3051			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Gender - Hepatic Disorders (AESI)
Safety Population

Gender: Male

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)	Total (N= 83)
Number of patients at risk		50 (100.0%)	33 (100.0%)	83 (100.0%)
Number of patients with events		1 (2.0%)	0	1 (1.2%)
Number of patients without events		49 (98.0%)	33 (100.0%)	82 (98.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.030 [0.080, 51.351]			
Stratified OR, 95% CI	2.419 [0.090, 64.695]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.000 [0.084, 47.665]			
Stratified RR, 95% CI	2.294 [0.101, 51.854]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.020 [-0.019, 0.059]			
Stratified ARR, 95% CI (CMH method)	0.022 [-0.019, 0.062]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3865			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Gender - Hepatic Disorders (AESI)
Safety Population

Gender: Female

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 22)	Total (N= 79)
Number of patients at risk		57 (100.0%)	22 (100.0%)	79 (100.0%)
Number of patients with events		1 (1.8%)	0	1 (1.3%)
Number of patients without events		56 (98.2%)	22 (100.0%)	78 (98.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.195 [0.047, 30.434]			
Stratified OR, 95% CI	1.000 [0.035, 28.302]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.190 [0.050, 28.152]			
Stratified RR, 95% CI	1.000 [0.047, 21.421]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.018 [-0.017, 0.052]			
Stratified ARR, 95% CI (CMH method)	0.014 [-0.017, 0.046]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5876			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Gender - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				1.0000
Female vs. Male		-	0.9999	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Age - Hepatic Disorders (AESI)
Safety Population

Age (years): < 65

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 27)	Total (N= 84)
Number of patients at risk		57 (100.0%)	27 (100.0%)	84 (100.0%)
Number of patients with events		1 (1.8%)	0	1 (1.2%)
Number of patients without events		56 (98.2%)	27 (100.0%)	83 (98.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.460 [0.058, 37.020]			
Stratified OR, 95% CI	1.098 [0.040, 30.000]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.448 [0.061, 34.434]			
Stratified RR, 95% CI	1.091 [0.049, 24.134]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.018 [-0.017, 0.052]			
Stratified ARR, 95% CI (CMH method)	0.014 [-0.017, 0.045]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5637			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Age - Hepatic Disorders (AESI)
Safety Population

Age (years): >= 65

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)	Total (N= 78)
Number of patients at risk		50 (100.0%)	28 (100.0%)	78 (100.0%)
Number of patients with events		1 (2.0%)	0	1 (1.3%)
Number of patients without events		49 (98.0%)	28 (100.0%)	77 (98.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.727 [0.068, 43.823]			
Stratified OR, 95% CI	2.739 [0.100, 74.872]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.706 [0.072, 40.531]			
Stratified RR, 95% CI	2.538 [0.115, 56.250]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.020 [-0.019, 0.059]			
Stratified ARR, 95% CI (CMH method)	0.026 [-0.019, 0.070]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3613			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Age - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				1.0000
>= 65 vs. < 65		-	1.0000	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by CVD Risk Category - Hepatic Disorders (AESI)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		2 (3.4%)	0	2 (2.2%)
Number of patients without events		57 (96.6%)	31 (100.0%)	88 (97.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.739 [0.127, 58.846]			
Stratified OR, 95% CI	2.778 [0.126, 61.175]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.667 [0.132, 53.878]			
Stratified RR, 95% CI	2.647 [0.134, 52.226]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.034 [-0.012, 0.080]			
Stratified ARR, 95% CI (CMH method)	0.033 [-0.012, 0.079]			
Test on Differences [c]				
Unstratified p-value	0.5433			
Stratified p-value	0.3051			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by CVD Risk Category - Hepatic Disorders (AESI)
Safety Population

CVD Risk Category: Multiple CV risk factors

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		48 (100.0%)	24 (100.0%)	72 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by CVD Risk Category - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	WARNING: Negative of Hessian not positive definite				-
Multiple CV risk factors vs. ASCVD and/or HeFH		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Hepatic Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: Other

	FDC vs. Placebo	FDC (N= 65)	Placebo (N= 34)	Total (N= 99)
Number of patients at risk		65 (100.0%)	34 (100.0%)	99 (100.0%)
Number of patients with events		2 (3.1%)	0	2 (2.0%)
Number of patients without events		63 (96.9%)	34 (100.0%)	97 (98.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.717 [0.127, 58.200]			
Stratified OR, 95% CI	2.778 [0.126, 61.175]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.652 [0.131, 53.716]			
Stratified RR, 95% CI	2.647 [0.134, 52.226]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.031 [-0.011, 0.073]			
Stratified ARR, 95% CI (CMH method)	0.030 [-0.011, 0.072]			
Test on Differences [c]				
Unstratified p-value	0.5444			
Stratified p-value	0.3051			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Hepatic Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		42 (100.0%)	21 (100.0%)	63 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	WARNING: Negative of Hessian not positive definite				-
High Intensity Statin vs. Other		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Hepatic Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

	FDC vs. Placebo	FDC (N= 32)	Placebo (N= 20)	Total (N= 52)
Number of patients at risk		32 (100.0%)	20 (100.0%)	52 (100.0%)
Number of patients with events		2 (6.3%)	0	2 (3.8%)
Number of patients without events		30 (93.8%)	20 (100.0%)	50 (96.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.361 [0.153, 73.675]			
Stratified OR, 95% CI	3.387 [0.147, 77.926]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.182 [0.161, 63.062]			
Stratified RR, 95% CI	3.056 [0.161, 57.929]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.063 [-0.021, 0.146]			
Stratified ARR, 95% CI (CMH method)	0.060 [-0.022, 0.143]			
Test on Differences [c]				
Unstratified p-value	0.5173			
Stratified p-value	0.2687			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Hepatic Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		42 (100.0%)	21 (100.0%)	63 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Hepatic Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: None

	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)	Total (N= 47)
Number of patients at risk		33 (100.0%)	14 (100.0%)	47 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		33 (100.0%)	14 (100.0%)	47 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	WARNING: Negative of Hessian not positive definite				-
High Intensity Statin vs. Other Intensity Statin		-	1.0000	1.0000	
None vs. Other Intensity Statin		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Race - Hepatic Disorders (AESI)
Safety Population

Race: White

	FDC vs. Placebo	FDC (N= 84)	Placebo (N= 48)	Total (N= 132)
Number of patients at risk		84 (100.0%)	48 (100.0%)	132 (100.0%)
Number of patients with events		2 (2.4%)	0	2 (1.5%)
Number of patients without events		82 (97.6%)	48 (100.0%)	130 (98.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.939 [0.138, 62.503]			
Stratified OR, 95% CI	3.113 [0.141, 68.965]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.882 [0.141, 58.824]			
Stratified RR, 95% CI	2.931 [0.149, 57.519]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.024 [-0.009, 0.056]			
Stratified ARR, 95% CI (CMH method)	0.024 [-0.009, 0.057]			
Test on Differences [c]				
Unstratified p-value	0.5337			
Stratified p-value	0.2794			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Race - Hepatic Disorders (AESI)
Safety Population

Race: non-White

	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)	Total (N= 30)
Number of patients at risk		23 (100.0%)	7 (100.0%)	30 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		23 (100.0%)	7 (100.0%)	30 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Race - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	WARNING: Negative of Hessian not positive definite				-
non-White vs. White		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Hepatic Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): < 130

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 16)	Total (N= 54)
Number of patients at risk		38 (100.0%)	16 (100.0%)	54 (100.0%)
Number of patients with events		1 (2.6%)	0	1 (1.9%)
Number of patients without events		37 (97.4%)	16 (100.0%)	53 (98.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.320 [0.051, 34.131]			
Stratified OR, 95% CI	2.429 [0.087, 67.573]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.308 [0.056, 30.501]			
Stratified RR, 95% CI	2.250 [0.103, 49.040]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.026 [-0.025, 0.077]			
Stratified ARR, 95% CI (CMH method)	0.042 [-0.033, 0.116]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3938			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Hepatic Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)	Total (N= 47)
Number of patients at risk		31 (100.0%)	16 (100.0%)	47 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		31 (100.0%)	16 (100.0%)	47 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Hepatic Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): >= 160

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)	Total (N= 61)
Number of patients at risk		38 (100.0%)	23 (100.0%)	61 (100.0%)
Number of patients with events		1 (2.6%)	0	1 (1.6%)
Number of patients without events		37 (97.4%)	23 (100.0%)	60 (98.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.880 [0.073, 48.094]			
Stratified OR, 95% CI	1.138 [0.040, 32.360]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.846 [0.078, 43.513]			
Stratified RR, 95% CI	1.125 [0.053, 23.993]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.026 [-0.025, 0.077]			
Stratified ARR, 95% CI (CMH method)	0.018 [-0.026, 0.063]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5637			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline LDL-C Category - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	WARNING: Negative of Hessian not positive definite				-
130 - < 160 vs. < 130		-	1.0000	1.0000	
>= 160 vs. < 130		-	0.9997	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by History of Diabetes - Hepatic Disorders (AESI)
Safety Population

History of Diabetes: Yes

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		48 (100.0%)	24 (100.0%)	72 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by History of Diabetes - Hepatic Disorders (AESI)
Safety Population

History of Diabetes: No

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		2 (3.4%)	0	2 (2.2%)
Number of patients without events		57 (96.6%)	31 (100.0%)	88 (97.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.739 [0.127, 58.846]			
Stratified OR, 95% CI	3.140 [0.140, 70.512]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.667 [0.132, 53.878]			
Stratified RR, 95% CI	2.917 [0.151, 56.509]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.034 [-0.012, 0.080]			
Stratified ARR, 95% CI (CMH method)	0.036 [-0.012, 0.084]			
Test on Differences [c]				
Unstratified p-value	0.5433			
Stratified p-value	0.2807			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by History of Diabetes - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	WARNING: Negative of Hessian not positive definite				-
No vs. Yes		-	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Hepatic Disorders (AESI)
Safety Population

BMI (kg/m^2): < 25

	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)	Total (N= 19)
Number of patients at risk		13 (100.0%)	6 (100.0%)	19 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		13 (100.0%)	6 (100.0%)	19 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Hepatic Disorders (AESI)
Safety Population

BMI (kg/m^2): 25 - < 30

	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)	Total (N= 49)
Number of patients at risk		27 (100.0%)	22 (100.0%)	49 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		27 (100.0%)	22 (100.0%)	49 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Hepatic Disorders (AESI)
Safety Population

BMI (kg/m^2): >= 30

	FDC vs. Placebo	FDC (N= 67)	Placebo (N= 27)	Total (N= 94)
Number of patients at risk		67 (100.0%)	27 (100.0%)	94 (100.0%)
Number of patients with events		2 (3.0%)	0	2 (2.1%)
Number of patients without events		65 (97.0%)	27 (100.0%)	92 (97.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.099 [0.098, 45.170]			
Stratified OR, 95% CI	2.297 [0.099, 53.241]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.059 [0.102, 41.531]			
Stratified RR, 95% CI	2.143 [0.114, 40.301]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.030 [-0.011, 0.071]			
Stratified ARR, 95% CI (CMH method)	0.030 [-0.012, 0.072]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3621			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by BMI - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	WARNING: Negative of Hessian not positive definite				-
25 - < 30 vs. < 25		-	1.0000	1.0000	
>= 30 vs. < 25		-	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Hypoglycemia (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		1 (0.9%)	0	1 (0.6%)
Number of patients without events		106 (99.1%)	55 (100.0%)	161 (99.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.563 [0.063, 39.012]			
Stratified OR, 95% CI	1.706 [0.065, 44.655]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.556 [0.064, 37.567]			
Stratified RR, 95% CI	1.667 [0.072, 38.420]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.009 [-0.009, 0.028]			
Stratified ARR, 95% CI (CMH method)	0.010 [-0.009, 0.028]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4631			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE - Hypoglycemia (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE - Hypoglycemia (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE - Hypoglycemia (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		1 (0.9%)	0	1 (0.6%)
Number of patients without events		106 (99.1%)	55 (100.0%)	161 (99.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.563 [0.063, 39.012]			
Stratified OR, 95% CI	1.706 [0.065, 44.655]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.556 [0.064, 37.567]			
Stratified RR, 95% CI	1.667 [0.072, 38.420]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.009 [-0.009, 0.028]			
Stratified ARR, 95% CI (CMH method)	0.010 [-0.009, 0.028]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4631			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Metabolic Acidosis (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE - Metabolic Acidosis (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE - Metabolic Acidosis (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE - Metabolic Acidosis (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Muscular Disorders (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		6 (5.6%)	3 (5.5%)	9 (5.6%)
Number of patients without events		101 (94.4%)	52 (94.5%)	153 (94.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.030 [0.247, 4.284]			
Stratified OR, 95% CI	0.964 [0.246, 3.779]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.028 [0.267, 3.955]			
Stratified RR, 95% CI	0.958 [0.273, 3.358]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.002 [-0.073, 0.076]			
Stratified ARR, 95% CI (CMH method)	0.003 [-0.071, 0.076]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9476			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Muscular Disorders (AESI)
Safety Population

Gender: Male

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)	Total (N= 83)
Number of patients at risk		50 (100.0%)	33 (100.0%)	83 (100.0%)
Number of patients with events		3 (6.0%)	1 (3.0%)	4 (4.8%)
Number of patients without events		47 (94.0%)	32 (97.0%)	79 (95.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.043 [0.203, 20.522]			
Stratified OR, 95% CI	1.728 [0.233, 12.838]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.980 [0.215, 18.232]			
Stratified RR, 95% CI	1.642 [0.261, 10.327]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.030 [-0.058, 0.118]			
Stratified ARR, 95% CI (CMH method)	0.034 [-0.052, 0.120]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4839			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Muscular Disorders (AESI)
Safety Population

Gender: Female

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 22)	Total (N= 79)
Number of patients at risk		57 (100.0%)	22 (100.0%)	79 (100.0%)
Number of patients with events		3 (5.3%)	2 (9.1%)	5 (6.3%)
Number of patients without events		54 (94.7%)	20 (90.9%)	74 (93.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.556 [0.086, 3.573]			
Stratified OR, 95% CI	0.557 [0.080, 3.861]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.579 [0.104, 3.234]			
Stratified RR, 95% CI	0.588 [0.107, 3.230]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.038 [-0.172, 0.095]			
Stratified ARR, 95% CI (CMH method)	-0.035 [-0.168, 0.098]			
Test on Differences [c]				
Unstratified p-value	0.6144			
Stratified p-value	0.5757			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Gender - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.3797
Female vs. Male		0.5465	0.3573	0.3908	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Muscular Disorders (AESI)
Safety Population

Age (years): < 65

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 27)	Total (N= 84)
Number of patients at risk		57 (100.0%)	27 (100.0%)	84 (100.0%)
Number of patients with events		4 (7.0%)	1 (3.7%)	5 (6.0%)
Number of patients without events		53 (93.0%)	26 (96.3%)	79 (94.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.962 [0.209, 18.451]			
Stratified OR, 95% CI	1.258 [0.177, 8.958]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.895 [0.222, 16.151]			
Stratified RR, 95% CI	1.208 [0.212, 6.869]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.033 [-0.064, 0.130]			
Stratified ARR, 95% CI (CMH method)	0.021 [-0.075, 0.116]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.6962			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Muscular Disorders (AESI)
Safety Population

Age (years): >= 65

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)	Total (N= 78)
Number of patients at risk		50 (100.0%)	28 (100.0%)	78 (100.0%)
Number of patients with events		2 (4.0%)	2 (7.1%)	4 (5.1%)
Number of patients without events		48 (96.0%)	26 (92.9%)	74 (94.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.542 [0.072, 4.072]			
Stratified OR, 95% CI	0.551 [0.088, 3.429]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.560 [0.083, 3.761]			
Stratified RR, 95% CI	0.577 [0.107, 3.101]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.031 [-0.141, 0.078]			
Stratified ARR, 95% CI (CMH method)	-0.033 [-0.141, 0.076]			
Test on Differences [c]				
Unstratified p-value	0.6153			
Stratified p-value	0.5402			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Table 1002FDC.053.204.17.2.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Age - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.3902
>= 65 vs. < 65		0.5589	0.5825	0.4047	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Muscular Disorders (AESI)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		4 (6.8%)	2 (6.5%)	6 (6.7%)
Number of patients without events		55 (93.2%)	29 (93.5%)	84 (93.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.055 [0.182, 6.105]			
Stratified OR, 95% CI	1.017 [0.166, 6.218]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.051 [0.204, 5.421]			
Stratified RR, 95% CI	1.017 [0.186, 5.554]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.003 [-0.104, 0.111]			
Stratified ARR, 95% CI (CMH method)	0.003 [-0.105, 0.111]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9578			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Muscular Disorders (AESI)
Safety Population

CVD Risk Category: Multiple CV risk factors

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		2 (4.2%)	1 (4.2%)	3 (4.2%)
Number of patients without events		46 (95.8%)	23 (95.8%)	69 (95.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.000 [0.086, 11.613]			
Stratified OR, 95% CI	1.067 [0.090, 12.686]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.000 [0.095, 10.485]			
Stratified RR, 95% CI	1.062 [0.104, 10.891]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.000 [-0.098, 0.098]			
Stratified ARR, 95% CI (CMH method)	0.003 [-0.095, 0.100]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9597			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by CVD Risk Category - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.9730
Multiple CV risk factors vs. ASCVD and/or HeFH		0.9528	0.7143	0.9729	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Muscular Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: Other

	FDC vs. Placebo	FDC (N= 65)	Placebo (N= 34)	Total (N= 99)
Number of patients at risk		65 (100.0%)	34 (100.0%)	99 (100.0%)
Number of patients with events		5 (7.7%)	2 (5.9%)	7 (7.1%)
Number of patients without events		60 (92.3%)	32 (94.1%)	92 (92.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.333 [0.245, 7.262]			
Stratified OR, 95% CI	1.321 [0.241, 7.245]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.308 [0.268, 6.390]			
Stratified RR, 95% CI	1.297 [0.263, 6.380]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.018 [-0.084, 0.120]			
Stratified ARR, 95% CI (CMH method)	0.018 [-0.084, 0.120]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7430			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Muscular Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		1 (2.4%)	1 (4.8%)	2 (3.2%)
Number of patients without events		41 (97.6%)	20 (95.2%)	61 (96.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.488 [0.029, 8.207]			
Stratified OR, 95% CI	0.520 [0.030, 9.005]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.500 [0.033, 7.604]			
Stratified RR, 95% CI	0.538 [0.036, 7.969]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.024 [-0.126, 0.078]			
Stratified ARR, 95% CI (CMH method)	-0.021 [-0.122, 0.080]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.6523			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity I - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.5516
High Intensity Statin vs. Other		0.7403	0.8594	0.5498	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Muscular Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

	FDC vs. Placebo	FDC (N= 32)	Placebo (N= 20)	Total (N= 52)
Number of patients at risk		32 (100.0%)	20 (100.0%)	52 (100.0%)
Number of patients with events		3 (9.4%)	1 (5.0%)	4 (7.7%)
Number of patients without events		29 (90.6%)	19 (95.0%)	48 (92.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.966 [0.190, 20.322]			
Stratified OR, 95% CI	1.381 [0.165, 11.592]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.875 [0.209, 16.806]			
Stratified RR, 95% CI	1.320 [0.184, 9.470]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.044 [-0.095, 0.183]			
Stratified ARR, 95% CI (CMH method)	0.044 [-0.095, 0.183]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5705			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Muscular Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		1 (2.4%)	1 (4.8%)	2 (3.2%)
Number of patients without events		41 (97.6%)	20 (95.2%)	61 (96.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.488 [0.029, 8.207]			
Stratified OR, 95% CI	0.520 [0.030, 9.005]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.500 [0.033, 7.604]			
Stratified RR, 95% CI	0.538 [0.036, 7.969]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.024 [-0.126, 0.078]			
Stratified ARR, 95% CI (CMH method)	-0.021 [-0.122, 0.080]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.6523			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Muscular Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: None

	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)	Total (N= 47)
Number of patients at risk		33 (100.0%)	14 (100.0%)	47 (100.0%)
Number of patients with events		2 (6.1%)	1 (7.1%)	3 (6.4%)
Number of patients without events		31 (93.9%)	13 (92.9%)	44 (93.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.839 [0.070, 10.078]			
Stratified OR, 95% CI	0.685 [0.076, 6.150]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.848 [0.084, 8.613]			
Stratified RR, 95% CI	0.698 [0.094, 5.163]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.011 [-0.168, 0.147]			
Stratified ARR, 95% CI (CMH method)	-0.010 [-0.167, 0.147]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8986			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity II - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.7385
High Intensity Statin vs. Other Intensity Statin		0.5743	0.9718	0.4586	
None vs. Other Intensity Statin		0.5743	0.7947	0.6262	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Muscular Disorders (AESI)
Safety Population

Race: White

	FDC vs. Placebo	FDC (N= 84)	Placebo (N= 48)	Total (N= 132)
Number of patients at risk		84 (100.0%)	48 (100.0%)	132 (100.0%)
Number of patients with events		3 (3.6%)	3 (6.3%)	6 (4.5%)
Number of patients without events		81 (96.4%)	45 (93.8%)	126 (95.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.556 [0.108, 2.868]			
Stratified OR, 95% CI	0.567 [0.112, 2.887]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.571 [0.120, 2.721]			
Stratified RR, 95% CI	0.584 [0.126, 2.703]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.027 [-0.106, 0.052]			
Stratified ARR, 95% CI (CMH method)	-0.025 [-0.105, 0.055]			
Test on Differences [c]				
Unstratified p-value	0.6676			
Stratified p-value	0.5149			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Muscular Disorders (AESI)
Safety Population

Race: non-White

	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)	Total (N= 30)
Number of patients at risk		23 (100.0%)	7 (100.0%)	30 (100.0%)
Number of patients with events		3 (13.0%)	0	3 (10.0%)
Number of patients without events		20 (87.0%)	7 (100.0%)	27 (90.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.561 [0.118, 55.665]			
Stratified OR, 95% CI	1.563 [0.127, 19.266]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.333 [0.135, 40.464]			
Stratified RR, 95% CI	1.402 [0.203, 9.674]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.130 [-0.007, 0.268]			
Stratified ARR, 95% CI (CMH method)	0.107 [-0.027, 0.241]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3768			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Race - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.1401
non-White vs. White		0.4821	<.0001	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Muscular Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): < 130

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 16)	Total (N= 54)
Number of patients at risk		38 (100.0%)	16 (100.0%)	54 (100.0%)
Number of patients with events		5 (13.2%)	1 (6.3%)	6 (11.1%)
Number of patients without events		33 (86.8%)	15 (93.8%)	48 (88.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.273 [0.244, 21.180]			
Stratified OR, 95% CI	2.169 [0.298, 15.771]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.105 [0.267, 16.618]			
Stratified RR, 95% CI	1.943 [0.347, 10.879]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.069 [-0.091, 0.229]			
Stratified ARR, 95% CI (CMH method)	0.100 [-0.070, 0.269]			
Test on Differences [c]				
Unstratified p-value	0.6570			
Stratified p-value	0.3225			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Muscular Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)	Total (N= 47)
Number of patients at risk		31 (100.0%)	16 (100.0%)	47 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		31 (100.0%)	16 (100.0%)	47 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Muscular Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): >= 160

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)	Total (N= 61)
Number of patients at risk		38 (100.0%)	23 (100.0%)	61 (100.0%)
Number of patients with events		1 (2.6%)	2 (8.7%)	3 (4.9%)
Number of patients without events		37 (97.4%)	21 (91.3%)	58 (95.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.284 [0.024, 3.320]			
Stratified OR, 95% CI	0.369 [0.041, 3.333]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.303 [0.029, 3.154]			
Stratified RR, 95% CI	0.411 [0.056, 3.040]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.061 [-0.187, 0.065]			
Stratified ARR, 95% CI (CMH method)	-0.055 [-0.190, 0.080]			
Test on Differences [c]				
Unstratified p-value	0.5507			
Stratified p-value	0.3573			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline LDL-C Category - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	WARNING: Negative of Hessian not positive definite				-
130 - < 160 vs. < 130		0.4801	0.9999	1.0000	
>= 160 vs. < 130		0.4801	0.7797	0.2237	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Muscular Disorders (AESI)
Safety Population

History of Diabetes: Yes

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		4 (8.3%)	1 (4.2%)	5 (6.9%)
Number of patients without events		44 (91.7%)	23 (95.8%)	67 (93.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.091 [0.221, 19.810]			
Stratified OR, 95% CI	1.343 [0.234, 7.724]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.000 [0.236, 16.928]			
Stratified RR, 95% CI	1.278 [0.271, 6.019]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.042 [-0.070, 0.153]			
Stratified ARR, 95% CI (CMH method)	0.041 [-0.073, 0.154]			
Test on Differences [c]				
Unstratified p-value	0.6588			
Stratified p-value	0.5259			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Muscular Disorders (AESI)
Safety Population

History of Diabetes: No

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		2 (3.4%)	2 (6.5%)	4 (4.4%)
Number of patients without events		57 (96.6%)	29 (93.5%)	86 (95.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.509 [0.068, 3.798]			
Stratified OR, 95% CI	0.524 [0.065, 4.241]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.525 [0.078, 3.552]			
Stratified RR, 95% CI	0.565 [0.090, 3.552]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.031 [-0.129, 0.067]			
Stratified ARR, 95% CI (CMH method)	-0.028 [-0.123, 0.068]			
Test on Differences [c]				
Unstratified p-value	0.6056			
Stratified p-value	0.5453			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by History of Diabetes - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.3450
No vs. Yes		0.5247	0.7143	0.3607	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Muscular Disorders (AESI)
Safety Population

BMI (kg/m^2): < 25

	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)	Total (N= 19)
Number of patients at risk		13 (100.0%)	6 (100.0%)	19 (100.0%)
Number of patients with events		1 (7.7%)	0	1 (5.3%)
Number of patients without events		12 (92.3%)	6 (100.0%)	18 (94.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.560 [0.055, 43.934]			
Stratified OR, 95% CI	3.000 [0.088, 102.05]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.500 [0.070, 32.291]			
Stratified RR, 95% CI	2.400 [0.130, 44.414]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.077 [-0.068, 0.222]			
Stratified ARR, 95% CI (CMH method)	0.126 [-0.105, 0.356]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3865			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Muscular Disorders (AESI)
Safety Population

BMI (kg/m^2): 25 - < 30

	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)	Total (N= 49)
Number of patients at risk		27 (100.0%)	22 (100.0%)	49 (100.0%)
Number of patients with events		1 (3.7%)	1 (4.5%)	2 (4.1%)
Number of patients without events		26 (96.3%)	21 (95.5%)	47 (95.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.808 [0.048, 13.698]			
Stratified OR, 95% CI	0.625 [0.031, 12.410]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.815 [0.054, 12.296]			
Stratified RR, 95% CI	0.667 [0.051, 8.729]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.008 [-0.121, 0.104]			
Stratified ARR, 95% CI (CMH method)	-0.017 [-0.130, 0.096]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7645			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Muscular Disorders (AESI)
Safety Population

BMI (kg/m^2): >= 30

	FDC vs. Placebo	FDC (N= 67)	Placebo (N= 27)	Total (N= 94)
Number of patients at risk		67 (100.0%)	27 (100.0%)	94 (100.0%)
Number of patients with events		4 (6.0%)	2 (7.4%)	6 (6.4%)
Number of patients without events		63 (94.0%)	25 (92.6%)	88 (93.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.794 [0.137, 4.611]			
Stratified OR, 95% CI	0.738 [0.141, 3.875]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.806 [0.157, 4.145]			
Stratified RR, 95% CI	0.760 [0.169, 3.417]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.014 [-0.128, 0.100]			
Stratified ARR, 95% CI (CMH method)	-0.008 [-0.121, 0.105]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8918			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by BMI - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.6477
25 - < 30 vs. < 25		<.0001	<.0001	<.0001	
>= 30 vs. < 25		<.0001	<.0001	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE - Muscular Disorders (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE - Muscular Disorders (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE - Muscular Disorders (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		6 (5.6%)	3 (5.5%)	9 (5.6%)
Number of patients without events		101 (94.4%)	52 (94.5%)	153 (94.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.030 [0.247, 4.284]			
Stratified OR, 95% CI	0.964 [0.246, 3.779]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.028 [0.267, 3.955]			
Stratified RR, 95% CI	0.958 [0.273, 3.358]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.002 [-0.073, 0.076]			
Stratified ARR, 95% CI (CMH method)	0.003 [-0.071, 0.076]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9476			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Gender - Muscular Disorders (AESI)
Safety Population

Gender: Male

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)	Total (N= 83)
Number of patients at risk		50 (100.0%)	33 (100.0%)	83 (100.0%)
Number of patients with events		3 (6.0%)	1 (3.0%)	4 (4.8%)
Number of patients without events		47 (94.0%)	32 (97.0%)	79 (95.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.043 [0.203, 20.522]			
Stratified OR, 95% CI	1.728 [0.233, 12.838]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.980 [0.215, 18.232]			
Stratified RR, 95% CI	1.642 [0.261, 10.327]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.030 [-0.058, 0.118]			
Stratified ARR, 95% CI (CMH method)	0.034 [-0.052, 0.120]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4839			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Gender - Muscular Disorders (AESI)
Safety Population

Gender: Female

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 22)	Total (N= 79)
Number of patients at risk		57 (100.0%)	22 (100.0%)	79 (100.0%)
Number of patients with events		3 (5.3%)	2 (9.1%)	5 (6.3%)
Number of patients without events		54 (94.7%)	20 (90.9%)	74 (93.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.556 [0.086, 3.573]			
Stratified OR, 95% CI	0.557 [0.080, 3.861]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.579 [0.104, 3.234]			
Stratified RR, 95% CI	0.588 [0.107, 3.230]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.038 [-0.172, 0.095]			
Stratified ARR, 95% CI (CMH method)	-0.035 [-0.168, 0.098]			
Test on Differences [c]				
Unstratified p-value	0.6144			
Stratified p-value	0.5757			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Gender - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.3797
Female vs. Male		0.5465	0.3573	0.3908	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Age - Muscular Disorders (AESI)
Safety Population

Age (years): < 65

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 27)	Total (N= 84)
Number of patients at risk		57 (100.0%)	27 (100.0%)	84 (100.0%)
Number of patients with events		4 (7.0%)	1 (3.7%)	5 (6.0%)
Number of patients without events		53 (93.0%)	26 (96.3%)	79 (94.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.962 [0.209, 18.451]			
Stratified OR, 95% CI	1.258 [0.177, 8.958]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.895 [0.222, 16.151]			
Stratified RR, 95% CI	1.208 [0.212, 6.869]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.033 [-0.064, 0.130]			
Stratified ARR, 95% CI (CMH method)	0.021 [-0.075, 0.116]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.6962			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Age - Muscular Disorders (AESI)
Safety Population

Age (years): >= 65

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)	Total (N= 78)
Number of patients at risk		50 (100.0%)	28 (100.0%)	78 (100.0%)
Number of patients with events		2 (4.0%)	2 (7.1%)	4 (5.1%)
Number of patients without events		48 (96.0%)	26 (92.9%)	74 (94.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.542 [0.072, 4.072]			
Stratified OR, 95% CI	0.551 [0.088, 3.429]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.560 [0.083, 3.761]			
Stratified RR, 95% CI	0.577 [0.107, 3.101]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.031 [-0.141, 0.078]			
Stratified ARR, 95% CI (CMH method)	-0.033 [-0.141, 0.076]			
Test on Differences [c]				
Unstratified p-value	0.6153			
Stratified p-value	0.5402			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Age - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.3902
>= 65 vs. < 65		0.5589	0.5825	0.4047	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by CVD Risk Category - Muscular Disorders (AESI)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		4 (6.8%)	2 (6.5%)	6 (6.7%)
Number of patients without events		55 (93.2%)	29 (93.5%)	84 (93.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.055 [0.182, 6.105]			
Stratified OR, 95% CI	1.017 [0.166, 6.218]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.051 [0.204, 5.421]			
Stratified RR, 95% CI	1.017 [0.186, 5.554]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.003 [-0.104, 0.111]			
Stratified ARR, 95% CI (CMH method)	0.003 [-0.105, 0.111]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9578			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by CVD Risk Category - Muscular Disorders (AESI)
Safety Population

CVD Risk Category: Multiple CV risk factors

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		2 (4.2%)	1 (4.2%)	3 (4.2%)
Number of patients without events		46 (95.8%)	23 (95.8%)	69 (95.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.000 [0.086, 11.613]			
Stratified OR, 95% CI	1.067 [0.090, 12.686]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.000 [0.095, 10.485]			
Stratified RR, 95% CI	1.062 [0.104, 10.891]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.000 [-0.098, 0.098]			
Stratified ARR, 95% CI (CMH method)	0.003 [-0.095, 0.100]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9597			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by CVD Risk Category - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.9730
Multiple CV risk factors vs. ASCVD and/or HeFH		0.9528	0.7143	0.9729	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Muscular Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: Other

	FDC vs. Placebo	FDC (N= 65)	Placebo (N= 34)	Total (N= 99)
Number of patients at risk		65 (100.0%)	34 (100.0%)	99 (100.0%)
Number of patients with events		5 (7.7%)	2 (5.9%)	7 (7.1%)
Number of patients without events		60 (92.3%)	32 (94.1%)	92 (92.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.333 [0.245, 7.262]			
Stratified OR, 95% CI	1.321 [0.241, 7.245]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.308 [0.268, 6.390]			
Stratified RR, 95% CI	1.297 [0.263, 6.380]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.018 [-0.084, 0.120]			
Stratified ARR, 95% CI (CMH method)	0.018 [-0.084, 0.120]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7430			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Muscular Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		1 (2.4%)	1 (4.8%)	2 (3.2%)
Number of patients without events		41 (97.6%)	20 (95.2%)	61 (96.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.488 [0.029, 8.207]			
Stratified OR, 95% CI	0.520 [0.030, 9.005]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.500 [0.033, 7.604]			
Stratified RR, 95% CI	0.538 [0.036, 7.969]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.024 [-0.126, 0.078]			
Stratified ARR, 95% CI (CMH method)	-0.021 [-0.122, 0.080]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.6523			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.5516
High Intensity Statin vs. Other		0.7403	0.8594	0.5498	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Muscular Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

	FDC vs. Placebo	FDC (N= 32)	Placebo (N= 20)	Total (N= 52)
Number of patients at risk		32 (100.0%)	20 (100.0%)	52 (100.0%)
Number of patients with events		3 (9.4%)	1 (5.0%)	4 (7.7%)
Number of patients without events		29 (90.6%)	19 (95.0%)	48 (92.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.966 [0.190, 20.322]			
Stratified OR, 95% CI	1.381 [0.165, 11.592]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.875 [0.209, 16.806]			
Stratified RR, 95% CI	1.320 [0.184, 9.470]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.044 [-0.095, 0.183]			
Stratified ARR, 95% CI (CMH method)	0.044 [-0.095, 0.183]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5705			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Muscular Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		1 (2.4%)	1 (4.8%)	2 (3.2%)
Number of patients without events		41 (97.6%)	20 (95.2%)	61 (96.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.488 [0.029, 8.207]			
Stratified OR, 95% CI	0.520 [0.030, 9.005]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.500 [0.033, 7.604]			
Stratified RR, 95% CI	0.538 [0.036, 7.969]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.024 [-0.126, 0.078]			
Stratified ARR, 95% CI (CMH method)	-0.021 [-0.122, 0.080]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.6523			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Muscular Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: None

	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)	Total (N= 47)
Number of patients at risk		33 (100.0%)	14 (100.0%)	47 (100.0%)
Number of patients with events		2 (6.1%)	1 (7.1%)	3 (6.4%)
Number of patients without events		31 (93.9%)	13 (92.9%)	44 (93.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.839 [0.070, 10.078]			
Stratified OR, 95% CI	0.685 [0.076, 6.150]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.848 [0.084, 8.613]			
Stratified RR, 95% CI	0.698 [0.094, 5.163]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.011 [-0.168, 0.147]			
Stratified ARR, 95% CI (CMH method)	-0.010 [-0.167, 0.147]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8986			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.7385
High Intensity Statin vs. Other Intensity Statin		0.5743	0.9718	0.4586	
None vs. Other Intensity Statin		0.5743	0.7947	0.6262	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Race - Muscular Disorders (AESI)
Safety Population

Race: White

	FDC vs. Placebo	FDC (N= 84)	Placebo (N= 48)	Total (N= 132)
Number of patients at risk		84 (100.0%)	48 (100.0%)	132 (100.0%)
Number of patients with events		3 (3.6%)	3 (6.3%)	6 (4.5%)
Number of patients without events		81 (96.4%)	45 (93.8%)	126 (95.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.556 [0.108, 2.868]			
Stratified OR, 95% CI	0.567 [0.112, 2.887]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.571 [0.120, 2.721]			
Stratified RR, 95% CI	0.584 [0.126, 2.703]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.027 [-0.106, 0.052]			
Stratified ARR, 95% CI (CMH method)	-0.025 [-0.105, 0.055]			
Test on Differences [c]				
Unstratified p-value	0.6676			
Stratified p-value	0.5149			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Race - Muscular Disorders (AESI)
Safety Population

Race: non-White

	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)	Total (N= 30)
Number of patients at risk		23 (100.0%)	7 (100.0%)	30 (100.0%)
Number of patients with events		3 (13.0%)	0	3 (10.0%)
Number of patients without events		20 (87.0%)	7 (100.0%)	27 (90.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.561 [0.118, 55.665]			
Stratified OR, 95% CI	1.563 [0.127, 19.266]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.333 [0.135, 40.464]			
Stratified RR, 95% CI	1.402 [0.203, 9.674]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.130 [-0.007, 0.268]			
Stratified ARR, 95% CI (CMH method)	0.107 [-0.027, 0.241]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3768			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Race - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.1401
non-White vs. White		0.4821	<.0001	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Muscular Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): < 130

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 16)	Total (N= 54)
Number of patients at risk		38 (100.0%)	16 (100.0%)	54 (100.0%)
Number of patients with events		5 (13.2%)	1 (6.3%)	6 (11.1%)
Number of patients without events		33 (86.8%)	15 (93.8%)	48 (88.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.273 [0.244, 21.180]			
Stratified OR, 95% CI	2.169 [0.298, 15.771]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.105 [0.267, 16.618]			
Stratified RR, 95% CI	1.943 [0.347, 10.879]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.069 [-0.091, 0.229]			
Stratified ARR, 95% CI (CMH method)	0.100 [-0.070, 0.269]			
Test on Differences [c]				
Unstratified p-value	0.6570			
Stratified p-value	0.3225			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Muscular Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)	Total (N= 47)
Number of patients at risk		31 (100.0%)	16 (100.0%)	47 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		31 (100.0%)	16 (100.0%)	47 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Muscular Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): >= 160

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)	Total (N= 61)
Number of patients at risk		38 (100.0%)	23 (100.0%)	61 (100.0%)
Number of patients with events		1 (2.6%)	2 (8.7%)	3 (4.9%)
Number of patients without events		37 (97.4%)	21 (91.3%)	58 (95.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.284 [0.024, 3.320]			
Stratified OR, 95% CI	0.369 [0.041, 3.333]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.303 [0.029, 3.154]			
Stratified RR, 95% CI	0.411 [0.056, 3.040]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.061 [-0.187, 0.065]			
Stratified ARR, 95% CI (CMH method)	-0.055 [-0.190, 0.080]			
Test on Differences [c]				
Unstratified p-value	0.5507			
Stratified p-value	0.3573			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline LDL-C Category - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	WARNING: Negative of Hessian not positive definite				-
130 - < 160 vs. < 130		0.4801	0.9999	1.0000	
>= 160 vs. < 130		0.4801	0.7797	0.2237	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by History of Diabetes - Muscular Disorders (AESI)
Safety Population

History of Diabetes: Yes

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		4 (8.3%)	1 (4.2%)	5 (6.9%)
Number of patients without events		44 (91.7%)	23 (95.8%)	67 (93.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.091 [0.221, 19.810]			
Stratified OR, 95% CI	1.343 [0.234, 7.724]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.000 [0.236, 16.928]			
Stratified RR, 95% CI	1.278 [0.271, 6.019]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.042 [-0.070, 0.153]			
Stratified ARR, 95% CI (CMH method)	0.041 [-0.073, 0.154]			
Test on Differences [c]				
Unstratified p-value	0.6588			
Stratified p-value	0.5259			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by History of Diabetes - Muscular Disorders (AESI)
Safety Population

History of Diabetes: No

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		2 (3.4%)	2 (6.5%)	4 (4.4%)
Number of patients without events		57 (96.6%)	29 (93.5%)	86 (95.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.509 [0.068, 3.798]			
Stratified OR, 95% CI	0.524 [0.065, 4.241]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.525 [0.078, 3.552]			
Stratified RR, 95% CI	0.565 [0.090, 3.552]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.031 [-0.129, 0.067]			
Stratified ARR, 95% CI (CMH method)	-0.028 [-0.123, 0.068]			
Test on Differences [c]				
Unstratified p-value	0.6056			
Stratified p-value	0.5453			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by History of Diabetes - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.3450
No vs. Yes		0.5247	0.7143	0.3607	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Muscular Disorders (AESI)
Safety Population

BMI (kg/m^2): < 25

	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)	Total (N= 19)
Number of patients at risk		13 (100.0%)	6 (100.0%)	19 (100.0%)
Number of patients with events		1 (7.7%)	0	1 (5.3%)
Number of patients without events		12 (92.3%)	6 (100.0%)	18 (94.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.560 [0.055, 43.934]			
Stratified OR, 95% CI	3.000 [0.088, 102.05]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.500 [0.070, 32.291]			
Stratified RR, 95% CI	2.400 [0.130, 44.414]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.077 [-0.068, 0.222]			
Stratified ARR, 95% CI (CMH method)	0.126 [-0.105, 0.356]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3865			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Muscular Disorders (AESI)
Safety Population

BMI (kg/m^2): 25 - < 30

	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)	Total (N= 49)
Number of patients at risk		27 (100.0%)	22 (100.0%)	49 (100.0%)
Number of patients with events		1 (3.7%)	1 (4.5%)	2 (4.1%)
Number of patients without events		26 (96.3%)	21 (95.5%)	47 (95.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.808 [0.048, 13.698]			
Stratified OR, 95% CI	0.625 [0.031, 12.410]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.815 [0.054, 12.296]			
Stratified RR, 95% CI	0.667 [0.051, 8.729]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.008 [-0.121, 0.104]			
Stratified ARR, 95% CI (CMH method)	-0.017 [-0.130, 0.096]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7645			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Muscular Disorders (AESI)
Safety Population

BMI (kg/m^2): >= 30

	FDC vs. Placebo	FDC (N= 67)	Placebo (N= 27)	Total (N= 94)
Number of patients at risk		67 (100.0%)	27 (100.0%)	94 (100.0%)
Number of patients with events		4 (6.0%)	2 (7.4%)	6 (6.4%)
Number of patients without events		63 (94.0%)	25 (92.6%)	88 (93.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.794 [0.137, 4.611]			
Stratified OR, 95% CI	0.738 [0.141, 3.875]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.806 [0.157, 4.145]			
Stratified RR, 95% CI	0.760 [0.169, 3.417]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.014 [-0.128, 0.100]			
Stratified ARR, 95% CI (CMH method)	-0.008 [-0.121, 0.105]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8918			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by BMI - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.6477
25 - < 30 vs. < 25		<.0001	<.0001	<.0001	
>= 30 vs. < 25		<.0001	<.0001	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Neurocognitive Disorders (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE - Neurocognitive Disorders (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE - Neurocognitive Disorders (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE - Neurocognitive Disorders (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		4 (3.7%)	0	4 (2.5%)
Number of patients without events		103 (96.3%)	55 (100.0%)	158 (97.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.826 [0.255, 91.279]			
Stratified OR, 95% CI	2.773 [0.301, 25.513]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.667 [0.256, 85.141]			
Stratified RR, 95% CI	2.616 [0.310, 22.037]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.037 [0.001, 0.073]			
Stratified ARR, 95% CI (CMH method)	0.038 [0.002, 0.075]			
Test on Differences [c]				
Unstratified p-value	0.3005			
Stratified p-value	0.1351			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Gender: Male

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)	Total (N= 83)
Number of patients at risk		50 (100.0%)	33 (100.0%)	83 (100.0%)
Number of patients with events		2 (4.0%)	0	2 (2.4%)
Number of patients without events		48 (96.0%)	33 (100.0%)	81 (97.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.454 [0.161, 74.258]			
Stratified OR, 95% CI	3.621 [0.157, 83.528]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.333 [0.165, 67.300]			
Stratified RR, 95% CI	3.235 [0.171, 61.206]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.040 [-0.014, 0.094]			
Stratified ARR, 95% CI (CMH method)	0.039 [-0.015, 0.093]			
Test on Differences [c]				
Unstratified p-value	0.5151			
Stratified p-value	0.2538			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Gender: Female

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 22)	Total (N= 79)
Number of patients at risk		57 (100.0%)	22 (100.0%)	79 (100.0%)
Number of patients with events		2 (3.5%)	0	2 (2.5%)
Number of patients without events		55 (96.5%)	22 (100.0%)	77 (97.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.027 [0.094, 43.912]			
Stratified OR, 95% CI	1.524 [0.143, 16.206]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.983 [0.099, 39.734]			
Stratified RR, 95% CI	1.464 [0.168, 12.776]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.035 [-0.013, 0.083]			
Stratified ARR, 95% CI (CMH method)	0.039 [-0.012, 0.090]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3431			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Gender - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				1.0000
Female vs. Male		-	0.9996	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Age (years): < 65

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 27)	Total (N= 84)
Number of patients at risk		57 (100.0%)	27 (100.0%)	84 (100.0%)
Number of patients with events		3 (5.3%)	0	3 (3.6%)
Number of patients without events		54 (94.7%)	27 (100.0%)	81 (96.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.532 [0.176, 70.834]			
Stratified OR, 95% CI	2.728 [0.275, 27.101]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.379 [0.181, 63.202]			
Stratified RR, 95% CI	2.466 [0.297, 20.451]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.053 [-0.005, 0.111]			
Stratified ARR, 95% CI (CMH method)	0.062 [-0.001, 0.125]			
Test on Differences [c]				
Unstratified p-value	0.5478			
Stratified p-value	0.1713			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Age (years): >= 65

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)	Total (N= 78)
Number of patients at risk		50 (100.0%)	28 (100.0%)	78 (100.0%)
Number of patients with events		1 (2.0%)	0	1 (1.3%)
Number of patients without events		49 (98.0%)	28 (100.0%)	77 (98.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.727 [0.068, 43.823]			
Stratified OR, 95% CI	1.645 [0.060, 44.968]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.706 [0.072, 40.531]			
Stratified RR, 95% CI	1.588 [0.072, 35.148]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.020 [-0.019, 0.059]			
Stratified ARR, 95% CI (CMH method)	0.019 [-0.019, 0.057]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4795			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Age - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				1.0000
>= 65 vs. < 65		-	0.9998	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		3 (5.1%)	0	3 (3.3%)
Number of patients without events		56 (94.9%)	31 (100.0%)	87 (96.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.903 [0.195, 78.001]			
Stratified OR, 95% CI	4.319 [0.208, 89.808]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.733 [0.199, 70.054]			
Stratified RR, 95% CI	3.889 [0.215, 70.338]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.051 [-0.005, 0.107]			
Stratified ARR, 95% CI (CMH method)	0.052 [-0.005, 0.108]			
Test on Differences [c]				
Unstratified p-value	0.5485			
Stratified p-value	0.1919			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

CVD Risk Category: Multiple CV risk factors

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		1 (2.1%)	0	1 (1.4%)
Number of patients without events		47 (97.9%)	24 (100.0%)	71 (98.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.547 [0.061, 39.412]			
Stratified OR, 95% CI	1.667 [0.064, 43.135]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.531 [0.065, 36.227]			
Stratified RR, 95% CI	1.636 [0.070, 38.135]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.021 [-0.020, 0.061]			
Stratified ARR, 95% CI (CMH method)	0.022 [-0.020, 0.063]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4661			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by CVD Risk Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				1.0000
Multiple CV risk factors vs. ASCVD and/or HeFH		-	0.9998	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline Statin Dose Intensity I: Other

	FDC vs. Placebo	FDC (N= 65)	Placebo (N= 34)	Total (N= 99)
Number of patients at risk		65 (100.0%)	34 (100.0%)	99 (100.0%)
Number of patients with events		1 (1.5%)	0	1 (1.0%)
Number of patients without events		64 (98.5%)	34 (100.0%)	98 (99.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.605 [0.064, 40.451]			
Stratified OR, 95% CI	1.667 [0.064, 43.135]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.591 [0.067, 38.037]			
Stratified RR, 95% CI	1.636 [0.070, 38.135]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.015 [-0.015, 0.045]			
Stratified ARR, 95% CI (CMH method)	0.016 [-0.015, 0.046]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4661			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		3 (7.1%)	0	3 (4.8%)
Number of patients without events		39 (92.9%)	21 (100.0%)	60 (95.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.810 [0.188, 77.250]			
Stratified OR, 95% CI	4.319 [0.208, 89.808]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.581 [0.193, 66.292]			
Stratified RR, 95% CI	3.889 [0.215, 70.338]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.071 [-0.006, 0.149]			
Stratified ARR, 95% CI (CMH method)	0.075 [-0.005, 0.155]			
Test on Differences [c]				
Unstratified p-value	0.5447			
Stratified p-value	0.1919			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity I - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				1.0000
High Intensity Statin vs. Other		-	0.9996	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

	FDC vs. Placebo	FDC (N= 32)	Placebo (N= 20)	Total (N= 52)
Number of patients at risk		32 (100.0%)	20 (100.0%)	52 (100.0%)
Number of patients with events		1 (3.1%)	0	1 (1.9%)
Number of patients without events		31 (96.9%)	20 (100.0%)	51 (98.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.952 [0.076, 50.281]			
Stratified OR, 95% CI	2.172 [0.080, 58.763]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.909 [0.082, 44.707]			
Stratified RR, 95% CI	2.063 [0.092, 46.113]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.031 [-0.029, 0.092]			
Stratified ARR, 95% CI (CMH method)	0.033 [-0.029, 0.094]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4142			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		3 (7.1%)	0	3 (4.8%)
Number of patients without events		39 (92.9%)	21 (100.0%)	60 (95.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.810 [0.188, 77.250]			
Stratified OR, 95% CI	4.319 [0.208, 89.808]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.581 [0.193, 66.292]			
Stratified RR, 95% CI	3.889 [0.215, 70.338]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.071 [-0.006, 0.149]			
Stratified ARR, 95% CI (CMH method)	0.075 [-0.005, 0.155]			
Test on Differences [c]				
Unstratified p-value	0.5447			
Stratified p-value	0.1919			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline Statin Dose Intensity II: None

	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)	Total (N= 47)
Number of patients at risk		33 (100.0%)	14 (100.0%)	47 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		33 (100.0%)	14 (100.0%)	47 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity II - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	WARNING: Negative of Hessian not positive definite				-
High Intensity Statin vs. Other Intensity Statin		-	0.9994	-	
None vs. Other Intensity Statin		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Race: White

	FDC vs. Placebo	FDC (N= 84)	Placebo (N= 48)	Total (N= 132)
Number of patients at risk		84 (100.0%)	48 (100.0%)	132 (100.0%)
Number of patients with events		2 (2.4%)	0	2 (1.5%)
Number of patients without events		82 (97.6%)	48 (100.0%)	130 (98.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.939 [0.138, 62.503]			
Stratified OR, 95% CI	3.788 [0.167, 86.129]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.882 [0.141, 58.824]			
Stratified RR, 95% CI	3.421 [0.178, 65.577]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.024 [-0.009, 0.056]			
Stratified ARR, 95% CI (CMH method)	0.026 [-0.008, 0.061]			
Test on Differences [c]				
Unstratified p-value	0.5337			
Stratified p-value	0.2399			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Race: non-White

	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)	Total (N= 30)
Number of patients at risk		23 (100.0%)	7 (100.0%)	30 (100.0%)
Number of patients with events		2 (8.7%)	0	2 (6.7%)
Number of patients without events		21 (91.3%)	7 (100.0%)	28 (93.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.744 [0.075, 40.624]			
Stratified OR, 95% CI	1.074 [0.090, 12.864]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.667 [0.089, 31.183]			
Stratified RR, 95% CI	1.061 [0.135, 8.346]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.087 [-0.028, 0.202]			
Stratified ARR, 95% CI (CMH method)	0.081 [-0.036, 0.199]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4643			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Race - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	WARNING: Negative of Hessian not positive definite				-
non-White vs. White		-	0.9997	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline LDL-C (mg/dL): < 130

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 16)	Total (N= 54)
Number of patients at risk		38 (100.0%)	16 (100.0%)	54 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		38 (100.0%)	16 (100.0%)	54 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)	Total (N= 47)
Number of patients at risk		31 (100.0%)	16 (100.0%)	47 (100.0%)
Number of patients with events		1 (3.2%)	0	1 (2.1%)
Number of patients without events		30 (96.8%)	16 (100.0%)	46 (97.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.623 [0.063, 42.116]			
Stratified OR, 95% CI	3.000 [0.088, 102.05]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.594 [0.069, 37.047]			
Stratified RR, 95% CI	2.400 [0.130, 44.414]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.032 [-0.030, 0.094]			
Stratified ARR, 95% CI (CMH method)	0.041 [-0.029, 0.111]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3865			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline LDL-C (mg/dL): >= 160

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)	Total (N= 61)
Number of patients at risk		38 (100.0%)	23 (100.0%)	61 (100.0%)
Number of patients with events		3 (7.9%)	0	3 (4.9%)
Number of patients without events		35 (92.1%)	23 (100.0%)	58 (95.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.634 [0.229, 93.884]			
Stratified OR, 95% CI	4.035 [0.380, 42.897]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.308 [0.233, 79.809]			
Stratified RR, 95% CI	3.182 [0.405, 24.992]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.079 [-0.007, 0.165]			
Stratified ARR, 95% CI (CMH method)	0.091 [-0.003, 0.186]			
Test on Differences [c]				
Unstratified p-value	0.2836			
Stratified p-value	0.1215			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline LDL-C Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	WARNING: Negative of Hessian not positive definite				-
130 - < 160 vs. < 130		-	0.9999	-	
>= 160 vs. < 130		-	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

History of Diabetes: Yes

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		4 (8.3%)	0	4 (5.6%)
Number of patients without events		44 (91.7%)	24 (100.0%)	68 (94.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.955 [0.256, 95.915]			
Stratified OR, 95% CI	3.573 [0.368, 34.700]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.592 [0.257, 81.944]			
Stratified RR, 95% CI	3.023 [0.375, 24.347]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.083 [0.005, 0.162]			
Stratified ARR, 95% CI (CMH method)	0.104 [0.018, 0.191]			
Test on Differences [c]				
Unstratified p-value	0.2939			
Stratified p-value	0.0783			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

History of Diabetes: No

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		59 (100.0%)	31 (100.0%)	90 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by History of Diabetes - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	WARNING: Negative of Hessian not positive definite				-
No vs. Yes		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

BMI (kg/m^2): < 25

	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)	Total (N= 19)
Number of patients at risk		13 (100.0%)	6 (100.0%)	19 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		13 (100.0%)	6 (100.0%)	19 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

BMI (kg/m^2): 25 - < 30

	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)	Total (N= 49)
Number of patients at risk		27 (100.0%)	22 (100.0%)	49 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		27 (100.0%)	22 (100.0%)	49 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

BMI (kg/m^2): >= 30

	FDC vs. Placebo	FDC (N= 67)	Placebo (N= 27)	Total (N= 94)
Number of patients at risk		67 (100.0%)	27 (100.0%)	94 (100.0%)
Number of patients with events		4 (6.0%)	0	4 (4.3%)
Number of patients without events		63 (94.0%)	27 (100.0%)	90 (95.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.898 [0.203, 74.901]			
Stratified OR, 95% CI	2.064 [0.215, 19.833]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.706 [0.206, 66.575]			
Stratified RR, 95% CI	1.928 [0.239, 15.582]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.060 [0.003, 0.116]			
Stratified ARR, 95% CI (CMH method)	0.052 [-0.002, 0.106]			
Test on Differences [c]				
Unstratified p-value	0.3214			
Stratified p-value	0.2341			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by BMI - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	WARNING: Negative of Hessian not positive definite				-
25 - < 30 vs. < 25		-	1.0000	1.0000	
>= 30 vs. < 25		-	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		4 (3.7%)	0	4 (2.5%)
Number of patients without events		103 (96.3%)	55 (100.0%)	158 (97.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.826 [0.255, 91.279]			
Stratified OR, 95% CI	2.773 [0.301, 25.513]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.667 [0.256, 85.141]			
Stratified RR, 95% CI	2.616 [0.310, 22.037]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.037 [0.001, 0.073]			
Stratified ARR, 95% CI (CMH method)	0.038 [0.002, 0.075]			
Test on Differences [c]				
Unstratified p-value	0.3005			
Stratified p-value	0.1351			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Gender - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Gender: Male

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)	Total (N= 83)
Number of patients at risk		50 (100.0%)	33 (100.0%)	83 (100.0%)
Number of patients with events		2 (4.0%)	0	2 (2.4%)
Number of patients without events		48 (96.0%)	33 (100.0%)	81 (97.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.454 [0.161, 74.258]			
Stratified OR, 95% CI	3.621 [0.157, 83.528]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.333 [0.165, 67.300]			
Stratified RR, 95% CI	3.235 [0.171, 61.206]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.040 [-0.014, 0.094]			
Stratified ARR, 95% CI (CMH method)	0.039 [-0.015, 0.093]			
Test on Differences [c]				
Unstratified p-value	0.5151			
Stratified p-value	0.2538			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Gender - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Gender: Female

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 22)	Total (N= 79)
Number of patients at risk		57 (100.0%)	22 (100.0%)	79 (100.0%)
Number of patients with events		2 (3.5%)	0	2 (2.5%)
Number of patients without events		55 (96.5%)	22 (100.0%)	77 (97.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.027 [0.094, 43.912]			
Stratified OR, 95% CI	1.524 [0.143, 16.206]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.983 [0.099, 39.734]			
Stratified RR, 95% CI	1.464 [0.168, 12.776]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.035 [-0.013, 0.083]			
Stratified ARR, 95% CI (CMH method)	0.039 [-0.012, 0.090]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3431			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Gender - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				1.0000
Female vs. Male		-	0.9996	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Age - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Age (years): < 65

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 27)	Total (N= 84)
Number of patients at risk		57 (100.0%)	27 (100.0%)	84 (100.0%)
Number of patients with events		3 (5.3%)	0	3 (3.6%)
Number of patients without events		54 (94.7%)	27 (100.0%)	81 (96.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.532 [0.176, 70.834]			
Stratified OR, 95% CI	2.728 [0.275, 27.101]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.379 [0.181, 63.202]			
Stratified RR, 95% CI	2.466 [0.297, 20.451]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.053 [-0.005, 0.111]			
Stratified ARR, 95% CI (CMH method)	0.062 [-0.001, 0.125]			
Test on Differences [c]				
Unstratified p-value	0.5478			
Stratified p-value	0.1713			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Age - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Age (years): >= 65

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)	Total (N= 78)
Number of patients at risk		50 (100.0%)	28 (100.0%)	78 (100.0%)
Number of patients with events		1 (2.0%)	0	1 (1.3%)
Number of patients without events		49 (98.0%)	28 (100.0%)	77 (98.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.727 [0.068, 43.823]			
Stratified OR, 95% CI	1.645 [0.060, 44.968]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.706 [0.072, 40.531]			
Stratified RR, 95% CI	1.588 [0.072, 35.148]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.020 [-0.019, 0.059]			
Stratified ARR, 95% CI (CMH method)	0.019 [-0.019, 0.057]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4795			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Age - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				1.0000
>= 65 vs. < 65		-	0.9998	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by CVD Risk Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		3 (5.1%)	0	3 (3.3%)
Number of patients without events		56 (94.9%)	31 (100.0%)	87 (96.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.903 [0.195, 78.001]			
Stratified OR, 95% CI	4.319 [0.208, 89.808]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.733 [0.199, 70.054]			
Stratified RR, 95% CI	3.889 [0.215, 70.338]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.051 [-0.005, 0.107]			
Stratified ARR, 95% CI (CMH method)	0.052 [-0.005, 0.108]			
Test on Differences [c]				
Unstratified p-value	0.5485			
Stratified p-value	0.1919			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by CVD Risk Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

CVD Risk Category: Multiple CV risk factors

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		1 (2.1%)	0	1 (1.4%)
Number of patients without events		47 (97.9%)	24 (100.0%)	71 (98.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.547 [0.061, 39.412]			
Stratified OR, 95% CI	1.667 [0.064, 43.135]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.531 [0.065, 36.227]			
Stratified RR, 95% CI	1.636 [0.070, 38.135]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.021 [-0.020, 0.061]			
Stratified ARR, 95% CI (CMH method)	0.022 [-0.020, 0.063]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4661			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by CVD Risk Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				1.0000
Multiple CV risk factors vs. ASCVD and/or HeFH		-	0.9998	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity I - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline Statin Dose Intensity I: Other

	FDC vs. Placebo	FDC (N= 65)	Placebo (N= 34)	Total (N= 99)
Number of patients at risk		65 (100.0%)	34 (100.0%)	99 (100.0%)
Number of patients with events		1 (1.5%)	0	1 (1.0%)
Number of patients without events		64 (98.5%)	34 (100.0%)	98 (99.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.605 [0.064, 40.451]			
Stratified OR, 95% CI	1.667 [0.064, 43.135]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.591 [0.067, 38.037]			
Stratified RR, 95% CI	1.636 [0.070, 38.135]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.015 [-0.015, 0.045]			
Stratified ARR, 95% CI (CMH method)	0.016 [-0.015, 0.046]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4661			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity I - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		3 (7.1%)	0	3 (4.8%)
Number of patients without events		39 (92.9%)	21 (100.0%)	60 (95.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.810 [0.188, 77.250]			
Stratified OR, 95% CI	4.319 [0.208, 89.808]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.581 [0.193, 66.292]			
Stratified RR, 95% CI	3.889 [0.215, 70.338]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.071 [-0.006, 0.149]			
Stratified ARR, 95% CI (CMH method)	0.075 [-0.005, 0.155]			
Test on Differences [c]				
Unstratified p-value	0.5447			
Stratified p-value	0.1919			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline Statin Intensity I - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				1.0000
High Intensity Statin vs. Other		-	0.9996	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

	FDC vs. Placebo	FDC (N= 32)	Placebo (N= 20)	Total (N= 52)
Number of patients at risk		32 (100.0%)	20 (100.0%)	52 (100.0%)
Number of patients with events		1 (3.1%)	0	1 (1.9%)
Number of patients without events		31 (96.9%)	20 (100.0%)	51 (98.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.952 [0.076, 50.281]			
Stratified OR, 95% CI	2.172 [0.080, 58.763]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.909 [0.082, 44.707]			
Stratified RR, 95% CI	2.063 [0.092, 46.113]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.031 [-0.029, 0.092]			
Stratified ARR, 95% CI (CMH method)	0.033 [-0.029, 0.094]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4142			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		3 (7.1%)	0	3 (4.8%)
Number of patients without events		39 (92.9%)	21 (100.0%)	60 (95.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.810 [0.188, 77.250]			
Stratified OR, 95% CI	4.319 [0.208, 89.808]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.581 [0.193, 66.292]			
Stratified RR, 95% CI	3.889 [0.215, 70.338]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.071 [-0.006, 0.149]			
Stratified ARR, 95% CI (CMH method)	0.075 [-0.005, 0.155]			
Test on Differences [c]				
Unstratified p-value	0.5447			
Stratified p-value	0.1919			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline Statin Dose Intensity II: None

	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)	Total (N= 47)
Number of patients at risk		33 (100.0%)	14 (100.0%)	47 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		33 (100.0%)	14 (100.0%)	47 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline Statin Intensity II - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	WARNING: Negative of Hessian not positive definite				-
High Intensity Statin vs. Other Intensity Statin		-	0.9994	-	
None vs. Other Intensity Statin		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Race - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Race: White

	FDC vs. Placebo	FDC (N= 84)	Placebo (N= 48)	Total (N= 132)
Number of patients at risk		84 (100.0%)	48 (100.0%)	132 (100.0%)
Number of patients with events		2 (2.4%)	0	2 (1.5%)
Number of patients without events		82 (97.6%)	48 (100.0%)	130 (98.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.939 [0.138, 62.503]			
Stratified OR, 95% CI	3.788 [0.167, 86.129]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.882 [0.141, 58.824]			
Stratified RR, 95% CI	3.421 [0.178, 65.577]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.024 [-0.009, 0.056]			
Stratified ARR, 95% CI (CMH method)	0.026 [-0.008, 0.061]			
Test on Differences [c]				
Unstratified p-value	0.5337			
Stratified p-value	0.2399			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Race - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Race: non-White

	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)	Total (N= 30)
Number of patients at risk		23 (100.0%)	7 (100.0%)	30 (100.0%)
Number of patients with events		2 (8.7%)	0	2 (6.7%)
Number of patients without events		21 (91.3%)	7 (100.0%)	28 (93.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.744 [0.075, 40.624]			
Stratified OR, 95% CI	1.074 [0.090, 12.864]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.667 [0.089, 31.183]			
Stratified RR, 95% CI	1.061 [0.135, 8.346]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.087 [-0.028, 0.202]			
Stratified ARR, 95% CI (CMH method)	0.081 [-0.036, 0.199]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4643			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Race - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	WARNING: Negative of Hessian not positive definite				-
non-White vs. White		-	0.9997	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline LDL-C (mg/dL): < 130

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 16)	Total (N= 54)
Number of patients at risk		38 (100.0%)	16 (100.0%)	54 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		38 (100.0%)	16 (100.0%)	54 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)	Total (N= 47)
Number of patients at risk		31 (100.0%)	16 (100.0%)	47 (100.0%)
Number of patients with events		1 (3.2%)	0	1 (2.1%)
Number of patients without events		30 (96.8%)	16 (100.0%)	46 (97.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.623 [0.063, 42.116]			
Stratified OR, 95% CI	3.000 [0.088, 102.05]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.594 [0.069, 37.047]			
Stratified RR, 95% CI	2.400 [0.130, 44.414]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.032 [-0.030, 0.094]			
Stratified ARR, 95% CI (CMH method)	0.041 [-0.029, 0.111]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3865			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline LDL-C (mg/dL): >= 160

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)	Total (N= 61)
Number of patients at risk		38 (100.0%)	23 (100.0%)	61 (100.0%)
Number of patients with events		3 (7.9%)	0	3 (4.9%)
Number of patients without events		35 (92.1%)	23 (100.0%)	58 (95.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.634 [0.229, 93.884]			
Stratified OR, 95% CI	4.035 [0.380, 42.897]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.308 [0.233, 79.809]			
Stratified RR, 95% CI	3.182 [0.405, 24.992]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.079 [-0.007, 0.165]			
Stratified ARR, 95% CI (CMH method)	0.091 [-0.003, 0.186]			
Test on Differences [c]				
Unstratified p-value	0.2836			
Stratified p-value	0.1215			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline LDL-C Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	WARNING: Negative of Hessian not positive definite				-
130 - < 160 vs. < 130		-	0.9999	-	
>= 160 vs. < 130		-	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by History of Diabetes - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

History of Diabetes: Yes

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		4 (8.3%)	0	4 (5.6%)
Number of patients without events		44 (91.7%)	24 (100.0%)	68 (94.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.955 [0.256, 95.915]			
Stratified OR, 95% CI	3.573 [0.368, 34.700]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.592 [0.257, 81.944]			
Stratified RR, 95% CI	3.023 [0.375, 24.347]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.083 [0.005, 0.162]			
Stratified ARR, 95% CI (CMH method)	0.104 [0.018, 0.191]			
Test on Differences [c]				
Unstratified p-value	0.2939			
Stratified p-value	0.0783			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by History of Diabetes - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

History of Diabetes: No

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		59 (100.0%)	31 (100.0%)	90 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by History of Diabetes - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	WARNING: Negative of Hessian not positive definite				-
No vs. Yes		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

BMI (kg/m^2): < 25

	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)	Total (N= 19)
Number of patients at risk		13 (100.0%)	6 (100.0%)	19 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		13 (100.0%)	6 (100.0%)	19 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

BMI (kg/m^2): 25 - < 30

	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)	Total (N= 49)
Number of patients at risk		27 (100.0%)	22 (100.0%)	49 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		27 (100.0%)	22 (100.0%)	49 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

BMI (kg/m^2): >= 30

	FDC vs. Placebo	FDC (N= 67)	Placebo (N= 27)	Total (N= 94)
Number of patients at risk		67 (100.0%)	27 (100.0%)	94 (100.0%)
Number of patients with events		4 (6.0%)	0	4 (4.3%)
Number of patients without events		63 (94.0%)	27 (100.0%)	90 (95.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.898 [0.203, 74.901]			
Stratified OR, 95% CI	2.064 [0.215, 19.833]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.706 [0.206, 66.575]			
Stratified RR, 95% CI	1.928 [0.239, 15.582]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.060 [0.003, 0.116]			
Stratified ARR, 95% CI (CMH method)	0.052 [-0.002, 0.106]			
Test on Differences [c]				
Unstratified p-value	0.3214			
Stratified p-value	0.2341			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by BMI - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	WARNING: Negative of Hessian not positive definite				-
25 - < 30 vs. < 25		-	1.0000	1.0000	
>= 30 vs. < 25		-	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Renal Disorders (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		4 (3.7%)	0	4 (2.5%)
Number of patients without events		103 (96.3%)	55 (100.0%)	158 (97.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.826 [0.255, 91.279]			
Stratified OR, 95% CI	2.867 [0.321, 25.640]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.667 [0.256, 85.141]			
Stratified RR, 95% CI	2.712 [0.331, 22.243]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.037 [0.001, 0.073]			
Stratified ARR, 95% CI (CMH method)	0.038 [0.002, 0.074]			
Test on Differences [c]				
Unstratified p-value	0.3005			
Stratified p-value	0.1419			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Renal Disorders (AESI)
Safety Population

Gender: Male

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)	Total (N= 83)
Number of patients at risk		50 (100.0%)	33 (100.0%)	83 (100.0%)
Number of patients with events		4 (8.0%)	0	4 (4.8%)
Number of patients without events		46 (92.0%)	33 (100.0%)	79 (95.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.484 [0.338, 124.54]			
Stratified OR, 95% CI	3.952 [0.431, 36.236]			
Relative Risk [a]				
Unstratified RR, 95% CI	6.000 [0.334, 107.89]			
Stratified RR, 95% CI	3.516 [0.438, 28.207]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.080 [0.005, 0.155]			
Stratified ARR, 95% CI (CMH method)	0.082 [0.006, 0.158]			
Test on Differences [c]				
Unstratified p-value	0.1476			
Stratified p-value	0.0910			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Renal Disorders (AESI)
Safety Population

Gender: Female

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 22)	Total (N= 79)
Number of patients at risk		57 (100.0%)	22 (100.0%)	79 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		57 (100.0%)	22 (100.0%)	79 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Gender - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	WARNING: Negative of Hessian not positive definite				-
Female vs. Male		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Renal Disorders (AESI)
Safety Population

Age (years): < 65

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 27)	Total (N= 84)
Number of patients at risk		57 (100.0%)	27 (100.0%)	84 (100.0%)
Number of patients with events		1 (1.8%)	0	1 (1.2%)
Number of patients without events		56 (98.2%)	27 (100.0%)	83 (98.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.460 [0.058, 37.020]			
Stratified OR, 95% CI	1.098 [0.040, 30.000]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.448 [0.061, 34.434]			
Stratified RR, 95% CI	1.091 [0.049, 24.134]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.018 [-0.017, 0.052]			
Stratified ARR, 95% CI (CMH method)	0.014 [-0.017, 0.045]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5637			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Renal Disorders (AESI)
Safety Population

Age (years): >= 65

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)	Total (N= 78)
Number of patients at risk		50 (100.0%)	28 (100.0%)	78 (100.0%)
Number of patients with events		3 (6.0%)	0	3 (3.8%)
Number of patients without events		47 (94.0%)	28 (100.0%)	75 (96.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.200 [0.209, 84.305]			
Stratified OR, 95% CI	2.838 [0.290, 27.805]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.980 [0.213, 74.388]			
Stratified RR, 95% CI	2.595 [0.309, 21.787]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.060 [-0.006, 0.126]			
Stratified ARR, 95% CI (CMH method)	0.063 [-0.005, 0.132]			
Test on Differences [c]				
Unstratified p-value	0.5491			
Stratified p-value	0.1717			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Age - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				1.0000
>= 65 vs. < 65		-	0.9995	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Renal Disorders (AESI)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		4 (6.8%)	0	4 (4.4%)
Number of patients without events		55 (93.2%)	31 (100.0%)	86 (95.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.108 [0.266, 98.013]			
Stratified OR, 95% CI	2.733 [0.297, 25.138]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.800 [0.267, 86.374]			
Stratified RR, 95% CI	2.580 [0.306, 21.743]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.068 [0.004, 0.132]			
Stratified ARR, 95% CI (CMH method)	0.068 [0.004, 0.133]			
Test on Differences [c]				
Unstratified p-value	0.2942			
Stratified p-value	0.1366			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Renal Disorders (AESI)
Safety Population

CVD Risk Category: Multiple CV risk factors

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		48 (100.0%)	24 (100.0%)	72 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by CVD Risk Category - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	WARNING: Negative of Hessian not positive definite				-
Multiple CV risk factors vs. ASCVD and/or HeFH		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Renal Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: Other

	FDC vs. Placebo	FDC (N= 65)	Placebo (N= 34)	Total (N= 99)
Number of patients at risk		65 (100.0%)	34 (100.0%)	99 (100.0%)
Number of patients with events		1 (1.5%)	0	1 (1.0%)
Number of patients without events		64 (98.5%)	34 (100.0%)	98 (99.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.605 [0.064, 40.451]			
Stratified OR, 95% CI	1.615 [0.062, 41.784]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.591 [0.067, 38.037]			
Stratified RR, 95% CI	1.588 [0.068, 37.034]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.015 [-0.015, 0.045]			
Stratified ARR, 95% CI (CMH method)	0.015 [-0.015, 0.045]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4729			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Renal Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		3 (7.1%)	0	3 (4.8%)
Number of patients without events		39 (92.9%)	21 (100.0%)	60 (95.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.810 [0.188, 77.250]			
Stratified OR, 95% CI	4.319 [0.208, 89.808]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.581 [0.193, 66.292]			
Stratified RR, 95% CI	3.889 [0.215, 70.338]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.071 [-0.006, 0.149]			
Stratified ARR, 95% CI (CMH method)	0.075 [-0.005, 0.155]			
Test on Differences [c]				
Unstratified p-value	0.5447			
Stratified p-value	0.1919			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity I - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				1.0000
High Intensity Statin vs. Other		-	0.9997	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Renal Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

	FDC vs. Placebo	FDC (N= 32)	Placebo (N= 20)	Total (N= 52)
Number of patients at risk		32 (100.0%)	20 (100.0%)	52 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		32 (100.0%)	20 (100.0%)	52 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Renal Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		3 (7.1%)	0	3 (4.8%)
Number of patients without events		39 (92.9%)	21 (100.0%)	60 (95.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.810 [0.188, 77.250]			
Stratified OR, 95% CI	4.319 [0.208, 89.808]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.581 [0.193, 66.292]			
Stratified RR, 95% CI	3.889 [0.215, 70.338]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.071 [-0.006, 0.149]			
Stratified ARR, 95% CI (CMH method)	0.075 [-0.005, 0.155]			
Test on Differences [c]				
Unstratified p-value	0.5447			
Stratified p-value	0.1919			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Renal Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: None

	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)	Total (N= 47)
Number of patients at risk		33 (100.0%)	14 (100.0%)	47 (100.0%)
Number of patients with events		1 (3.0%)	0	1 (2.1%)
Number of patients without events		32 (97.0%)	14 (100.0%)	46 (97.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.338 [0.051, 34.863]			
Stratified OR, 95% CI	1.452 [0.053, 40.040]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.324 [0.057, 30.653]			
Stratified RR, 95% CI	1.412 [0.064, 30.974]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.030 [-0.028, 0.089]			
Stratified ARR, 95% CI (CMH method)	0.031 [-0.028, 0.090]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5083			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity II - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	WARNING: Negative of Hessian not positive definite				-
High Intensity Statin vs. Other Intensity Statin		-	0.9995	-	
None vs. Other Intensity Statin		-	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Renal Disorders (AESI)
Safety Population

Race: White

	FDC vs. Placebo	FDC (N= 84)	Placebo (N= 48)	Total (N= 132)
Number of patients at risk		84 (100.0%)	48 (100.0%)	132 (100.0%)
Number of patients with events		2 (2.4%)	0	2 (1.5%)
Number of patients without events		82 (97.6%)	48 (100.0%)	130 (98.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.939 [0.138, 62.503]			
Stratified OR, 95% CI	3.113 [0.141, 68.965]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.882 [0.141, 58.824]			
Stratified RR, 95% CI	2.931 [0.149, 57.519]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.024 [-0.009, 0.056]			
Stratified ARR, 95% CI (CMH method)	0.024 [-0.009, 0.057]			
Test on Differences [c]				
Unstratified p-value	0.5337			
Stratified p-value	0.2794			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Renal Disorders (AESI)
Safety Population

Race: non-White

	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)	Total (N= 30)
Number of patients at risk		23 (100.0%)	7 (100.0%)	30 (100.0%)
Number of patients with events		2 (8.7%)	0	2 (6.7%)
Number of patients without events		21 (91.3%)	7 (100.0%)	28 (93.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.744 [0.075, 40.624]			
Stratified OR, 95% CI	1.923 [0.066, 55.839]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.667 [0.089, 31.183]			
Stratified RR, 95% CI	1.667 [0.108, 25.833]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.087 [-0.028, 0.202]			
Stratified ARR, 95% CI (CMH method)	0.077 [-0.038, 0.192]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4533			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Race - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	WARNING: Negative of Hessian not positive definite				-
non-White vs. White		-	0.9997	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Renal Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): < 130

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 16)	Total (N= 54)
Number of patients at risk		38 (100.0%)	16 (100.0%)	54 (100.0%)
Number of patients with events		1 (2.6%)	0	1 (1.9%)
Number of patients without events		37 (97.4%)	16 (100.0%)	53 (98.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.320 [0.051, 34.131]			
Stratified OR, 95% CI	1.545 [0.057, 42.147]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.308 [0.056, 30.501]			
Stratified RR, 95% CI	1.500 [0.068, 33.263]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.026 [-0.025, 0.077]			
Stratified ARR, 95% CI (CMH method)	0.032 [-0.034, 0.097]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4927			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Renal Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)	Total (N= 47)
Number of patients at risk		31 (100.0%)	16 (100.0%)	47 (100.0%)
Number of patients with events		1 (3.2%)	0	1 (2.1%)
Number of patients without events		30 (96.8%)	16 (100.0%)	46 (97.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.623 [0.063, 42.116]			
Stratified OR, 95% CI	2.077 [0.068, 63.417]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.594 [0.069, 37.047]			
Stratified RR, 95% CI	1.875 [0.093, 37.632]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.032 [-0.030, 0.094]			
Stratified ARR, 95% CI (CMH method)	0.035 [-0.030, 0.100]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4497			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Renal Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): >= 160

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)	Total (N= 61)
Number of patients at risk		38 (100.0%)	23 (100.0%)	61 (100.0%)
Number of patients with events		2 (5.3%)	0	2 (3.3%)
Number of patients without events		36 (94.7%)	23 (100.0%)	59 (96.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.219 [0.148, 70.065]			
Stratified OR, 95% CI	1.605 [0.143, 17.989]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.077 [0.154, 61.400]			
Stratified RR, 95% CI	1.517 [0.182, 12.642]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.053 [-0.018, 0.124]			
Stratified ARR, 95% CI (CMH method)	0.046 [-0.024, 0.115]			
Test on Differences [c]				
Unstratified p-value	0.5224			
Stratified p-value	0.3359			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline LDL-C Category - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				1.0000
130 - < 160 vs. < 130		-	1.0000	-	
>= 160 vs. < 130		-	0.9998	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Renal Disorders (AESI)
Safety Population

History of Diabetes: Yes

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		1 (2.1%)	0	1 (1.4%)
Number of patients without events		47 (97.9%)	24 (100.0%)	71 (98.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.547 [0.061, 39.412]			
Stratified OR, 95% CI	1.421 [0.048, 42.218]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.531 [0.065, 36.227]			
Stratified RR, 95% CI	1.364 [0.066, 27.970]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.021 [-0.020, 0.061]			
Stratified ARR, 95% CI (CMH method)	0.018 [-0.020, 0.057]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5271			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Renal Disorders (AESI)
Safety Population

History of Diabetes: No

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		3 (5.1%)	0	3 (3.3%)
Number of patients without events		56 (94.9%)	31 (100.0%)	87 (96.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.903 [0.195, 78.001]			
Stratified OR, 95% CI	2.015 [0.207, 19.661]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.733 [0.199, 70.054]			
Stratified RR, 95% CI	1.910 [0.227, 16.074]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.051 [-0.005, 0.107]			
Stratified ARR, 95% CI (CMH method)	0.045 [-0.008, 0.098]			
Test on Differences [c]				
Unstratified p-value	0.5485			
Stratified p-value	0.2452			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by History of Diabetes - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				1.0000
No vs. Yes		-	0.9995	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Renal Disorders (AESI)
Safety Population

BMI (kg/m^2): < 25

	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)	Total (N= 19)
Number of patients at risk		13 (100.0%)	6 (100.0%)	19 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		13 (100.0%)	6 (100.0%)	19 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Renal Disorders (AESI)
Safety Population

BMI (kg/m^2): 25 - < 30

	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)	Total (N= 49)
Number of patients at risk		27 (100.0%)	22 (100.0%)	49 (100.0%)
Number of patients with events		1 (3.7%)	0	1 (2.0%)
Number of patients without events		26 (96.3%)	22 (100.0%)	48 (98.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.547 [0.099, 65.663]			
Stratified OR, 95% CI	2.294 [0.080, 66.018]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.464 [0.105, 57.664]			
Stratified RR, 95% CI	2.100 [0.099, 44.404]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.037 [-0.034, 0.108]			
Stratified ARR, 95% CI (CMH method)	0.035 [-0.036, 0.106]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4142			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Renal Disorders (AESI)
Safety Population

BMI (kg/m^2): >= 30

	FDC vs. Placebo	FDC (N= 67)	Placebo (N= 27)	Total (N= 94)
Number of patients at risk		67 (100.0%)	27 (100.0%)	94 (100.0%)
Number of patients with events		3 (4.5%)	0	3 (3.2%)
Number of patients without events		64 (95.5%)	27 (100.0%)	91 (96.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.984 [0.149, 59.743]			
Stratified OR, 95% CI	1.438 [0.145, 14.223]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.882 [0.154, 53.997]			
Stratified RR, 95% CI	1.396 [0.168, 11.602]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.045 [-0.005, 0.094]			
Stratified ARR, 95% CI (CMH method)	0.037 [-0.009, 0.083]			
Test on Differences [c]				
Unstratified p-value	0.5546			
Stratified p-value	0.3299			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by BMI - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	WARNING: Negative of Hessian not positive definite				-
25 - < 30 vs. < 25		-	0.9989	-	
>= 30 vs. < 25		-	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE - Renal Disorders (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE - Renal Disorders (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE - Renal Disorders (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		4 (3.7%)	0	4 (2.5%)
Number of patients without events		103 (96.3%)	55 (100.0%)	158 (97.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.826 [0.255, 91.279]			
Stratified OR, 95% CI	2.867 [0.321, 25.640]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.667 [0.256, 85.141]			
Stratified RR, 95% CI	2.712 [0.331, 22.243]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.037 [0.001, 0.073]			
Stratified ARR, 95% CI (CMH method)	0.038 [0.002, 0.074]			
Test on Differences [c]				
Unstratified p-value	0.3005			
Stratified p-value	0.1419			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Gender - Renal Disorders (AESI)
Safety Population

Gender: Male

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 33)	Total (N= 83)
Number of patients at risk		50 (100.0%)	33 (100.0%)	83 (100.0%)
Number of patients with events		4 (8.0%)	0	4 (4.8%)
Number of patients without events		46 (92.0%)	33 (100.0%)	79 (95.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.484 [0.338, 124.54]			
Stratified OR, 95% CI	3.952 [0.431, 36.236]			
Relative Risk [a]				
Unstratified RR, 95% CI	6.000 [0.334, 107.89]			
Stratified RR, 95% CI	3.516 [0.438, 28.207]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.080 [0.005, 0.155]			
Stratified ARR, 95% CI (CMH method)	0.082 [0.006, 0.158]			
Test on Differences [c]				
Unstratified p-value	0.1476			
Stratified p-value	0.0910			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Gender - Renal Disorders (AESI)
Safety Population

Gender: Female

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 22)	Total (N= 79)
Number of patients at risk		57 (100.0%)	22 (100.0%)	79 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		57 (100.0%)	22 (100.0%)	79 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Gender - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	WARNING: Negative of Hessian not positive definite				-
Female vs. Male		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Age - Renal Disorders (AESI)
Safety Population

Age (years): < 65

	FDC vs. Placebo	FDC (N= 57)	Placebo (N= 27)	Total (N= 84)
Number of patients at risk		57 (100.0%)	27 (100.0%)	84 (100.0%)
Number of patients with events		1 (1.8%)	0	1 (1.2%)
Number of patients without events		56 (98.2%)	27 (100.0%)	83 (98.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.460 [0.058, 37.020]			
Stratified OR, 95% CI	1.098 [0.040, 30.000]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.448 [0.061, 34.434]			
Stratified RR, 95% CI	1.091 [0.049, 24.134]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.018 [-0.017, 0.052]			
Stratified ARR, 95% CI (CMH method)	0.014 [-0.017, 0.045]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5637			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Age - Renal Disorders (AESI)
Safety Population

Age (years): >= 65

	FDC vs. Placebo	FDC (N= 50)	Placebo (N= 28)	Total (N= 78)
Number of patients at risk		50 (100.0%)	28 (100.0%)	78 (100.0%)
Number of patients with events		3 (6.0%)	0	3 (3.8%)
Number of patients without events		47 (94.0%)	28 (100.0%)	75 (96.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.200 [0.209, 84.305]			
Stratified OR, 95% CI	2.838 [0.290, 27.805]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.980 [0.213, 74.388]			
Stratified RR, 95% CI	2.595 [0.309, 21.787]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.060 [-0.006, 0.126]			
Stratified ARR, 95% CI (CMH method)	0.063 [-0.005, 0.132]			
Test on Differences [c]				
Unstratified p-value	0.5491			
Stratified p-value	0.1717			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Table 1002FDC.053.204.32.2.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Age - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				1.0000
>= 65 vs. < 65		-	0.9995	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by CVD Risk Category - Renal Disorders (AESI)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		4 (6.8%)	0	4 (4.4%)
Number of patients without events		55 (93.2%)	31 (100.0%)	86 (95.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.108 [0.266, 98.013]			
Stratified OR, 95% CI	2.733 [0.297, 25.138]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.800 [0.267, 86.374]			
Stratified RR, 95% CI	2.580 [0.306, 21.743]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.068 [0.004, 0.132]			
Stratified ARR, 95% CI (CMH method)	0.068 [0.004, 0.133]			
Test on Differences [c]				
Unstratified p-value	0.2942			
Stratified p-value	0.1366			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by CVD Risk Category - Renal Disorders (AESI)
Safety Population

CVD Risk Category: Multiple CV risk factors

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		48 (100.0%)	24 (100.0%)	72 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by CVD Risk Category - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	WARNING: Negative of Hessian not positive definite				-
Multiple CV risk factors vs. ASCVD and/or HeFH		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Renal Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: Other

	FDC vs. Placebo	FDC (N= 65)	Placebo (N= 34)	Total (N= 99)
Number of patients at risk		65 (100.0%)	34 (100.0%)	99 (100.0%)
Number of patients with events		1 (1.5%)	0	1 (1.0%)
Number of patients without events		64 (98.5%)	34 (100.0%)	98 (99.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.605 [0.064, 40.451]			
Stratified OR, 95% CI	1.615 [0.062, 41.784]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.591 [0.067, 38.037]			
Stratified RR, 95% CI	1.588 [0.068, 37.034]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.015 [-0.015, 0.045]			
Stratified ARR, 95% CI (CMH method)	0.015 [-0.015, 0.045]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4729			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Renal Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		3 (7.1%)	0	3 (4.8%)
Number of patients without events		39 (92.9%)	21 (100.0%)	60 (95.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.810 [0.188, 77.250]			
Stratified OR, 95% CI	4.319 [0.208, 89.808]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.581 [0.193, 66.292]			
Stratified RR, 95% CI	3.889 [0.215, 70.338]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.071 [-0.006, 0.149]			
Stratified ARR, 95% CI (CMH method)	0.075 [-0.005, 0.155]			
Test on Differences [c]				
Unstratified p-value	0.5447			
Stratified p-value	0.1919			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				1.0000
High Intensity Statin vs. Other		-	0.9997	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Renal Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

	FDC vs. Placebo	FDC (N= 32)	Placebo (N= 20)	Total (N= 52)
Number of patients at risk		32 (100.0%)	20 (100.0%)	52 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		32 (100.0%)	20 (100.0%)	52 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Renal Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

	FDC vs. Placebo	FDC (N= 42)	Placebo (N= 21)	Total (N= 63)
Number of patients at risk		42 (100.0%)	21 (100.0%)	63 (100.0%)
Number of patients with events		3 (7.1%)	0	3 (4.8%)
Number of patients without events		39 (92.9%)	21 (100.0%)	60 (95.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.810 [0.188, 77.250]			
Stratified OR, 95% CI	4.319 [0.208, 89.808]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.581 [0.193, 66.292]			
Stratified RR, 95% CI	3.889 [0.215, 70.338]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.071 [-0.006, 0.149]			
Stratified ARR, 95% CI (CMH method)	0.075 [-0.005, 0.155]			
Test on Differences [c]				
Unstratified p-value	0.5447			
Stratified p-value	0.1919			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Renal Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: None

	FDC vs. Placebo	FDC (N= 33)	Placebo (N= 14)	Total (N= 47)
Number of patients at risk		33 (100.0%)	14 (100.0%)	47 (100.0%)
Number of patients with events		1 (3.0%)	0	1 (2.1%)
Number of patients without events		32 (97.0%)	14 (100.0%)	46 (97.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.338 [0.051, 34.863]			
Stratified OR, 95% CI	1.452 [0.053, 40.040]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.324 [0.057, 30.653]			
Stratified RR, 95% CI	1.412 [0.064, 30.974]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.030 [-0.028, 0.089]			
Stratified ARR, 95% CI (CMH method)	0.031 [-0.028, 0.090]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5083			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	WARNING: Negative of Hessian not positive definite				-
High Intensity Statin vs. Other Intensity Statin		-	0.9995	-	
None vs. Other Intensity Statin		-	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Race - Renal Disorders (AESI)
Safety Population

Race: White

	FDC vs. Placebo	FDC (N= 84)	Placebo (N= 48)	Total (N= 132)
Number of patients at risk		84 (100.0%)	48 (100.0%)	132 (100.0%)
Number of patients with events		2 (2.4%)	0	2 (1.5%)
Number of patients without events		82 (97.6%)	48 (100.0%)	130 (98.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.939 [0.138, 62.503]			
Stratified OR, 95% CI	3.113 [0.141, 68.965]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.882 [0.141, 58.824]			
Stratified RR, 95% CI	2.931 [0.149, 57.519]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.024 [-0.009, 0.056]			
Stratified ARR, 95% CI (CMH method)	0.024 [-0.009, 0.057]			
Test on Differences [c]				
Unstratified p-value	0.5337			
Stratified p-value	0.2794			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Race - Renal Disorders (AESI)
Safety Population

Race: non-White

	FDC vs. Placebo	FDC (N= 23)	Placebo (N= 7)	Total (N= 30)
Number of patients at risk		23 (100.0%)	7 (100.0%)	30 (100.0%)
Number of patients with events		2 (8.7%)	0	2 (6.7%)
Number of patients without events		21 (91.3%)	7 (100.0%)	28 (93.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.744 [0.075, 40.624]			
Stratified OR, 95% CI	1.923 [0.066, 55.839]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.667 [0.089, 31.183]			
Stratified RR, 95% CI	1.667 [0.108, 25.833]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.087 [-0.028, 0.202]			
Stratified ARR, 95% CI (CMH method)	0.077 [-0.038, 0.192]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4533			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Race - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	WARNING: Negative of Hessian not positive definite				-
non-White vs. White		-	0.9997	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Renal Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): < 130

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 16)	Total (N= 54)
Number of patients at risk		38 (100.0%)	16 (100.0%)	54 (100.0%)
Number of patients with events		1 (2.6%)	0	1 (1.9%)
Number of patients without events		37 (97.4%)	16 (100.0%)	53 (98.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.320 [0.051, 34.131]			
Stratified OR, 95% CI	1.545 [0.057, 42.147]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.308 [0.056, 30.501]			
Stratified RR, 95% CI	1.500 [0.068, 33.263]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.026 [-0.025, 0.077]			
Stratified ARR, 95% CI (CMH method)	0.032 [-0.034, 0.097]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4927			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Renal Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

	FDC vs. Placebo	FDC (N= 31)	Placebo (N= 16)	Total (N= 47)
Number of patients at risk		31 (100.0%)	16 (100.0%)	47 (100.0%)
Number of patients with events		1 (3.2%)	0	1 (2.1%)
Number of patients without events		30 (96.8%)	16 (100.0%)	46 (97.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.623 [0.063, 42.116]			
Stratified OR, 95% CI	2.077 [0.068, 63.417]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.594 [0.069, 37.047]			
Stratified RR, 95% CI	1.875 [0.093, 37.632]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.032 [-0.030, 0.094]			
Stratified ARR, 95% CI (CMH method)	0.035 [-0.030, 0.100]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4497			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Renal Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): >= 160

	FDC vs. Placebo	FDC (N= 38)	Placebo (N= 23)	Total (N= 61)
Number of patients at risk		38 (100.0%)	23 (100.0%)	61 (100.0%)
Number of patients with events		2 (5.3%)	0	2 (3.3%)
Number of patients without events		36 (94.7%)	23 (100.0%)	59 (96.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.219 [0.148, 70.065]			
Stratified OR, 95% CI	1.605 [0.143, 17.989]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.077 [0.154, 61.400]			
Stratified RR, 95% CI	1.517 [0.182, 12.642]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.053 [-0.018, 0.124]			
Stratified ARR, 95% CI (CMH method)	0.046 [-0.024, 0.115]			
Test on Differences [c]				
Unstratified p-value	0.5224			
Stratified p-value	0.3359			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline LDL-C Category - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				1.0000
130 - < 160 vs. < 130		-	1.0000	-	
>= 160 vs. < 130		-	0.9998	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by History of Diabetes - Renal Disorders (AESI)
Safety Population

History of Diabetes: Yes

	FDC vs. Placebo	FDC (N= 48)	Placebo (N= 24)	Total (N= 72)
Number of patients at risk		48 (100.0%)	24 (100.0%)	72 (100.0%)
Number of patients with events		1 (2.1%)	0	1 (1.4%)
Number of patients without events		47 (97.9%)	24 (100.0%)	71 (98.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.547 [0.061, 39.412]			
Stratified OR, 95% CI	1.421 [0.048, 42.218]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.531 [0.065, 36.227]			
Stratified RR, 95% CI	1.364 [0.066, 27.970]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.021 [-0.020, 0.061]			
Stratified ARR, 95% CI (CMH method)	0.018 [-0.020, 0.057]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5271			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by History of Diabetes - Renal Disorders (AESI)
Safety Population

History of Diabetes: No

	FDC vs. Placebo	FDC (N= 59)	Placebo (N= 31)	Total (N= 90)
Number of patients at risk		59 (100.0%)	31 (100.0%)	90 (100.0%)
Number of patients with events		3 (5.1%)	0	3 (3.3%)
Number of patients without events		56 (94.9%)	31 (100.0%)	87 (96.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.903 [0.195, 78.001]			
Stratified OR, 95% CI	2.015 [0.207, 19.661]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.733 [0.199, 70.054]			
Stratified RR, 95% CI	1.910 [0.227, 16.074]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.051 [-0.005, 0.107]			
Stratified ARR, 95% CI (CMH method)	0.045 [-0.008, 0.098]			
Test on Differences [c]				
Unstratified p-value	0.5485			
Stratified p-value	0.2452			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by History of Diabetes - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				1.0000
No vs. Yes		-	0.9995	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Renal Disorders (AESI)
Safety Population

BMI (kg/m^2): < 25

	FDC vs. Placebo	FDC (N= 13)	Placebo (N= 6)	Total (N= 19)
Number of patients at risk		13 (100.0%)	6 (100.0%)	19 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		13 (100.0%)	6 (100.0%)	19 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Renal Disorders (AESI)
Safety Population

BMI (kg/m^2): 25 - < 30

	FDC vs. Placebo	FDC (N= 27)	Placebo (N= 22)	Total (N= 49)
Number of patients at risk		27 (100.0%)	22 (100.0%)	49 (100.0%)
Number of patients with events		1 (3.7%)	0	1 (2.0%)
Number of patients without events		26 (96.3%)	22 (100.0%)	48 (98.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.547 [0.099, 65.663]			
Stratified OR, 95% CI	2.294 [0.080, 66.018]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.464 [0.105, 57.664]			
Stratified RR, 95% CI	2.100 [0.099, 44.404]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.037 [-0.034, 0.108]			
Stratified ARR, 95% CI (CMH method)	0.035 [-0.036, 0.106]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4142			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Renal Disorders (AESI)
Safety Population

BMI (kg/m^2): >= 30

	FDC vs. Placebo	FDC (N= 67)	Placebo (N= 27)	Total (N= 94)
Number of patients at risk		67 (100.0%)	27 (100.0%)	94 (100.0%)
Number of patients with events		3 (4.5%)	0	3 (3.2%)
Number of patients without events		64 (95.5%)	27 (100.0%)	91 (96.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.984 [0.149, 59.743]			
Stratified OR, 95% CI	1.438 [0.145, 14.223]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.882 [0.154, 53.997]			
Stratified RR, 95% CI	1.396 [0.168, 11.602]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.045 [-0.005, 0.094]			
Stratified ARR, 95% CI (CMH method)	0.037 [-0.009, 0.083]			
Test on Differences [c]				
Unstratified p-value	0.5546			
Stratified p-value	0.3299			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Placebo.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by BMI - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	WARNING: Negative of Hessian not positive definite				-
25 - < 30 vs. < 25		-	0.9989	-	
>= 30 vs. < 25		-	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Gout (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE - Gout (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE - Gout (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE - Gout (AESI)
Safety Population

	FDC vs. Placebo	FDC (N= 107)	Placebo (N= 55)	Total (N= 162)
Number of patients at risk		107 (100.0%)	55 (100.0%)	162 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	55 (100.0%)	162 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

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	FDC (N= 108)	Ezetimibe (N= 109)	Total
Duration of treatment (days)			
n	107	109	216
Mean	82.1	78.7	80.4
Median	84.0	84.0	84.0
Range	8 - 112	3 - 105	3 - 112
Duration category (days)			
0-<35	3 (2.8%)	7 (6.4%)	10 (4.6%)
35-<63	3 (2.8%)	4 (3.7%)	7 (3.2%)
63-<80	8 (7.5%)	3 (2.8%)	11 (5.1%)
80-<91	86 (80.4%)	88 (80.7%)	174 (80.6%)
>=91	7 (6.5%)	7 (6.4%)	14 (6.5%)

Abbreviations: FDC=fixed dose combination, N=number of patients.
Note: Duration of treatment = the day of end of treatment - the day of start of treatment + 1.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12
Full Analysis Set

Statistic	FDC vs. Ezetimibe	FDC (N= 108)	Ezetimibe (N= 109)	Total (N= 217)
Number of patients at risk		108 (100.0%)	109 (100.0%)	217 (100.0%)
Number of patients with events		29 (26.9%)	10 (9.2%)	39 (18.0%)
Number of patients without events		79 (73.1%)	99 (90.8%)	178 (82.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.634 [1.671, 7.906]			
Stratified OR, 95% CI	3.304 [1.423, 7.673]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.927 [1.501, 5.707]			
Stratified RR, 95% CI	2.226 [1.165, 4.251]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.177 [0.077, 0.276]			
Stratified ARR, 95% CI (CMH method)	0.177 [0.080, 0.275]			
Test on Differences [c]				
Unstratified p-value	0.0007			
Stratified p-value	0.0005			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Gender
Full Analysis Set

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		12 (24.0%)	9 (17.3%)	21 (20.6%)
Number of patients without events		38 (76.0%)	43 (82.7%)	81 (79.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.509 [0.573, 3.973]			
Stratified OR, 95% CI	1.613 [0.562, 4.628]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.387 [0.641, 3.001]			
Stratified RR, 95% CI	1.315 [0.645, 2.679]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.067 [-0.090, 0.224]			
Stratified ARR, 95% CI (CMH method)	0.083 [-0.067, 0.233]			
Test on Differences [c]				
Unstratified p-value	0.4034			
Stratified p-value	0.2824			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Gender
Full Analysis Set

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 58)	Ezetimibe (N= 57)	Total (N= 115)
Number of patients at risk		58 (100.0%)	57 (100.0%)	115 (100.0%)
Number of patients with events		17 (29.3%)	1 (1.8%)	18 (15.7%)
Number of patients without events		41 (70.7%)	56 (98.2%)	97 (84.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	23.220 [2.969, 181.57]			
Stratified OR, 95% CI	9.732 [2.429, 38.990]			
Relative Risk [a]				
Unstratified RR, 95% CI	16.707 [2.299, 121.41]			
Stratified RR, 95% CI	6.865 [1.936, 24.342]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.276 [0.154, 0.398]			
Stratified ARR, 95% CI (CMH method)	0.270 [0.149, 0.392]			
Test on Differences [c]				
Unstratified p-value	<.0001			
Stratified p-value	<.0001			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with LDL-C <70 mg/dL at Week 12 by Gender
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.0033
Female vs. Male		0.4067	0.0272	0.0219	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia,
LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, LR=likelihood ratio.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Age
Full Analysis Set

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 58)	Ezetimibe (N= 48)	Total (N= 106)
Number of patients at risk		58 (100.0%)	48 (100.0%)	106 (100.0%)
Number of patients with events		11 (19.0%)	5 (10.4%)	16 (15.1%)
Number of patients without events		47 (81.0%)	43 (89.6%)	90 (84.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.013 [0.647, 6.263]			
Stratified OR, 95% CI	1.759 [0.523, 5.915]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.821 [0.680, 4.878]			
Stratified RR, 95% CI	1.430 [0.545, 3.754]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.085 [-0.047, 0.218]			
Stratified ARR, 95% CI (CMH method)	0.081 [-0.048, 0.211]			
Test on Differences [c]				
Unstratified p-value	0.2210			
Stratified p-value	0.2407			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Age
Full Analysis Set

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		18 (36.0%)	5 (8.2%)	23 (20.7%)
Number of patients without events		32 (64.0%)	56 (91.8%)	88 (79.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.300 [2.136, 18.585]			
Stratified OR, 95% CI	5.192 [1.745, 15.447]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.392 [1.755, 10.994]			
Stratified RR, 95% CI	3.036 [1.322, 6.972]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.278 [0.128, 0.428]			
Stratified ARR, 95% CI (CMH method)	0.280 [0.131, 0.429]			
Test on Differences [c]				
Unstratified p-value	0.0003			
Stratified p-value	0.0003			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with LDL-C <70 mg/dL at Week 12 by Age
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.2030
>= 65 vs. < 65		0.2334	0.6907	0.1999	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia,
LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, LR=likelihood ratio.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by CVD Risk Category
Full Analysis Set

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 60)	Ezetimibe (N= 62)	Total (N= 122)
Number of patients at risk		60 (100.0%)	62 (100.0%)	122 (100.0%)
Number of patients with events		20 (33.3%)	9 (14.5%)	29 (23.8%)
Number of patients without events		40 (66.7%)	53 (85.5%)	93 (76.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.944 [1.212, 7.151]			
Stratified OR, 95% CI	2.766 [1.105, 6.921]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.296 [1.138, 4.634]			
Stratified RR, 95% CI	2.022 [1.001, 4.085]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.188 [0.040, 0.336]			
Stratified ARR, 95% CI (CMH method)	0.184 [0.035, 0.332]			
Test on Differences [c]				
Unstratified p-value	0.0146			
Stratified p-value	0.0174			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by CVD Risk Category
Full Analysis Set

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		9 (18.8%)	1 (2.1%)	10 (10.5%)
Number of patients without events		39 (81.3%)	46 (97.9%)	85 (89.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	10.615 [1.288, 87.521]			
Stratified OR, 95% CI	6.118 [0.964, 38.832]			
Relative Risk [a]				
Unstratified RR, 95% CI	8.812 [1.162, 66.862]			
Stratified RR, 95% CI	4.919 [0.886, 27.296]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.166 [0.048, 0.284]			
Stratified ARR, 95% CI (CMH method)	0.166 [0.048, 0.284]			
Test on Differences [c]				
Unstratified p-value	0.0154			
Stratified p-value	0.0092			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with LDL-C <70 mg/dL at Week 12 by CVD Risk Category
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.1574
Multiple CV risk factors vs. ASCVD and/or HeFH		0.0203	0.0639	0.2190	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia,
LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, LR=likelihood ratio.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Baseline Statin Intensity I
Full Analysis Set

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 66)	Ezetimibe (N= 70)	Total (N= 136)
Number of patients at risk		66 (100.0%)	70 (100.0%)	136 (100.0%)
Number of patients with events		17 (25.8%)	3 (4.3%)	20 (14.7%)
Number of patients without events		49 (74.2%)	67 (95.7%)	116 (85.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	7.748 [2.151, 27.909]			
Stratified OR, 95% CI	6.758 [1.939, 23.551]			
Relative Risk [a]				
Unstratified RR, 95% CI	6.010 [1.846, 19.567]			
Stratified RR, 95% CI	4.871 [1.626, 14.592]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.215 [0.099, 0.330]			
Stratified ARR, 95% CI (CMH method)	0.218 [0.103, 0.332]			
Test on Differences [c]				
Unstratified p-value	0.0005			
Stratified p-value	0.0003			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Baseline Statin Intensity I
Full Analysis Set

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		12 (28.6%)	7 (17.9%)	19 (23.5%)
Number of patients without events		30 (71.4%)	32 (82.1%)	62 (76.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.829 [0.635, 5.261]			
Stratified OR, 95% CI	1.843 [0.619, 5.488]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.592 [0.698, 3.629]			
Stratified RR, 95% CI	1.530 [0.682, 3.431]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.106 [-0.076, 0.288]			
Stratified ARR, 95% CI (CMH method)	0.106 [-0.073, 0.284]			
Test on Differences [c]				
Unstratified p-value	0.2596			
Stratified p-value	0.2586			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with LDL-C <70 mg/dL at Week 12 by Baseline Statin Intensity I
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.0575
High Intensity Statin vs. Other		0.0029	0.0301	0.0705	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia,
LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, LR=likelihood ratio.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Baseline Statin Intensity II
Full Analysis Set

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 38)	Total (N= 71)
Number of patients at risk		33 (100.0%)	38 (100.0%)	71 (100.0%)
Number of patients with events		10 (30.3%)	3 (7.9%)	13 (18.3%)
Number of patients without events		23 (69.7%)	35 (92.1%)	58 (81.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.072 [1.259, 20.433]			
Stratified OR, 95% CI	5.090 [1.283, 20.184]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.838 [1.153, 12.782]			
Stratified RR, 95% CI	3.369 [1.137, 9.987]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.224 [0.045, 0.403]			
Stratified ARR, 95% CI (CMH method)	0.226 [0.054, 0.397]			
Test on Differences [c]				
Unstratified p-value	0.0286			
Stratified p-value	0.0117			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Baseline Statin Intensity II
Full Analysis Set

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		12 (28.6%)	7 (17.9%)	19 (23.5%)
Number of patients without events		30 (71.4%)	32 (82.1%)	62 (76.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.829 [0.635, 5.261]			
Stratified OR, 95% CI	1.843 [0.619, 5.488]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.592 [0.698, 3.629]			
Stratified RR, 95% CI	1.530 [0.682, 3.431]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.106 [-0.076, 0.288]			
Stratified ARR, 95% CI (CMH method)	0.106 [-0.073, 0.284]			
Test on Differences [c]				
Unstratified p-value	0.2596			
Stratified p-value	0.2586			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Baseline Statin Intensity II
Full Analysis Set

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		7 (21.2%)	0	7 (10.8%)
Number of patients without events		26 (78.8%)	32 (100.0%)	58 (89.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	18.396 [1.004, 337.13]			
Stratified OR, 95% CI	9.691 [1.138, 82.522]			
Relative Risk [a]				
Unstratified RR, 95% CI	14.559 [0.866, 244.83]			
Stratified RR, 95% CI	7.705 [1.016, 58.437]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.212 [0.073, 0.352]			
Stratified ARR, 95% CI (CMH method)	0.211 [0.072, 0.350]			
Test on Differences [c]				
Unstratified p-value	0.0110			
Stratified p-value	0.0069			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with LDL-C <70 mg/dL at Week 12 by Baseline Statin Intensity II
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.0429
High Intensity Statin vs. Other Intensity Statin		0.0284	0.2073	0.2368	
None vs. Other Intensity Statin		0.0284	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia,
LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, LR=likelihood ratio.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Race
Full Analysis Set

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 85)	Ezetimibe (N= 91)	Total (N= 176)
Number of patients at risk		85 (100.0%)	91 (100.0%)	176 (100.0%)
Number of patients with events		24 (28.2%)	8 (8.8%)	32 (18.2%)
Number of patients without events		61 (71.8%)	83 (91.2%)	144 (81.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.082 [1.717, 9.702]			
Stratified OR, 95% CI	3.580 [1.355, 9.464]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.212 [1.527, 6.755]			
Stratified RR, 95% CI	2.335 [1.107, 4.925]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.194 [0.082, 0.306]			
Stratified ARR, 95% CI (CMH method)	0.204 [0.094, 0.314]			
Test on Differences [c]				
Unstratified p-value	0.0008			
Stratified p-value	0.0004			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Race
Full Analysis Set

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		5 (21.7%)	2 (11.1%)	7 (17.1%)
Number of patients without events		18 (78.3%)	16 (88.9%)	34 (82.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.222 [0.377, 13.082]			
Stratified OR, 95% CI	1.632 [0.255, 10.434]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.957 [0.428, 8.940]			
Stratified RR, 95% CI	1.208 [0.346, 4.216]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.106 [-0.116, 0.329]			
Stratified ARR, 95% CI (CMH method)	0.066 [-0.164, 0.297]			
Test on Differences [c]				
Unstratified p-value	0.4376			
Stratified p-value	0.5732			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with LDL-C <70 mg/dL at Week 12 by Race
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.5782
non-White vs. White		0.0021	0.7540	0.5658	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia,
LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, LR=likelihood ratio.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Baseline LDL-C Category
Full Analysis Set

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 39)	Ezetimibe (N= 38)	Total (N= 77)
Number of patients at risk		39 (100.0%)	38 (100.0%)	77 (100.0%)
Number of patients with events		16 (41.0%)	8 (21.1%)	24 (31.2%)
Number of patients without events		23 (59.0%)	30 (78.9%)	53 (68.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.609 [0.952, 7.146]			
Stratified OR, 95% CI	2.002 [0.676, 5.933]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.949 [0.947, 4.010]			
Stratified RR, 95% CI	1.279 [0.670, 2.439]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.200 [-0.002, 0.401]			
Stratified ARR, 95% CI (CMH method)	0.187 [-0.018, 0.392]			
Test on Differences [c]				
Unstratified p-value	0.0585			
Stratified p-value	0.0775			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Baseline LDL-C Category
Full Analysis Set

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		10 (32.3%)	2 (4.4%)	12 (15.8%)
Number of patients without events		21 (67.7%)	43 (95.6%)	64 (84.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	10.238 [2.056, 50.981]			
Stratified OR, 95% CI	7.121 [1.689, 30.029]			
Relative Risk [a]				
Unstratified RR, 95% CI	7.258 [1.707, 30.868]			
Stratified RR, 95% CI	4.805 [1.411, 16.364]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.278 [0.103, 0.453]			
Stratified ARR, 95% CI (CMH method)	0.284 [0.108, 0.459]			
Test on Differences [c]				
Unstratified p-value	0.0025			
Stratified p-value	0.0012			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by Baseline LDL-C Category
Full Analysis Set

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		3 (7.9%)	0	3 (4.7%)
Number of patients without events		35 (92.1%)	26 (100.0%)	61 (95.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.225 [0.259, 105.54]			
Stratified OR, 95% CI	4.200 [0.190, 93.081]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.846 [0.261, 90.059]			
Stratified RR, 95% CI	3.500 [0.205, 59.848]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.079 [-0.007, 0.165]			
Stratified ARR, 95% CI (CMH method)	0.063 [-0.016, 0.143]			
Test on Differences [c]				
Unstratified p-value	0.2649			
Stratified p-value	0.2135			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with LDL-C <70 mg/dL at Week 12 by Baseline LDL-C Category
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.1170
130 - < 160 vs. < 130		0.0700	0.0405	0.1111	
>= 160 vs. < 130		0.0700	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia,
LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, LR=likelihood ratio.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by History of Diabetes
Full Analysis Set

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 49)	Ezetimibe (N= 61)	Total (N= 110)
Number of patients at risk		49 (100.0%)	61 (100.0%)	110 (100.0%)
Number of patients with events		14 (28.6%)	7 (11.5%)	21 (19.1%)
Number of patients without events		35 (71.4%)	54 (88.5%)	89 (80.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.086 [1.133, 8.405]			
Stratified OR, 95% CI	3.227 [1.071, 9.723]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.490 [1.090, 5.685]			
Stratified RR, 95% CI	2.104 [0.927, 4.777]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.171 [0.021, 0.321]			
Stratified ARR, 95% CI (CMH method)	0.184 [0.039, 0.329]			
Test on Differences [c]				
Unstratified p-value	0.0234			
Stratified p-value	0.0135			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by History of Diabetes
Full Analysis Set

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		15 (25.4%)	3 (6.3%)	18 (16.8%)
Number of patients without events		44 (74.6%)	45 (93.8%)	89 (83.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.114 [1.383, 18.903]			
Stratified OR, 95% CI	4.123 [1.137, 14.950]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.068 [1.250, 13.233]			
Stratified RR, 95% CI	2.910 [1.002, 8.452]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.192 [0.061, 0.322]			
Stratified ARR, 95% CI (CMH method)	0.179 [0.051, 0.308]			
Test on Differences [c]				
Unstratified p-value	0.0094			
Stratified p-value	0.0125			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with LDL-C <70 mg/dL at Week 12 by History of Diabetes
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.4943
No vs. Yes		0.0304	0.3591	0.5040	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia,
LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, LR=likelihood ratio.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by BMI
Full Analysis Set

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		6 (46.2%)	1 (7.7%)	7 (26.9%)
Number of patients without events		7 (53.8%)	12 (92.3%)	19 (73.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	10.286 [1.018, 103.95]			
Stratified OR, 95% CI	4.504 [0.717, 28.272]			
Relative Risk [a]				
Unstratified RR, 95% CI	6.000 [0.835, 43.131]			
Stratified RR, 95% CI	2.516 [0.688, 9.197]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.385 [0.077, 0.692]			
Stratified ARR, 95% CI (CMH method)	0.495 [0.149, 0.842]			
Test on Differences [c]				
Unstratified p-value	0.0730			
Stratified p-value	0.0166			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by BMI
Full Analysis Set

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		6 (22.2%)	2 (5.4%)	8 (12.5%)
Number of patients without events		21 (77.8%)	35 (94.6%)	56 (87.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.000 [0.923, 27.078]			
Stratified OR, 95% CI	4.135 [0.893, 19.142]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.111 [0.898, 18.825]			
Stratified RR, 95% CI	2.617 [0.833, 8.219]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.168 [-0.005, 0.341]			
Stratified ARR, 95% CI (CMH method)	0.175 [0.013, 0.336]			
Test on Differences [c]				
Unstratified p-value	0.0612			
Stratified p-value	0.0312			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with LDL-C <70 mg/dL at Week 12 by BMI
Full Analysis Set

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 68)	Ezetimibe (N= 59)	Total (N= 127)
Number of patients at risk		68 (100.0%)	59 (100.0%)	127 (100.0%)
Number of patients with events		17 (25.0%)	7 (11.9%)	24 (18.9%)
Number of patients without events		51 (75.0%)	52 (88.1%)	103 (81.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.476 [0.947, 6.475]			
Stratified OR, 95% CI	2.152 [0.788, 5.874]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.107 [0.939, 4.728]			
Stratified RR, 95% CI	1.746 [0.798, 3.821]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.131 [-0.001, 0.263]			
Stratified ARR, 95% CI (CMH method)	0.129 [-0.002, 0.259]			
Test on Differences [c]				
Unstratified p-value	0.0593			
Stratified p-value	0.0614			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with LDL-C <70 mg/dL at Week 12 by BMI
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.4876
25 - < 30 vs. < 25		0.0750	0.7652	0.7661	
>= 30 vs. < 25		0.0750	0.6722	0.3360	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia,
LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, LR=likelihood ratio.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data)
Full Analysis Set

Statistic	FDC vs. Ezetimibe	FDC (N= 108)	Ezetimibe (N= 109)
Observed data:			
LDL-C at Baseline:			
n		108	109
Mean		152.02	147.45
Standard deviation		38.869	38.723
Percent Change from Baseline:			
n		105	103
Mean (SE)		-32.62 (2.566)	-21.79 (2.123)
Standard deviation		26.295	21.542
Median		-38.27	-24.51
Minimum		-83.5	-68.9
Maximum		43.3	47.0
Imputed data:			
n		108	109
LS Mean for Percent Change from Baseline (SE)		-31.48 (2.497)	-21.01 (2.039)
95%-CI		[-36.37 , -26.59]	[-25.00 , -17.01]
Difference of LS Means (SE)	-10.47 (3.224)		
95%-CI	[-16.79 , -4.15]		
p-value	0.0012		
Hedges' g (SE)	-0.44 (0.137)		
95%-CI	[-0.71 , -0.17]		
p-value	0.0015		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Gender
Full Analysis Set

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)
Observed data:			
LDL-C at Baseline:			
n		50	52
Mean		148.25	135.64
Standard deviation		33.437	35.841
Percent Change from Baseline:			
n		48	49
Mean (SE)		-34.37 (3.395)	-22.91 (3.074)
Standard deviation		23.521	21.521
Median		-38.42	-24.43
Minimum		-70.3	-68.9
Maximum		30.5	39.4
Imputed data:			
n		50	52
LS Mean for Percent Change from Baseline (SE)		-32.53 (3.402)	-21.91 (3.065)
95%-CI		[-39.20 , -25.86]	[-27.91 , -15.90]
Difference of LS Means (SE)	-10.62 (4.591)		
95%-CI	[-19.62 , -1.62]		
p-value	0.0207		
Hedges' g (SE)	-0.46 (0.199)		
95%-CI	[-0.85 , -0.06]		
p-value	0.0239		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Gender
Full Analysis Set

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 58)	Ezetimibe (N= 57)
Observed data:			
LDL-C at Baseline:			
n		58	57
Mean		155.27	158.22
Standard deviation		43.032	38.399
Percent Change from Baseline:			
n		57	54
Mean (SE)		-31.15 (3.781)	-20.78 (2.955)
Standard deviation		28.547	21.712
Median		-38.27	-25.35
Minimum		-83.5	-65.3
Maximum		43.3	47.0
Imputed data:			
n		58	57
LS Mean for Percent Change from Baseline (SE)		-30.95 (3.693)	-19.87 (2.720)
95%-CI		[-38.18 , -23.71]	[-25.20 , -14.54]
Difference of LS Means (SE)	-11.08 (4.582)		
95%-CI	[-20.06 , -2.10]		
p-value	0.0156		
Hedges' g (SE)	-0.45 (0.188)		
95%-CI	[-0.82 , -0.07]		
p-value	0.0190		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Gender
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Gender	Convergence criteria met				0.9275
Female vs. Male		0.0351	0.6626	0.9275	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other),subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Age
Full Analysis Set

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 58)	Ezetimibe (N= 48)
Observed data:			
LDL-C at Baseline:			
n		58	48
Mean		155.34	154.75
Standard deviation		41.673	44.371
Percent Change from Baseline:			
n		55	45
Mean (SE)		-31.14 (3.295)	-26.77 (2.900)
Standard deviation		24.436	19.452
Median		-35.31	-27.53
Minimum		-70.5	-68.9
Maximum		30.5	37.6
Imputed data:			
n		58	48
LS Mean for Percent Change from Baseline (SE)		-28.86 (3.135)	-25.63 (3.071)
95%-CI		[-35.00 , -22.72]	[-31.65 , -19.61]
Difference of LS Means (SE)	-3.23 (4.396)		
95%-CI	[-11.84 , 5.39]		
p-value	0.4629		
Hedges' g (SE)	-0.14 (0.194)		
95%-CI	[-0.53 , 0.24]		
p-value	0.4692		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Age
Full Analysis Set

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)
Observed data:			
LDL-C at Baseline:			
n		50	61
Mean		148.16	141.70
Standard deviation		35.363	32.873
Percent Change from Baseline:			
n		50	58
Mean (SE)		-34.26 (4.011)	-17.93 (2.947)
Standard deviation		28.360	22.440
Median		-43.27	-19.32
Minimum		-83.5	-65.3
Maximum		43.3	47.0
Imputed data:			
n		50	61
LS Mean for Percent Change from Baseline (SE)		-33.50 (4.056)	-17.36 (2.719)
95%-CI		[-41.65 , -25.35]	[-22.81 , -11.92]
Difference of LS Means (SE)	-16.14 (4.892)		
95%-CI	[-25.86 , -6.41]		
p-value	0.0014		
Hedges' g (SE)	-0.64 (0.194)		
95%-CI	[-1.03 , -0.26]		
p-value	0.0012		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Table 1002FDC.053b.102.1.2.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Age
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Age (years)	Convergence criteria met				0.0458
>= 65 vs. < 65		0.4332	0.0428	0.0458	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other),subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by CVD Risk Category
Full Analysis Set

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 60)	Ezetimibe (N= 62)
Observed data:			
LDL-C at Baseline:			
n		60	62
Mean		148.22	138.82
Standard deviation		44.055	39.218
Percent Change from Baseline:			
n		57	58
Mean (SE)		-38.48 (2.777)	-23.22 (3.056)
Standard deviation		20.963	23.271
Median		-42.86	-26.11
Minimum		-70.5	-68.9
Maximum		24.2	47.0
Imputed data:			
n		60	62
LS Mean for Percent Change from Baseline (SE)		-35.90 (2.815)	-22.30 (2.973)
95%-CI		[-41.41 , -30.38]	[-28.13 , -16.47]
Difference of LS Means (SE)	-13.59 (4.100)		
95%-CI	[-21.63 , -5.56]		
p-value	0.0009		
Hedges' g (SE)	-0.60 (0.184)		
95%-CI	[-0.96 , -0.23]		
p-value	0.0015		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline statin dose intensity (high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by CVD Risk Category
Full Analysis Set

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)
Observed data:			
LDL-C at Baseline:			
n		48	47
Mean		156.77	158.83
Standard deviation		31.009	35.330
Percent Change from Baseline:			
n		48	45
Mean (SE)		-25.67 (4.367)	-19.96 (2.860)
Standard deviation		30.256	19.185
Median		-37.36	-22.35
Minimum		-83.5	-61.5
Maximum		43.3	37.6
Imputed data:			
n		48	47
LS Mean for Percent Change from Baseline (SE)		-26.13 (4.356)	-19.26 (2.711)
95%-CI		[-34.67 , -17.59]	[-24.57 , -13.94]
Difference of LS Means (SE)	-6.88 (5.128)		
95%-CI	[-16.93 , 3.18]		
p-value	0.1800		
Hedges' g (SE)	-0.27 (0.204)		
95%-CI	[-0.68 , 0.13]		
p-value	0.1876		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline statin dose intensity (high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Table 1002FDC.053b.102.1.3.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by CVD Risk Category
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
CVD Risk Category	Convergence criteria met				0.3205
Multiple CV risk factors vs. ASCVD and/or HeFH		0.0022	0.2148	0.3205	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol.
[a] Two-sided t-test p-value from ANCOVA including treatment, baseline statin dose intensity (high statin intensity vs other), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline Statin Intensity I
Full Analysis Set

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 66)	Ezetimibe (N= 70)
Observed data:			
LDL-C at Baseline:			
n		66	70
Mean		156.73	148.33
Standard deviation		38.619	35.359
Percent Change from Baseline:			
n		64	66
Mean (SE)		-32.94 (3.324)	-20.20 (2.541)
Standard deviation		26.592	20.645
Median		-38.34	-22.99
Minimum		-70.3	-65.3
Maximum		43.3	47.0
Imputed data:			
n		66	70
LS Mean for Percent Change from Baseline (SE)		-31.56 (3.216)	-19.78 (2.487)
95%-CI		[-37.86 , -25.25]	[-24.65 , -14.91]
Difference of LS Means (SE)	-11.78 (4.070)		
95%-CI	[-19.75 , -3.80]		
p-value	0.0038		
Hedges' g (SE)	-0.50 (0.173)		
95%-CI	[-0.84 , -0.15]		
p-value	0.0047		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline Statin Intensity I
Full Analysis Set

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)
Observed data:			
LDL-C at Baseline:			
n		42	39
Mean		144.62	145.87
Standard deviation		38.556	44.580
Percent Change from Baseline:			
n		41	37
Mean (SE)		-32.13 (4.083)	-24.64 (3.793)
Standard deviation		26.145	23.071
Median		-38.27	-28.92
Minimum		-83.5	-68.9
Maximum		30.5	20.4
Imputed data:			
n		42	39
LS Mean for Percent Change from Baseline (SE)		-31.35 (4.029)	-23.29 (3.561)
95%-CI		[-39.25 , -23.46]	[-30.27 , -16.31]
Difference of LS Means (SE)	-8.07 (5.374)		
95%-CI	[-18.60 , 2.47]		
p-value	0.1333		
Hedges' g (SE)	-0.33 (0.222)		
95%-CI	[-0.77 , 0.11]		
p-value	0.1425		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Table 1002FDC.053b.102.1.4.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline Statin Intensity I
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Baseline Statin Dose Intensity I	Convergence criteria met				0.5825
High Intensity Statin vs. Other		0.0041	0.3834	0.5825	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol.
[a] Two-sided t-test p-value from ANCOVA including treatment, baseline CVD risk category (ASCVD and/or HeFH vs. multiple cardiovascular risk factors), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline Statin Intensity II
Full Analysis Set

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 38)
Observed data:			
LDL-C at Baseline:			
n		33	38
Mean		142.11	134.46
Standard deviation		31.614	23.137
Percent Change from Baseline:			
n		31	36
Mean (SE)		-26.49 (4.792)	-18.30 (4.148)
Standard deviation		26.682	24.888
Median		-28.06	-19.47
Minimum		-70.3	-65.3
Maximum		40.1	47.0
Imputed data:			
n		33	38
LS Mean for Percent Change from Baseline (SE)		-24.60 (4.503)	-18.66 (4.039)
95%-CI		[-33.42 , -15.77]	[-26.58 , -10.74]
Difference of LS Means (SE)	-5.94 (6.058)		
95%-CI	[-17.81 , 5.94]		
p-value	0.3270		
Hedges' g (SE)	-0.23 (0.236)		
95%-CI	[-0.70 , 0.24]		
p-value	0.3300		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline Statin Intensity II
Full Analysis Set

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)
Observed data:			
LDL-C at Baseline:			
n		42	39
Mean		144.62	145.87
Standard deviation		38.556	44.580
Percent Change from Baseline:			
n		41	37
Mean (SE)		-32.13 (4.083)	-24.64 (3.793)
Standard deviation		26.145	23.071
Median		-38.27	-28.92
Minimum		-83.5	-68.9
Maximum		30.5	20.4
Imputed data:			
n		42	39
LS Mean for Percent Change from Baseline (SE)		-31.35 (4.029)	-23.29 (3.561)
95%-CI		[-39.25 , -23.46]	[-30.27 , -16.31]
Difference of LS Means (SE)	-8.07 (5.374)		
95%-CI	[-18.60 , 2.47]		
p-value	0.1333		
Hedges' g (SE)	-0.33 (0.222)		
95%-CI	[-0.77 , 0.11]		
p-value	0.1425		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline Statin Intensity II
Full Analysis Set

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)
Observed data:			
LDL-C at Baseline:			
n		33	32
Mean		171.35	164.80
Standard deviation		39.863	40.351
Percent Change from Baseline:			
n		33	30
Mean (SE)		-39.00 (4.426)	-22.48 (2.568)
Standard deviation		25.428	14.068
Median		-45.26	-24.38
Minimum		-67.3	-41.4
Maximum		43.3	6.2
Imputed data:			
n		33	32
LS Mean for Percent Change from Baseline (SE)		-38.74 (4.431)	-21.41 (2.535)
95%-CI		[-47.77 , -29.71]	[-26.59 , -16.22]
Difference of LS Means (SE)	-17.33 (5.111)		
95%-CI	[-27.60 , -7.07]		
p-value	0.0014		
Hedges' g (SE)	-0.83 (0.256)		
95%-CI	[-1.34 , -0.31]		
p-value	0.0020		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline Statin Intensity II
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Baseline Statin Dose Intensity II	Convergence criteria met				0.3363
High Intensity Statin vs. Other Intensity Statin		0.2779	0.4562	0.8059	
None vs. Other Intensity Statin		0.2779	0.9968	0.1623	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol.
[a] Two-sided t-test p-value from ANCOVA including treatment, baseline CVD risk category (ASCVD and/or HeFH vs. multiple cardiovascular risk factors), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Race
Full Analysis Set

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 85)	Ezetimibe (N= 91)
Observed data:			
LDL-C at Baseline:			
n		85	91
Mean		151.39	147.86
Standard deviation		38.000	40.517
Percent Change from Baseline:			
n		82	86
Mean (SE)		-32.80 (2.831)	-22.49 (2.265)
Standard deviation		25.634	21.001
Median		-38.76	-25.35
Minimum		-70.3	-68.9
Maximum		43.3	39.4
Imputed data:			
n		85	91
LS Mean for Percent Change from Baseline (SE)		-31.66 (2.738)	-21.47 (2.197)
95%-CI		[-37.02 , -26.29]	[-25.77 , -17.16]
Difference of LS Means (SE)	-10.19 (3.514)		
95%-CI	[-17.08 , -3.30]		
p-value	0.0037		
Hedges' g (SE)	-0.44 (0.152)		
95%-CI	[-0.74 , -0.14]		
p-value	0.0044		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Race
Full Analysis Set

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)
Observed data:			
LDL-C at Baseline:			
n		23	18
Mean		154.33	145.39
Standard deviation		42.747	28.805
Percent Change from Baseline:			
n		23	17
Mean (SE)		-32.00 (6.075)	-18.27 (5.938)
Standard deviation		29.134	24.482
Median		-30.79	-17.24
Minimum		-83.5	-65.3
Maximum		40.1	47.0
Imputed data:			
n		23	18
LS Mean for Percent Change from Baseline (SE)		-30.19 (6.436)	-19.36 (6.110)
95%-CI		[-43.64 , -16.74]	[-32.21 , -6.51]
Difference of LS Means (SE)	-10.83 (9.076)		
95%-CI	[-29.21 , 7.56]		
p-value	0.2403		
Hedges' g (SE)	-0.37 (0.311)		
95%-CI	[-1.00 , 0.26]		
p-value	0.2436		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Table 1002FDC.053b.102.1.6.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Race
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Race	Convergence criteria met				0.9172
non-White vs. White		0.0044	0.7260	0.9172	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other),subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline LDL-C Category
Full Analysis Set

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 39)	Ezetimibe (N= 38)
Observed data:			
LDL-C at Baseline:			
n		39	38
Mean		116.00	113.14
Standard deviation		10.803	10.284
Percent Change from Baseline:			
n		38	36
Mean (SE)		-26.75 (4.124)	-17.85 (4.221)
Standard deviation		25.422	25.327
Median		-30.10	-22.72
Minimum		-63.4	-68.9
Maximum		43.3	47.0
Imputed data:			
n		39	38
LS Mean for Percent Change from Baseline (SE)		-26.45 (4.139)	-17.91 (4.093)
95%-CI		[-34.56 , -18.34]	[-25.94 , -9.89]
Difference of LS Means (SE)	-8.53 (5.846)		
95%-CI	[-19.99 , 2.92]		
p-value	0.1444		
Hedges' g (SE)	-0.33 (0.227)		
95%-CI	[-0.78 , 0.12]		
p-value	0.1497		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline LDL-C Category
Full Analysis Set

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)
Observed data:			
LDL-C at Baseline:			
n		31	45
Mean		142.66	144.53
Standard deviation		7.605	9.039
Percent Change from Baseline:			
n		30	42
Mean (SE)		-34.47 (4.900)	-20.91 (3.022)
Standard deviation		26.837	19.582
Median		-43.00	-21.14
Minimum		-83.5	-65.3
Maximum		24.2	37.6
Imputed data:			
n		31	45
LS Mean for Percent Change from Baseline (SE)		-32.94 (5.103)	-19.82 (2.918)
95%-CI		[-42.94 , -22.94]	[-25.54 , -14.10]
Difference of LS Means (SE)	-13.12 (5.888)		
95%-CI	[-24.66 , -1.58]		
p-value	0.0258		
Hedges' g (SE)	-0.55 (0.235)		
95%-CI	[-1.02 , -0.08]		
p-value	0.0218		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline LDL-C Category
Full Analysis Set

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)
Observed data:			
LDL-C at Baseline:			
n		38	26
Mean		196.62	202.63
Standard deviation		26.805	34.728
Percent Change from Baseline:			
n		37	25
Mean (SE)		-37.16 (4.327)	-28.96 (3.485)
Standard deviation		26.318	17.423
Median		-41.08	-33.88
Minimum		-70.5	-63.8
Maximum		40.1	6.2
Imputed data:			
n		38	26
LS Mean for Percent Change from Baseline (SE)		-36.53 (4.373)	-27.07 (3.533)
95%-CI		[-45.10 , -27.96]	[-33.99 , -20.14]
Difference of LS Means (SE)	-9.46 (5.634)		
95%-CI	[-20.50 , 1.58]		
p-value	0.0932		
Hedges' g (SE)	-0.39 (0.254)		
95%-CI	[-0.90 , 0.11]		
p-value	0.1264		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Table 1002FDC.053b.102.1.7.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by Baseline LDL-C Category
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Baseline LDL-C (mg/dL)	Convergence criteria met				0.6914
130 - < 160 vs. < 130		0.1087	0.3916	0.4985	
>= 160 vs. < 130		0.1087	0.3955	0.9863	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other),subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by History of Diabetes
Full Analysis Set

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 49)	Ezetimibe (N= 61)
Observed data:			
LDL-C at Baseline:			
n		49	61
Mean		145.42	142.11
Standard deviation		34.196	34.565
Percent Change from Baseline:			
n		48	57
Mean (SE)		-31.95 (3.854)	-20.58 (2.984)
Standard deviation		26.702	22.529
Median		-37.70	-21.37
Minimum		-83.5	-68.9
Maximum		43.3	39.4
Imputed data:			
n		49	61
LS Mean for Percent Change from Baseline (SE)		-31.56 (3.780)	-19.67 (2.890)
95%-CI		[-38.97 , -24.15]	[-25.33 , -14.00]
Difference of LS Means (SE)	-11.89 (4.761)		
95%-CI	[-21.22 , -2.56]		
p-value	0.0125		
Hedges' g (SE)	-0.48 (0.193)		
95%-CI	[-0.87 , -0.10]		
p-value	0.0137		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by History of Diabetes
Full Analysis Set

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)
Observed data:			
LDL-C at Baseline:			
n		59	48
Mean		157.50	154.23
Standard deviation		41.857	42.854
Percent Change from Baseline:			
n		57	46
Mean (SE)		-33.19 (3.467)	-23.30 (3.007)
Standard deviation		26.172	20.397
Median		-39.58	-26.94
Minimum		-70.5	-65.3
Maximum		40.1	47.0
Imputed data:			
n		59	48
LS Mean for Percent Change from Baseline (SE)		-31.71 (3.390)	-22.51 (2.905)
95%-CI		[-38.35 , -25.07]	[-28.20 , -16.81]
Difference of LS Means (SE)	-9.20 (4.472)		
95%-CI	[-17.97 , -0.44]		
p-value	0.0396		
Hedges' g (SE)	-0.39 (0.195)		
95%-CI	[-0.77 , -0.00]		
p-value	0.0492		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Table 1002FDC.053b.102.1.8.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by History of Diabetes
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
History of Diabetes	Convergence criteria met				0.5785
No vs. Yes		0.0080	0.8983	0.5785	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other),subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by BMI
Full Analysis Set

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)
Observed data:			
LDL-C at Baseline:			
n		13	13
Mean		144.54	165.12
Standard deviation		37.764	55.839
Percent Change from Baseline:			
n		13	13
Mean (SE)		-40.61 (7.334)	-22.13 (7.650)
Standard deviation		26.442	27.581
Median		-45.26	-30.60
Minimum		-83.5	-63.8
Maximum		24.2	47.0
Imputed data:			
n		13	13
LS Mean for Percent Change from Baseline (SE)		-40.71 (7.598)	-19.81 (7.842)
95%-CI		[-57.19 , -24.23]	[-36.89 , -2.73]
Difference of LS Means (SE)	-20.90 (11.177)		
95%-CI	[-43.97 , 2.18]		
p-value	0.0739		
Hedges' g (SE)	-0.73 (0.393)		
95%-CI	[-1.54 , 0.08]		
p-value	0.0767		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by BMI
Full Analysis Set

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)
Observed data:			
LDL-C at Baseline:			
n		27	37
Mean		145.57	132.23
Standard deviation		32.480	25.453
Percent Change from Baseline:			
n		26	35
Mean (SE)		-24.51 (5.546)	-17.91 (3.469)
Standard deviation		28.277	20.525
Median		-29.27	-24.51
Minimum		-59.6	-41.3
Maximum		40.1	39.4
Imputed data:			
n		27	37
LS Mean for Percent Change from Baseline (SE)		-23.79 (5.232)	-17.88 (3.333)
95%-CI		[-34.05 , -13.54]	[-24.41 , -11.34]
Difference of LS Means (SE)	-5.92 (6.219)		
95%-CI	[-18.10 , 6.27]		
p-value	0.3416		
Hedges' g (SE)	-0.25 (0.251)		
95%-CI	[-0.75 , 0.25]		
p-value	0.3241		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by BMI
Full Analysis Set

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 68)	Ezetimibe (N= 59)
Observed data:			
LDL-C at Baseline:			
n		68	59
Mean		156.01	153.10
Standard deviation		41.282	38.661
Percent Change from Baseline:			
n		66	55
Mean (SE)		-34.25 (3.084)	-24.18 (2.785)
Standard deviation		25.058	20.655
Median		-39.70	-24.43
Minimum		-70.5	-68.9
Maximum		43.3	20.4
Imputed data:			
n		68	59
LS Mean for Percent Change from Baseline (SE)		-32.62 (2.955)	-22.64 (2.824)
95%-CI		[-38.41 , -26.83]	[-28.17 , -17.10]
Difference of LS Means (SE)	-9.98 (4.080)		
95%-CI	[-17.98 , -1.98]		
p-value	0.0144		
Hedges' g (SE)	-0.43 (0.179)		
95%-CI	[-0.78 , -0.07]		
p-value	0.0181		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were imputed through multiple imputation using a pattern mixture model (PMM) accounting for treatment adherence.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Imputed Data) by BMI
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
BMI (kg/m^2)	Convergence criteria met				0.1832
25 - < 30 vs. < 25		0.0236	0.9448	0.1656	
>= 30 vs. < 25		0.0236	0.7311	0.2697	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other),subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data)
Full Analysis Set

Statistic	FDC vs. Ezitimibe	FDC (N= 108)	Ezetimibe (N= 109)
LDL-C at Baseline:			
n		105	103
Mean		152.06	148.14
Standard deviation		38.962	39.491
Percent Change from Baseline:			
n		105	103
Mean (SE)		-32.62 (2.566)	-21.79 (2.123)
Standard deviation		26.295	21.542
Median		-38.27	-24.51
Minimum		-83.5	-68.9
Maximum		43.3	47.0
LS Mean for Percent Change from Baseline (SE)		-32.47 (2.500)	-21.90 (2.075)
95%-CI		[-37.43 , -27.51]	[-26.02 , -17.79]
Difference of LS Means (SE)	-10.56 (3.250)		
95%-CI	[-16.97 , -4.16]		
p-value	0.0014		
Hedges' g (SE)	-0.45 (0.140)		
95%-CI	[-0.72 , -0.17]		
p-value	0.0016		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Gender
Full Analysis Set

Gender: Male

Statistic	FDC vs. Ezitimibe	FDC (N= 50)	Ezetimibe (N= 52)
LDL-C at Baseline:			
n		48	49
Mean		147.53	136.19
Standard deviation		33.170	36.635
Percent Change from Baseline:			
n		48	49
Mean (SE)		-34.37 (3.395)	-22.91 (3.074)
Standard deviation		23.521	21.521
Median		-38.42	-24.43
Minimum		-70.3	-68.9
Maximum		30.5	39.4
LS Mean for Percent Change from Baseline (SE)		-34.00 (3.361)	-22.72 (3.066)
95%-CI		[-40.76 , -27.23]	[-28.88 , -16.55]
Difference of LS Means (SE)	-11.28 (4.567)		
95%-CI	[-20.35 , -2.21]		
p-value	0.0154		
Hedges' g (SE)	-0.50 (0.205)		
95%-CI	[-0.91 , -0.09]		
p-value	0.0164		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Gender
Full Analysis Set

Gender: Female

Statistic	FDC vs. Ezitimibe	FDC (N= 58)	Ezetimibe (N= 57)
LDL-C at Baseline:			
n		57	54
Mean		155.87	158.98
Standard deviation		43.168	39.168
Percent Change from Baseline:			
n		57	54
Mean (SE)		-31.15 (3.781)	-20.78 (2.955)
Standard deviation		28.547	21.712
Median		-38.27	-25.35
Minimum		-83.5	-65.3
Maximum		43.3	47.0
LS Mean for Percent Change from Baseline (SE)		-31.55 (3.715)	-20.77 (2.819)
95%-CI		[-38.99 , -24.10]	[-26.43 , -15.12]
Difference of LS Means (SE)	-10.78 (4.663)		
95%-CI	[-20.03 , -1.52]		
p-value	0.0229		
Hedges' g (SE)	-0.43 (0.191)		
95%-CI	[-0.81 , -0.05]		
p-value	0.0255		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Table 1002FDC.053b.102.2.1.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Gender
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Gender	Convergence criteria met				0.9070
Female vs. Male		0.0232	0.7110	0.9070	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CV=cardio-vascular, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high intensity statin vs. other statin), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] Type 3 F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Age
Full Analysis Set

Age (years): < 65

Statistic	FDC vs. Ezitimibe	FDC (N= 58)	Ezetimibe (N= 48)
LDL-C at Baseline:			
n		55	45
Mean		155.60	156.23
Standard deviation		41.977	45.280
Percent Change from Baseline:			
n		55	45
Mean (SE)		-31.14 (3.295)	-26.77 (2.900)
Standard deviation		24.436	19.452
Median		-35.31	-27.53
Minimum		-70.5	-68.9
Maximum		30.5	37.6
LS Mean for Percent Change from Baseline (SE)		-30.52 (3.132)	-26.84 (3.018)
95%-CI		[-36.80 , -24.24]	[-32.94 , -20.74]
Difference of LS Means (SE)	-3.68 (4.356)		
95%-CI	[-12.34 , 4.97]		
p-value	0.3998		
Hedges' g (SE)	-0.17 (0.200)		
95%-CI	[-0.56 , 0.23]		
p-value	0.4063		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Age
Full Analysis Set

Age (years): >= 65

Statistic	FDC vs. Ezitimibe	FDC (N= 50)	Ezetimibe (N= 61)
LDL-C at Baseline:			
n		50	58
Mean		148.16	141.86
Standard deviation		35.363	33.409
Percent Change from Baseline:			
n		50	58
Mean (SE)		-34.26 (4.011)	-17.93 (2.947)
Standard deviation		28.360	22.440
Median		-43.27	-19.32
Minimum		-83.5	-65.3
Maximum		43.3	47.0
LS Mean for Percent Change from Baseline (SE)		-33.62 (4.058)	-18.15 (2.833)
95%-CI		[-41.78 , -25.46]	[-23.83 , -12.47]
Difference of LS Means (SE)	-15.46 (4.955)		
95%-CI	[-25.31 , -5.62]		
p-value	0.0024		
Hedges' g (SE)	-0.61 (0.196)		
95%-CI	[-1.00 , -0.22]		
p-value	0.0023		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Table 1002FDC.053b.102.2.2.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Age
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Age (years)	Convergence criteria met				0.0732
>= 65 vs. < 65		0.3595	0.0386	0.0732	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CV=cardio-vascular, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high intensity statin vs. other statin), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] Type 3 F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by CVD Risk Category
Full Analysis Set

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezitimibe	FDC (N= 60)	Ezetimibe (N= 62)
LDL-C at Baseline:			
n		57	58
Mean		148.09	138.99
Standard deviation		44.465	40.138
Percent Change from Baseline:			
n		57	58
Mean (SE)		-38.48 (2.777)	-23.22 (3.056)
Standard deviation		20.963	23.271
Median		-42.86	-26.11
Minimum		-70.5	-68.9
Maximum		24.2	47.0
LS Mean for Percent Change from Baseline (SE)		-37.80 (2.720)	-23.38 (3.019)
95%-CI		[-43.25 , -32.35]	[-29.43 , -17.33]
Difference of LS Means (SE)	-14.42 (4.070)		
95%-CI	[-22.49 , -6.36]		
p-value	0.0006		
Hedges' g (SE)	-0.66 (0.190)		
95%-CI	[-1.03 , -0.28]		
p-value	0.0008		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline statin dose intensity (high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by CVD Risk Category
Full Analysis Set

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezitimibe	FDC (N= 48)	Ezetimibe (N= 47)
LDL-C at Baseline:			
n		48	45
Mean		156.77	159.93
Standard deviation		31.009	35.716
Percent Change from Baseline:			
n		48	45
Mean (SE)		-25.67 (4.367)	-19.96 (2.860)
Standard deviation		30.256	19.185
Median		-37.36	-22.35
Minimum		-83.5	-61.5
Maximum		43.3	37.6
LS Mean for Percent Change from Baseline (SE)		-26.20 (4.356)	-19.96 (2.800)
95%-CI		[-34.97 , -17.44]	[-25.60 , -14.32]
Difference of LS Means (SE)	-6.24 (5.178)		
95%-CI	[-16.55 , 4.06]		
p-value	0.2314		
Hedges' g (SE)	-0.24 (0.207)		
95%-CI	[-0.65 , 0.17]		
p-value	0.2394		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline statin dose intensity (high statin intensity vs other) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Table 1002FDC.053b.102.2.3.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by CVD Risk Category
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
CVD Risk Category	Convergence criteria met				0.2163
Multiple CV risk factors vs. ASCVD and/or HeFH		0.0015	0.2000	0.2163	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CV=cardio-vascular, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy.
[a] Two-sided t-test p-value from ANCOVA including treatment, baseline statin dose intensity (high intensity statin vs. other statin), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] Type 3 F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline Statin Intensity I
Full Analysis Set

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezitimibe	FDC (N= 66)	Ezetimibe (N= 70)
LDL-C at Baseline:			
n		64	66
Mean		157.70	149.05
Standard deviation		38.815	35.884
Percent Change from Baseline:			
n		64	66
Mean (SE)		-32.94 (3.324)	-20.20 (2.541)
Standard deviation		26.592	20.645
Median		-38.34	-22.99
Minimum		-70.3	-65.3
Maximum		43.3	47.0
LS Mean for Percent Change from Baseline (SE)		-32.57 (3.239)	-20.63 (2.500)
95%-CI		[-39.04 , -26.09]	[-25.62 , -15.64]
Difference of LS Means (SE)	-11.94 (4.099)		
95%-CI	[-20.06 , -3.82]		
p-value	0.0043		
Hedges' g (SE)	-0.51 (0.177)		
95%-CI	[-0.86 , -0.16]		
p-value	0.0046		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline CV risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline Statin Intensity I
Full Analysis Set

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezitimibe	FDC (N= 42)	Ezetimibe (N= 39)
LDL-C at Baseline:			
n		41	37
Mean		143.26	146.51
Standard deviation		37.997	45.710
Percent Change from Baseline:			
n		41	37
Mean (SE)		-32.13 (4.083)	-24.64 (3.793)
Standard deviation		26.145	23.071
Median		-38.27	-28.92
Minimum		-83.5	-68.9
Maximum		30.5	20.4
LS Mean for Percent Change from Baseline (SE)		-32.30 (4.010)	-24.15 (3.707)
95%-CI		[-40.40 , -24.19]	[-31.67 , -16.63]
Difference of LS Means (SE)	-8.14 (5.461)		
95%-CI	[-19.02 , 2.74]		
p-value	0.1401		
Hedges' g (SE)	-0.33 (0.226)		
95%-CI	[-0.78 , 0.12]		
p-value	0.1455		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline CV risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Table 1002FDC.053b.102.2.4.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline Statin Intensity I
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Baseline Statin Dose Intensity I	Convergence criteria met				0.5962
High Intensity Statin vs. Other		0.0047	0.4190	0.5962	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CV=cardio-vascular, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy.
[a] Two-sided t-test p-value from ANCOVA including treatment, baseline CV risk category (ASCVD and/or HeFH vs. multiple cardiovascular risk factors), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] Type 3 F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline Statin Intensity II
Full Analysis Set

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezitimibe	FDC (N= 33)	Ezetimibe (N= 38)
LDL-C at Baseline:			
n		31	36
Mean		143.16	135.54
Standard deviation		32.335	23.293
Percent Change from Baseline:			
n		31	36
Mean (SE)		-26.49 (4.792)	-18.30 (4.148)
Standard deviation		26.682	24.888
Median		-28.06	-19.47
Minimum		-70.3	-65.3
Maximum		40.1	47.0
LS Mean for Percent Change from Baseline (SE)		-26.24 (4.647)	-19.01 (4.057)
95%-CI		[-35.77 , -16.71]	[-27.25 , -10.77]
Difference of LS Means (SE)	-7.23 (6.178)		
95%-CI	[-19.60 , 5.15]		
p-value	0.2469		
Hedges' g (SE)	-0.29 (0.243)		
95%-CI	[-0.77 , 0.20]		
p-value	0.2459		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline CV risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline Statin Intensity II
Full Analysis Set

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezitimibe	FDC (N= 42)	Ezetimibe (N= 39)
LDL-C at Baseline:			
n		41	37
Mean		143.26	146.51
Standard deviation		37.997	45.710
Percent Change from Baseline:			
n		41	37
Mean (SE)		-32.13 (4.083)	-24.64 (3.793)
Standard deviation		26.145	23.071
Median		-38.27	-28.92
Minimum		-83.5	-68.9
Maximum		30.5	20.4
LS Mean for Percent Change from Baseline (SE)		-32.30 (4.010)	-24.15 (3.707)
95%-CI		[-40.40 , -24.19]	[-31.67 , -16.63]
Difference of LS Means (SE)	-8.14 (5.461)		
95%-CI	[-19.02 , 2.74]		
p-value	0.1401		
Hedges' g (SE)	-0.33 (0.226)		
95%-CI	[-0.78 , 0.12]		
p-value	0.1455		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline CV risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline Statin Intensity II
Full Analysis Set

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezitimibe	FDC (N= 33)	Ezetimibe (N= 32)
LDL-C at Baseline:			
n		33	30
Mean		171.35	165.27
Standard deviation		39.863	41.626
Percent Change from Baseline:			
n		33	30
Mean (SE)		-39.00 (4.426)	-22.48 (2.568)
Standard deviation		25.428	14.068
Median		-45.26	-24.38
Minimum		-67.3	-41.4
Maximum		43.3	6.2
LS Mean for Percent Change from Baseline (SE)		-38.82 (4.415)	-22.77 (2.540)
95%-CI		[-47.82 , -29.83]	[-27.97 , -17.56]
Difference of LS Means (SE)	-16.06 (5.098)		
95%-CI	[-26.29 , -5.82]		
p-value	0.0028		
Hedges' g (SE)	-0.77 (0.258)		
95%-CI	[-1.28 , -0.25]		
p-value	0.0043		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and baseline CV risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors) as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline Statin Intensity II
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Baseline Statin Dose Intensity II	Convergence criteria met				0.5121
High Intensity Statin vs. Other Intensity Statin		0.1980	0.4246	0.9246	
None vs. Other Intensity Statin		0.1980	0.8361	0.3004	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CV=cardio-vascular, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy.
[a] Two-sided t-test p-value from ANCOVA including treatment, baseline CV risk category (ASCVD and/or HeFH vs. multiple cardiovascular risk factors), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] Type 3 F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Race
Full Analysis Set

Race: White

Statistic	FDC vs. Ezitimibe	FDC (N= 85)	Ezetimibe (N= 91)
LDL-C at Baseline:			
n		82	86
Mean		151.42	148.57
Standard deviation		38.091	41.298
Percent Change from Baseline:			
n		82	86
Mean (SE)		-32.80 (2.831)	-22.49 (2.265)
Standard deviation		25.634	21.001
Median		-38.76	-25.35
Minimum		-70.3	-68.9
Maximum		43.3	39.4
LS Mean for Percent Change from Baseline (SE)		-32.89 (2.738)	-22.39 (2.220)
95%-CI		[-38.34 , -27.44]	[-26.81 , -17.98]
Difference of LS Means (SE)	-10.50 (3.529)		
95%-CI	[-17.47 , -3.52]		
p-value	0.0034		
Hedges' g (SE)	-0.46 (0.156)		
95%-CI	[-0.77 , -0.15]		
p-value	0.0036		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Race
Full Analysis Set

Race: non-White

Statistic	FDC vs. Ezitimibe	FDC (N= 23)	Ezetimibe (N= 18)
LDL-C at Baseline:			
n		23	17
Mean		154.33	145.97
Standard deviation		42.747	29.583
Percent Change from Baseline:			
n		23	17
Mean (SE)		-32.00 (6.075)	-18.27 (5.938)
Standard deviation		29.134	24.482
Median		-30.79	-17.24
Minimum		-83.5	-65.3
Maximum		40.1	47.0
LS Mean for Percent Change from Baseline (SE)		-30.56 (6.386)	-20.02 (6.452)
95%-CI		[-43.92 , -17.21]	[-33.65 , -6.39]
Difference of LS Means (SE)	-10.54 (9.251)		
95%-CI	[-29.31 , 8.23]		
p-value	0.2621		
Hedges' g (SE)	-0.36 (0.316)		
95%-CI	[-1.00 , 0.28]		
p-value	0.2667		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Table 1002FDC.053b.102.2.6.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Race
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Race	Convergence criteria met				0.9857
non-White vs. White		0.0038	0.6774	0.9857	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CV=cardio-vascular, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high intensity statin vs. other statin), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] Type 3 F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline LDL-C Category
Full Analysis Set

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezitimibe	FDC (N= 39)	Ezetimibe (N= 38)
LDL-C at Baseline:			
n		38	36
Mean		115.87	113.04
Standard deviation		10.917	10.539
Percent Change from Baseline:			
n		38	36
Mean (SE)		-26.75 (4.124)	-17.85 (4.221)
Standard deviation		25.422	25.327
Median		-30.10	-22.72
Minimum		-63.4	-68.9
Maximum		43.3	47.0
LS Mean for Percent Change from Baseline (SE)		-27.26 (4.178)	-18.17 (4.126)
95%-CI		[-35.73 , -18.78]	[-26.56 , -9.78]
Difference of LS Means (SE)	-9.09 (5.903)		
95%-CI	[-20.87 , 2.69]		
p-value	0.1284		
Hedges' g (SE)	-0.36 (0.232)		
95%-CI	[-0.82 , 0.11]		
p-value	0.1295		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline LDL-C Category
Full Analysis Set

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezitimibe	FDC (N= 31)	Ezetimibe (N= 45)
LDL-C at Baseline:			
n		30	42
Mean		143.07	144.90
Standard deviation		7.387	9.016
Percent Change from Baseline:			
n		30	42
Mean (SE)		-34.47 (4.900)	-20.91 (3.022)
Standard deviation		26.837	19.582
Median		-43.00	-21.14
Minimum		-83.5	-65.3
Maximum		24.2	37.6
LS Mean for Percent Change from Baseline (SE)		-34.23 (5.080)	-21.09 (3.017)
95%-CI		[-44.63 , -23.82]	[-27.19 , -14.99]
Difference of LS Means (SE)	-13.14 (5.915)		
95%-CI	[-25.04 , -1.24]		
p-value	0.0312		
Hedges' g (SE)	-0.56 (0.241)		
95%-CI	[-1.04 , -0.08]		
p-value	0.0238		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline LDL-C Category
Full Analysis Set

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezitimibe	FDC (N= 38)	Ezetimibe (N= 26)
LDL-C at Baseline:			
n		37	25
Mean		196.51	204.12
Standard deviation		27.167	34.591
Percent Change from Baseline:			
n		37	25
Mean (SE)		-37.16 (4.327)	-28.96 (3.485)
Standard deviation		26.318	17.423
Median		-41.08	-33.88
Minimum		-70.5	-63.8
Maximum		40.1	6.2
LS Mean for Percent Change from Baseline (SE)		-37.47 (4.338)	-28.21 (3.605)
95%-CI		[-46.29 , -28.65]	[-35.65 , -20.76]
Difference of LS Means (SE)	-9.26 (5.671)		
95%-CI	[-20.62 , 2.09]		
p-value	0.1079		
Hedges' g (SE)	-0.39 (0.258)		
95%-CI	[-0.91 , 0.13]		
p-value	0.1352		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Table 1002FDC.053b.102.2.7.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by Baseline LDL-C Category
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
Baseline LDL-C (mg/dL)	Convergence criteria met				0.7573
130 - < 160 vs. < 130		0.0806	0.2070	0.5593	
>= 160 vs. < 130		0.0806	0.2211	0.8950	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CV=cardio-vascular, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high intensity statin vs. other statin), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] Type 3 F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by History of Diabetes
Full Analysis Set

History of Diabetes: Yes

Statistic	FDC vs. Ezitimibe	FDC (N= 49)	Ezetimibe (N= 61)
LDL-C at Baseline:			
n		48	57
Mean		145.93	143.04
Standard deviation		34.370	35.365
Percent Change from Baseline:			
n		48	57
Mean (SE)		-31.95 (3.854)	-20.58 (2.984)
Standard deviation		26.702	22.529
Median		-37.70	-21.37
Minimum		-83.5	-68.9
Maximum		43.3	39.4
LS Mean for Percent Change from Baseline (SE)		-32.28 (3.797)	-20.67 (2.950)
95%-CI		[-39.92 , -24.64]	[-26.58 , -14.75]
Difference of LS Means (SE)	-11.61 (4.813)		
95%-CI	[-21.17 , -2.05]		
p-value	0.0179		
Hedges' g (SE)	-0.48 (0.197)		
95%-CI	[-0.87 , -0.09]		
p-value	0.0175		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by History of Diabetes
Full Analysis Set

History of Diabetes: No

Statistic	FDC vs. Ezitimibe	FDC (N= 59)	Ezetimibe (N= 48)
LDL-C at Baseline:			
n		57	46
Mean		157.22	154.46
Standard deviation		42.053	43.643
Percent Change from Baseline:			
n		57	46
Mean (SE)		-33.19 (3.467)	-23.30 (3.007)
Standard deviation		26.172	20.397
Median		-39.58	-26.94
Minimum		-70.5	-65.3
Maximum		40.1	47.0
LS Mean for Percent Change from Baseline (SE)		-32.89 (3.396)	-23.34 (2.967)
95%-CI		[-39.70 , -26.08]	[-29.32 , -17.36]
Difference of LS Means (SE)	-9.55 (4.513)		
95%-CI	[-18.50 , -0.59]		
p-value	0.0369		
Hedges' g (SE)	-0.41 (0.199)		
95%-CI	[-0.80 , -0.01]		
p-value	0.0437		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Table 1002FDC.053b.102.2.8.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by History of Diabetes
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
History of Diabetes	Convergence criteria met				0.6618
No vs. Yes		0.0099	0.9630	0.6618	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CV=cardio-vascular, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high intensity statin vs. other statin), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] Type 3 F-test p-value from ANCOVA model defined as above.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by BMI
Full Analysis Set

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezitimibe	FDC (N= 13)	Ezetimibe (N= 13)
LDL-C at Baseline:			
n		13	13
Mean		144.54	165.12
Standard deviation		37.764	55.839
Percent Change from Baseline:			
n		13	13
Mean (SE)		-40.61 (7.334)	-22.13 (7.650)
Standard deviation		26.442	27.581
Median		-45.26	-30.60
Minimum		-83.5	-63.8
Maximum		24.2	47.0
LS Mean for Percent Change from Baseline (SE)		-40.71 (7.598)	-19.81 (7.842)
95%-CI		[-57.19 , -24.23]	[-36.89 , -2.73]
Difference of LS Means (SE)	-20.90 (11.177)		
95%-CI	[-43.97 , 2.18]		
p-value	0.0739		
Hedges' g (SE)	-0.73 (0.393)		
95%-CI	[-1.54 , 0.08]		
p-value	0.0767		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by BMI
Full Analysis Set

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezitimibe	FDC (N= 27)	Ezetimibe (N= 37)
LDL-C at Baseline:			
n		26	35
Mean		143.46	132.63
Standard deviation		31.174	26.074
Percent Change from Baseline:			
n		26	35
Mean (SE)		-24.51 (5.546)	-17.91 (3.469)
Standard deviation		28.277	20.525
Median		-29.27	-24.51
Minimum		-59.6	-41.3
Maximum		40.1	39.4
LS Mean for Percent Change from Baseline (SE)		-25.11 (5.247)	-18.80 (3.459)
95%-CI		[-35.97 , -14.25]	[-25.84 , -11.76]
Difference of LS Means (SE)	-6.31 (6.283)		
95%-CI	[-19.00 , 6.38]		
p-value	0.3211		
Hedges' g (SE)	-0.27 (0.257)		
95%-CI	[-0.78 , 0.25]		
p-value	0.3028		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Summary and ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by BMI
Full Analysis Set

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezitimibe	FDC (N= 68)	Ezetimibe (N= 59)
LDL-C at Baseline:			
n		66	55
Mean		156.92	154.00
Standard deviation		41.556	39.554
Percent Change from Baseline:			
n		66	55
Mean (SE)		-34.25 (3.084)	-24.18 (2.785)
Standard deviation		25.058	20.655
Median		-39.70	-24.43
Minimum		-70.5	-68.9
Maximum		43.3	20.4
LS Mean for Percent Change from Baseline (SE)		-33.66 (2.961)	-23.89 (2.823)
95%-CI		[-39.57 , -27.75]	[-29.55 , -18.22]
Difference of LS Means (SE)	-9.77 (4.082)		
95%-CI	[-17.86 , -1.69]		
p-value	0.0182		
Hedges' g (SE)	-0.43 (0.183)		
95%-CI	[-0.79 , -0.06]		
p-value	0.0213		

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy, N=number of patients, n=number of patients with non-missing values at specified time point, SE=standard error.
Note: Percent change from baseline for LDL-C was analyzed using ANCOVA, with treatment and randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other)as factors and baseline LDL-C as a covariate. Missing data for LDL-C were not imputed.
Baseline is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1).

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of ANCOVA of Percent Change from Baseline to Week 12 in LDL-C (Observed Data) by BMI
Full Analysis Set

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction F-test p-value [b]
BMI (kg/m^2)	Convergence criteria met				0.3816
25 - < 30 vs. < 25		0.0204	0.9198	0.1706	
>= 30 vs. < 25		0.0204	0.5639	0.2380	

Abbreviations: ANCOVA=analysis of covariance, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CV=cardio-vascular, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LLT=lipid-lowering therapy.
[a] Two-sided t-test p-value from ANCOVA including treatment, randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high intensity statin vs. other statin), subgroup, treatment x subgroup interaction, and baseline LDL-C.
[b] Type 3 F-test p-value from ANCOVA model defined as above.

Table 1002FDC.053b.200.1	Frequency Summary of TEAEs	1
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MedDRA SOC and PT	FDC (N= 107)	Ezetimibe (N= 109)
Any TEAE	63(58.9%)	58(53.2%)
Infections and infestations	27(25.2%)	16(14.7%)
Urinary tract infection	8(7.5%)	3(2.8%)
Nasopharyngitis	4(3.7%)	4(3.7%)
Bronchitis	3(2.8%)	3(2.8%)
Influenza	3(2.8%)	2(1.8%)
Upper respiratory tract infection	3(2.8%)	0
Gastroenteritis viral	2(1.9%)	0
Otitis media acute	2(1.9%)	0
Acarodermatitis	1(0.9%)	0
Acute sinusitis	1(0.9%)	0
Conjunctivitis	1(0.9%)	0
Rhinovirus infection	1(0.9%)	0
Herpes zoster	0	1(0.9%)
Pharyngitis streptococcal	0	1(0.9%)
Pneumonia	0	1(0.9%)
Staphylococcal bacteraemia	0	1(0.9%)
Subcutaneous abscess	0	1(0.9%)
Tooth infection	0	2(1.8%)
Vulvovaginal mycotic infection	0	1(0.9%)
Investigations	14(13.1%)	9(8.3%)
Blood creatinine increased	3(2.8%)	0
Blood uric acid increased	3(2.8%)	0
Blood albumin decreased	1(0.9%)	0
Blood glucose increased	1(0.9%)	0
Blood testosterone decreased	1(0.9%)	0
Blood triglycerides increased	1(0.9%)	0
Electrocardiogram QRS complex prolonged	1(0.9%)	0
Electrocardiogram change	1(0.9%)	0
Eosinophil count increased	1(0.9%)	0
Haemoglobin decreased	1(0.9%)	0
Liver function test abnormal	1(0.9%)	0
Liver function test increased	1(0.9%)	0
Protein total decreased	1(0.9%)	0
Protein urine present	1(0.9%)	1(0.9%)
Blood creatine phosphokinase increased	0	2(1.8%)
Blood lactate dehydrogenase increased	0	2(1.8%)
Blood potassium increased	0	2(1.8%)
Haemoglobin increased	0	1(0.9%)
Platelet count increased	0	1(0.9%)
Urine analysis abnormal	0	1(0.9%)
Musculoskeletal and connective tissue disorders	13(12.1%)	18(16.5%)
Back pain	3(2.8%)	4(3.7%)
Muscle spasms	2(1.9%)	4(3.7%)
Myalgia	2(1.9%)	2(1.8%)
Pain in extremity	2(1.9%)	1(0.9%)
Spinal osteoarthritis	2(1.9%)	0
Arthralgia	1(0.9%)	4(3.7%)
Intervertebral disc degeneration	1(0.9%)	0
Neck mass	1(0.9%)	0
Osteoarthritis	1(0.9%)	0
Rheumatoid arthritis	1(0.9%)	0

Abbreviations: N=number of patients, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

MedDRA SOC and PT	FDC (N= 107)	Ezetimibe (N= 109)
Bursitis	0	1(0.9%)
Exostosis	0	1(0.9%)
Joint swelling	0	1(0.9%)
Musculoskeletal discomfort	0	1(0.9%)
Musculoskeletal pain	0	1(0.9%)
Gastrointestinal disorders	11(10.3%)	8(7.3%)
Constipation	4(3.7%)	2(1.8%)
Diarrhoea	3(2.8%)	2(1.8%)
Abdominal pain	2(1.9%)	1(0.9%)
Nausea	2(1.9%)	1(0.9%)
Oral discomfort	2(1.9%)	0
Anorectal discomfort	1(0.9%)	0
Dry mouth	1(0.9%)	0
Dysphagia	1(0.9%)	0
Flatulence	1(0.9%)	0
Gastritis	1(0.9%)	0
Gastrointestinal pain	1(0.9%)	0
Oesophagitis	1(0.9%)	0
Vomiting	1(0.9%)	0
Abdominal distension	0	1(0.9%)
Chronic gastritis	0	1(0.9%)
Dyspepsia	0	1(0.9%)
Hiatus hernia	0	1(0.9%)
Stomatitis	0	1(0.9%)
Toothache	0	1(0.9%)
Nervous system disorders	8(7.5%)	7(6.4%)
Dizziness	2(1.9%)	2(1.8%)
Headache	2(1.9%)	2(1.8%)
Syncope	2(1.9%)	0
Dysgeusia	1(0.9%)	0
Hemiparesis	1(0.9%)	0
Horner's syndrome	1(0.9%)	0
Restless legs syndrome	1(0.9%)	0
Sinus headache	1(0.9%)	0
Transient ischaemic attack	1(0.9%)	0
Hypersomnia	0	1(0.9%)
Lethargy	0	1(0.9%)
Nerve root compression	0	1(0.9%)
Metabolism and nutrition disorders	7(6.5%)	3(2.8%)
Diabetes mellitus inadequate control	2(1.9%)	0
Hypokalaemia	2(1.9%)	0
Decreased appetite	1(0.9%)	0
Dehydration	1(0.9%)	0
Hyperuricaemia	1(0.9%)	0
Hypoglycaemia	1(0.9%)	0
Diabetes mellitus	0	2(1.8%)
Hypercalcaemia	0	1(0.9%)
Vitamin D deficiency	0	1(0.9%)
Cardiac disorders	6(5.6%)	7(6.4%)
Acute myocardial infarction	1(0.9%)	3(2.8%)
Angina pectoris	1(0.9%)	1(0.9%)

Abbreviations: N=number of patients, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

MedDRA SOC and PT	FDC (N= 107)	Ezetimibe (N= 109)
Atrial fibrillation	1(0.9%)	0
Coronary artery disease	1(0.9%)	0
Myocardial ischaemia	1(0.9%)	0
Palpitations	1(0.9%)	1(0.9%)
Atrial flutter	0	1(0.9%)
Cardiac failure congestive	0	1(0.9%)
Sinus bradycardia	0	1(0.9%)
General disorders and administration site conditions	6(5.6%)	3(2.8%)
Fatigue	3(2.8%)	1(0.9%)
Asthenia	1(0.9%)	0
Chest discomfort	1(0.9%)	0
Feeling jittery	1(0.9%)	0
Non-cardiac chest pain	1(0.9%)	1(0.9%)
Cyst	0	1(0.9%)
Respiratory, thoracic and mediastinal disorders	6(5.6%)	6(5.5%)
Cough	3(2.8%)	1(0.9%)
Asthma	1(0.9%)	0
Oropharyngeal pain	1(0.9%)	0
Sinus congestion	1(0.9%)	0
Chronic obstructive pulmonary disease	0	1(0.9%)
Chronic respiratory failure	0	1(0.9%)
Dyspnoea	0	1(0.9%)
Respiratory failure	0	1(0.9%)
Rhinorrhoea	0	1(0.9%)
Vascular disorders	4(3.7%)	4(3.7%)
Hypertension	3(2.8%)	2(1.8%)
Raynaud's phenomenon	1(0.9%)	0
Aortic aneurysm	0	1(0.9%)
Deep vein thrombosis	0	1(0.9%)
Psychiatric disorders	3(2.8%)	2(1.8%)
Anxiety	2(1.9%)	0
Agitation	1(0.9%)	0
Depression	0	1(0.9%)
Insomnia	0	1(0.9%)
Renal and urinary disorders	3(2.8%)	2(1.8%)
Acute kidney injury	1(0.9%)	0
Chromaturia	1(0.9%)	0
Glycosuria	1(0.9%)	0
Proteinuria	1(0.9%)	0
Haematuria	0	1(0.9%)
Renal artery occlusion	0	1(0.9%)
Injury, poisoning and procedural complications	2(1.9%)	7(6.4%)
Arthropod bite	1(0.9%)	0
Skin abrasion	1(0.9%)	0
Anaesthetic complication pulmonary	0	1(0.9%)
Coronary vascular graft stenosis	0	1(0.9%)
Dislocation of vertebra	0	1(0.9%)
Joint dislocation	0	1(0.9%)
Limb injury	0	1(0.9%)

Abbreviations: N=number of patients, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

MedDRA SOC and PT	FDC (N= 107)	Ezetimibe (N= 109)
Road traffic accident	0	1(0.9%)
Spinal compression fracture	0	1(0.9%)
Wrist fracture	0	1(0.9%)
Reproductive system and breast disorders	2(1.9%)	1(0.9%)
Prostatitis	2(1.9%)	0
Ovarian cyst	0	1(0.9%)
Blood and lymphatic system disorders	1(0.9%)	1(0.9%)
Anaemia	1(0.9%)	1(0.9%)
Ear and labyrinth disorders	1(0.9%)	0
Hypoacusis	1(0.9%)	0
Endocrine disorders	1(0.9%)	0
Hypothyroidism	1(0.9%)	0
Eye disorders	1(0.9%)	0
Eyelids pruritus	1(0.9%)	0
Hepatobiliary disorders	1(0.9%)	0
Non-alcoholic fatty liver	1(0.9%)	0
Skin and subcutaneous tissue disorders	1(0.9%)	3(2.8%)
Dermatitis contact	1(0.9%)	1(0.9%)
Rash	0	1(0.9%)
Urticaria	0	1(0.9%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1(0.9%)
Ovarian cancer	0	1(0.9%)

Abbreviations: N=number of patients, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

MedDRA SOC and PT	FDC (N= 107)	Placebo (N= 109)
Any TESAE	8(7.5%)	10(9.2%)
Cardiac disorders	5(4.7%)	4(3.7%)
Acute myocardial infarction	1(0.9%)	3(2.8%)
Angina pectoris	1(0.9%)	0
Atrial fibrillation	1(0.9%)	0
Coronary artery disease	1(0.9%)	0
Myocardial ischaemia	1(0.9%)	0
Cardiac failure congestive	0	1(0.9%)
General disorders and administration site conditions	1(0.9%)	0
Non-cardiac chest pain	1(0.9%)	0
Infections and infestations	1(0.9%)	1(0.9%)
Rhinovirus infection	1(0.9%)	0
Pneumonia	0	1(0.9%)
Nervous system disorders	1(0.9%)	0
Hemiparesis	1(0.9%)	0
Injury, poisoning and procedural complications	0	2(1.8%)
Coronary vascular graft stenosis	0	1(0.9%)
Limb injury	0	1(0.9%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1(0.9%)
Ovarian cancer	0	1(0.9%)
Renal and urinary disorders	0	1(0.9%)
Renal artery occlusion	0	1(0.9%)
Respiratory, thoracic and mediastinal disorders	0	2(1.8%)
Chronic respiratory failure	0	1(0.9%)
Respiratory failure	0	1(0.9%)
Vascular disorders	0	1(0.9%)
Deep vein thrombosis	0	1(0.9%)

Abbreviations: N=number of patients, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

MedDRA SOC and PT	FDC (N= 107)	Placebo (N= 109)
Any TEAE	9(8.4%)	9(8.3%)
Cardiac disorders	5(4.7%)	4(3.7%)
Acute myocardial infarction	1(0.9%)	3(2.8%)
Angina pectoris	1(0.9%)	1(0.9%)
Atrial fibrillation	1(0.9%)	0
Coronary artery disease	1(0.9%)	0
Myocardial ischaemia	1(0.9%)	0
Cardiac failure congestive	0	1(0.9%)
Gastrointestinal disorders	1(0.9%)	1(0.9%)
Constipation	1(0.9%)	0
Abdominal pain	0	1(0.9%)
General disorders and administration site conditions	1(0.9%)	0
Non-cardiac chest pain	1(0.9%)	0
Metabolism and nutrition disorders	1(0.9%)	0
Hypokalaemia	1(0.9%)	0
Nervous system disorders	1(0.9%)	0
Hemiparesis	1(0.9%)	0
Horner's syndrome	1(0.9%)	0
Transient ischaemic attack	1(0.9%)	0
Injury, poisoning and procedural complications	0	1(0.9%)
Wrist fracture	0	1(0.9%)
Musculoskeletal and connective tissue disorders	0	1(0.9%)
Arthralgia	0	1(0.9%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1(0.9%)
Ovarian cancer	0	1(0.9%)
Renal and urinary disorders	0	1(0.9%)
Renal artery occlusion	0	1(0.9%)
Respiratory, thoracic and mediastinal disorders	0	1(0.9%)
Chronic respiratory failure	0	1(0.9%)
Vascular disorders	0	1(0.9%)
Deep vein thrombosis	0	1(0.9%)

Abbreviations: N=number of patients, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Frequency Summary of TEAEs Resulting in Discontinuation of Investigational Medicinal Product

MedDRA SOC and PT	FDC (N= 107)	Placebo (N= 109)
Any TEAE	7(6.5%)	10(9.2%)
Gastrointestinal disorders	2(1.9%)	2(1.8%)
Oral discomfort	2(1.9%)	0
Gastrointestinal pain	1(0.9%)	0
Abdominal pain	0	1(0.9%)
Constipation	0	1(0.9%)
General disorders and administration site conditions	2(1.9%)	1(0.9%)
Asthenia	1(0.9%)	0
Fatigue	1(0.9%)	0
Non-cardiac chest pain	0	1(0.9%)
Investigations	1(0.9%)	0
Blood glucose increased	1(0.9%)	0
Metabolism and nutrition disorders	1(0.9%)	0
Hypoglycaemia	1(0.9%)	0
Musculoskeletal and connective tissue disorders	1(0.9%)	2(1.8%)
Pain in extremity	1(0.9%)	0
Musculoskeletal discomfort	0	1(0.9%)
Myalgia	0	1(0.9%)
Nervous system disorders	1(0.9%)	1(0.9%)
Dysgeusia	1(0.9%)	0
Lethargy	0	1(0.9%)
Psychiatric disorders	1(0.9%)	0
Agitation	1(0.9%)	0
Cardiac disorders	0	1(0.9%)
Acute myocardial infarction	0	1(0.9%)
Injury, poisoning and procedural complications	0	1(0.9%)
Joint dislocation	0	1(0.9%)
Wrist fracture	0	1(0.9%)
Renal and urinary disorders	0	1(0.9%)
Renal artery occlusion	0	1(0.9%)
Respiratory, thoracic and mediastinal disorders	0	1(0.9%)
Chronic respiratory failure	0	1(0.9%)
Skin and subcutaneous tissue disorders	0	1(0.9%)
Urticaria	0	1(0.9%)

Abbreviations: N=number of patients, PT=preferred term, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.

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Table 1002FDC.053b.202.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		63 (58.9%)	58 (53.2%)	121 (56.0%)
Number of patients without events		44 (41.1%)	51 (46.8%)	95 (44.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.259 [0.735, 2.157]			
Stratified OR, 95% CI	1.279 [0.740, 2.210]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.107 [0.873, 1.402]			
Stratified RR, 95% CI	1.081 [0.856, 1.364]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.057 [-0.075, 0.189]			
Stratified ARR, 95% CI (CMH method)	0.060 [-0.071, 0.191]			
Test on Differences [c]				
Unstratified p-value	0.4015			
Stratified p-value	0.3754			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender
Safety Population

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		28 (56.0%)	27 (51.9%)	55 (53.9%)
Number of patients without events		22 (44.0%)	25 (48.1%)	47 (46.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.178 [0.540, 2.570]			
Stratified OR, 95% CI	1.287 [0.566, 2.929]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.079 [0.753, 1.544]			
Stratified RR, 95% CI	1.049 [0.734, 1.498]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.041 [-0.153, 0.234]			
Stratified ARR, 95% CI (CMH method)	0.067 [-0.124, 0.257]			
Test on Differences [c]				
Unstratified p-value	0.6796			
Stratified p-value	0.5028			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender
Safety Population

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 57)	Total (N= 114)
Number of patients at risk		57 (100.0%)	57 (100.0%)	114 (100.0%)
Number of patients with events		35 (61.4%)	31 (54.4%)	66 (57.9%)
Number of patients without events		22 (38.6%)	26 (45.6%)	48 (42.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.334 [0.633, 2.813]			
Stratified OR, 95% CI	1.324 [0.618, 2.838]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.129 [0.824, 1.546]			
Stratified RR, 95% CI	1.100 [0.811, 1.493]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.070 [-0.111, 0.251]			
Stratified ARR, 95% CI (CMH method)	0.067 [-0.113, 0.246]			
Test on Differences [c]				
Unstratified p-value	0.4480			
Stratified p-value	0.4739			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Table 1002FDC.053b.202.1.1.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Gender
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.8508
Female vs. Male		0.6797	0.7972	0.8509	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Table 1002FDC.053b.202.1.2
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age
Safety Population

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 48)	Total (N= 105)
Number of patients at risk		57 (100.0%)	48 (100.0%)	105 (100.0%)
Number of patients with events		35 (61.4%)	22 (45.8%)	57 (54.3%)
Number of patients without events		22 (38.6%)	26 (54.2%)	48 (45.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.880 [0.863, 4.097]			
Stratified OR, 95% CI	1.815 [0.811, 4.061]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.340 [0.925, 1.940]			
Stratified RR, 95% CI	1.233 [0.872, 1.745]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.156 [-0.034, 0.345]			
Stratified ARR, 95% CI (CMH method)	0.141 [-0.046, 0.328]			
Test on Differences [c]				
Unstratified p-value	0.1106			
Stratified p-value	0.1477			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age
Safety Population

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		28 (56.0%)	36 (59.0%)	64 (57.7%)
Number of patients without events		22 (44.0%)	25 (41.0%)	47 (42.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.884 [0.415, 1.883]			
Stratified OR, 95% CI	0.910 [0.420, 1.971]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.949 [0.687, 1.310]			
Stratified RR, 95% CI	0.962 [0.694, 1.334]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.030 [-0.215, 0.155]			
Stratified ARR, 95% CI (CMH method)	-0.022 [-0.208, 0.163]			
Test on Differences [c]				
Unstratified p-value	0.7490			
Stratified p-value	0.8155			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.1615
>= 65 vs. < 65		0.1214	0.1828	0.1685	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category
Safety Population

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 62)	Total (N= 121)
Number of patients at risk		59 (100.0%)	62 (100.0%)	121 (100.0%)
Number of patients with events		36 (61.0%)	39 (62.9%)	75 (62.0%)
Number of patients without events		23 (39.0%)	23 (37.1%)	46 (38.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.923 [0.443, 1.924]			
Stratified OR, 95% CI	0.937 [0.448, 1.958]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.970 [0.733, 1.283]			
Stratified RR, 95% CI	0.975 [0.738, 1.288]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.019 [-0.192, 0.154]			
Stratified ARR, 95% CI (CMH method)	-0.015 [-0.188, 0.158]			
Test on Differences [c]				
Unstratified p-value	0.8308			
Stratified p-value	0.8637			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category
Safety Population

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		27 (56.3%)	19 (40.4%)	46 (48.4%)
Number of patients without events		21 (43.8%)	28 (59.6%)	49 (51.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.895 [0.839, 4.281]			
Stratified OR, 95% CI	1.917 [0.844, 4.351]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.391 [0.907, 2.134]			
Stratified RR, 95% CI	1.390 [0.910, 2.124]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.158 [-0.040, 0.357]			
Stratified ARR, 95% CI (CMH method)	0.160 [-0.038, 0.357]			
Test on Differences [c]				
Unstratified p-value	0.1228			
Stratified p-value	0.1220			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Table 1002FDC.053b.202.1.3.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by CVD Risk Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.1608
Multiple CV risk factors vs. ASCVD and/or HeFH		0.8310	0.0287	0.1662	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 65)	Ezetimibe (N= 70)	Total (N= 135)
Number of patients at risk		65 (100.0%)	70 (100.0%)	135 (100.0%)
Number of patients with events		40 (61.5%)	39 (55.7%)	79 (58.5%)
Number of patients without events		25 (38.5%)	31 (44.3%)	56 (41.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.272 [0.640, 2.528]			
Stratified OR, 95% CI	1.300 [0.648, 2.606]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.105 [0.832, 1.467]			
Stratified RR, 95% CI	1.083 [0.818, 1.436]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.058 [-0.108, 0.224]			
Stratified ARR, 95% CI (CMH method)	0.063 [-0.102, 0.228]			
Test on Differences [c]				
Unstratified p-value	0.4925			
Stratified p-value	0.4577			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		23 (54.8%)	19 (48.7%)	42 (51.9%)
Number of patients without events		19 (45.2%)	20 (51.3%)	39 (48.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.274 [0.532, 3.053]			
Stratified OR, 95% CI	1.275 [0.524, 3.103]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.124 [0.736, 1.717]			
Stratified RR, 95% CI	1.088 [0.719, 1.646]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.060 [-0.157, 0.278]			
Stratified ARR, 95% CI (CMH method)	0.060 [-0.156, 0.275]			
Test on Differences [c]				
Unstratified p-value	0.5865			
Stratified p-value	0.5902			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity I
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.9463
High Intensity Statin vs. Other		0.4923	0.4932	0.9463	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 32)	Ezetimibe (N= 38)	Total (N= 70)
Number of patients at risk		32 (100.0%)	38 (100.0%)	70 (100.0%)
Number of patients with events		15 (46.9%)	17 (44.7%)	32 (45.7%)
Number of patients without events		17 (53.1%)	21 (55.3%)	38 (54.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.090 [0.424, 2.801]			
Stratified OR, 95% CI	1.101 [0.411, 2.945]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.048 [0.629, 1.746]			
Stratified RR, 95% CI	0.978 [0.582, 1.645]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.021 [-0.213, 0.256]			
Stratified ARR, 95% CI (CMH method)	0.026 [-0.208, 0.260]			
Test on Differences [c]				
Unstratified p-value	0.8580			
Stratified p-value	0.8274			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		23 (54.8%)	19 (48.7%)	42 (51.9%)
Number of patients without events		19 (45.2%)	20 (51.3%)	39 (48.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.274 [0.532, 3.053]			
Stratified OR, 95% CI	1.275 [0.524, 3.103]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.124 [0.736, 1.717]			
Stratified RR, 95% CI	1.088 [0.719, 1.646]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.060 [-0.157, 0.278]			
Stratified ARR, 95% CI (CMH method)	0.060 [-0.156, 0.275]			
Test on Differences [c]				
Unstratified p-value	0.5865			
Stratified p-value	0.5902			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		25 (75.8%)	22 (68.8%)	47 (72.3%)
Number of patients without events		8 (24.2%)	10 (31.3%)	18 (27.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.420 [0.477, 4.234]			
Stratified OR, 95% CI	1.446 [0.480, 4.359]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.102 [0.814, 1.492]			
Stratified RR, 95% CI	1.113 [0.825, 1.501]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.070 [-0.147, 0.287]			
Stratified ARR, 95% CI (CMH method)	0.073 [-0.143, 0.290]			
Test on Differences [c]				
Unstratified p-value	0.5279			
Stratified p-value	0.5138			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity II
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.9779
High Intensity Statin vs. Other Intensity Statin		0.8578	0.7267	0.8356	
None vs. Other Intensity Statin		0.8578	0.0468	0.8680	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race
Safety Population

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 84)	Ezetimibe (N= 91)	Total (N= 175)
Number of patients at risk		84 (100.0%)	91 (100.0%)	175 (100.0%)
Number of patients with events		52 (61.9%)	49 (53.8%)	101 (57.7%)
Number of patients without events		32 (38.1%)	42 (46.2%)	74 (42.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.393 [0.762, 2.546]			
Stratified OR, 95% CI	1.409 [0.764, 2.600]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.150 [0.892, 1.482]			
Stratified RR, 95% CI	1.132 [0.882, 1.453]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.081 [-0.065, 0.226]			
Stratified ARR, 95% CI (CMH method)	0.082 [-0.063, 0.227]			
Test on Differences [c]				
Unstratified p-value	0.2810			
Stratified p-value	0.2730			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race
Safety Population

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		11 (47.8%)	9 (50.0%)	20 (48.8%)
Number of patients without events		12 (52.2%)	9 (50.0%)	21 (51.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.917 [0.267, 3.149]			
Stratified OR, 95% CI	0.686 [0.159, 2.963]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.957 [0.510, 1.794]			
Stratified RR, 95% CI	0.661 [0.415, 1.053]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.022 [-0.330, 0.287]			
Stratified ARR, 95% CI (CMH method)	-0.062 [-0.376, 0.252]			
Test on Differences [c]				
Unstratified p-value	0.8901			
Stratified p-value	0.7107			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Table 1002FDC.053b.202.1.6.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Race
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.5983
non-White vs. White		0.2811	0.7713	0.5951	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 38)	Total (N= 76)
Number of patients at risk		38 (100.0%)	38 (100.0%)	76 (100.0%)
Number of patients with events		19 (50.0%)	21 (55.3%)	40 (52.6%)
Number of patients without events		19 (50.0%)	17 (44.7%)	36 (47.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.810 [0.329, 1.995]			
Stratified OR, 95% CI	0.725 [0.279, 1.886]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.905 [0.590, 1.388]			
Stratified RR, 95% CI	0.770 [0.482, 1.230]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.053 [-0.277, 0.172]			
Stratified ARR, 95% CI (CMH method)	-0.038 [-0.279, 0.203]			
Test on Differences [c]				
Unstratified p-value	0.6459			
Stratified p-value	0.7504			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		17 (54.8%)	19 (42.2%)	36 (47.4%)
Number of patients without events		14 (45.2%)	26 (57.8%)	40 (52.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.662 [0.661, 4.178]			
Stratified OR, 95% CI	1.675 [0.620, 4.524]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.299 [0.814, 2.074]			
Stratified RR, 95% CI	1.310 [0.844, 2.032]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.126 [-0.101, 0.353]			
Stratified ARR, 95% CI (CMH method)	0.115 [-0.104, 0.335]			
Test on Differences [c]				
Unstratified p-value	0.2790			
Stratified p-value	0.3170			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		27 (71.1%)	18 (69.2%)	45 (70.3%)
Number of patients without events		11 (28.9%)	8 (30.8%)	19 (29.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.091 [0.367, 3.240]			
Stratified OR, 95% CI	1.009 [0.313, 3.254]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.026 [0.740, 1.423]			
Stratified RR, 95% CI	0.954 [0.704, 1.294]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.018 [-0.210, 0.247]			
Stratified ARR, 95% CI (CMH method)	0.002 [-0.228, 0.232]			
Test on Differences [c]				
Unstratified p-value	0.8755			
Stratified p-value	0.9856			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline LDL-C Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.5310
130 - < 160 vs. < 130		0.6465	0.2366	0.2636	
>= 160 vs. < 130		0.6465	0.2502	0.6463	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes
Safety Population

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 61)	Total (N= 109)
Number of patients at risk		48 (100.0%)	61 (100.0%)	109 (100.0%)
Number of patients with events		26 (54.2%)	31 (50.8%)	57 (52.3%)
Number of patients without events		22 (45.8%)	30 (49.2%)	52 (47.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.144 [0.536, 2.440]			
Stratified OR, 95% CI	1.291 [0.573, 2.909]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.066 [0.745, 1.526]			
Stratified RR, 95% CI	1.090 [0.765, 1.555]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.033 [-0.155, 0.222]			
Stratified ARR, 95% CI (CMH method)	0.060 [-0.126, 0.246]			
Test on Differences [c]				
Unstratified p-value	0.7284			
Stratified p-value	0.5283			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes
Safety Population

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		37 (62.7%)	27 (56.3%)	64 (59.8%)
Number of patients without events		22 (37.3%)	21 (43.8%)	43 (40.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.308 [0.601, 2.845]			
Stratified OR, 95% CI	1.476 [0.656, 3.323]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.115 [0.811, 1.532]			
Stratified RR, 95% CI	1.121 [0.834, 1.508]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.065 [-0.122, 0.251]			
Stratified ARR, 95% CI (CMH method)	0.088 [-0.094, 0.269]			
Test on Differences [c]				
Unstratified p-value	0.4977			
Stratified p-value	0.3533			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by History of Diabetes
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.8539
No vs. Yes		0.7275	0.5708	0.8541	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI
Safety Population

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		8 (61.5%)	6 (46.2%)	14 (53.8%)
Number of patients without events		5 (38.5%)	7 (53.8%)	12 (46.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.867 [0.392, 8.894]			
Stratified OR, 95% CI	1.650 [0.279, 9.760]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.333 [0.644, 2.760]			
Stratified RR, 95% CI	1.067 [0.692, 1.645]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.154 [-0.225, 0.532]			
Stratified ARR, 95% CI (CMH method)	0.131 [-0.211, 0.472]			
Test on Differences [c]				
Unstratified p-value	0.4314			
Stratified p-value	0.4917			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI
Safety Population

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		14 (51.9%)	24 (64.9%)	38 (59.4%)
Number of patients without events		13 (48.1%)	13 (35.1%)	26 (40.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.583 [0.212, 1.606]			
Stratified OR, 95% CI	0.596 [0.206, 1.718]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.799 [0.518, 1.234]			
Stratified RR, 95% CI	0.867 [0.549, 1.370]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.130 [-0.373, 0.113]			
Stratified ARR, 95% CI (CMH method)	-0.132 [-0.384, 0.119]			
Test on Differences [c]				
Unstratified p-value	0.2952			
Stratified p-value	0.3032			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI
Safety Population

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 67)	Ezetimibe (N= 59)	Total (N= 126)
Number of patients at risk		67 (100.0%)	59 (100.0%)	126 (100.0%)
Number of patients with events		41 (61.2%)	28 (47.5%)	69 (54.8%)
Number of patients without events		26 (38.8%)	31 (52.5%)	57 (45.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.746 [0.859, 3.547]			
Stratified OR, 95% CI	1.758 [0.845, 3.655]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.289 [0.928, 1.792]			
Stratified RR, 95% CI	1.215 [0.889, 1.660]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.137 [-0.035, 0.310]			
Stratified ARR, 95% CI (CMH method)	0.134 [-0.036, 0.303]			
Test on Differences [c]				
Unstratified p-value	0.1221			
Stratified p-value	0.1293			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by BMI
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.1773
25 - < 30 vs. < 25		0.4384	0.2922	0.2366	
>= 30 vs. < 25		0.4384	0.9326	0.9345	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		8 (7.5%)	10 (9.2%)	18 (8.3%)
Number of patients without events		99 (92.5%)	99 (90.8%)	198 (91.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.800 [0.303, 2.111]			
Stratified OR, 95% CI	0.809 [0.291, 2.245]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.815 [0.334, 1.986]			
Stratified RR, 95% CI	0.843 [0.352, 2.018]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.017 [-0.091, 0.057]			
Stratified ARR, 95% CI (CMH method)	-0.016 [-0.087, 0.055]			
Test on Differences [c]				
Unstratified p-value	0.6517			
Stratified p-value	0.6678			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Table 1002FDC.053b.202.2.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Gender
Safety Population

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		3 (6.0%)	7 (13.5%)	10 (9.8%)
Number of patients without events		47 (94.0%)	45 (86.5%)	92 (90.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.410 [0.100, 1.686]			
Stratified OR, 95% CI	0.469 [0.109, 2.014]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.446 [0.122, 1.628]			
Stratified RR, 95% CI	0.526 [0.148, 1.867]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.075 [-0.188, 0.039]			
Stratified ARR, 95% CI (CMH method)	-0.061 [-0.172, 0.051]			
Test on Differences [c]				
Unstratified p-value	0.3194			
Stratified p-value	0.3023			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Gender
Safety Population

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 57)	Total (N= 114)
Number of patients at risk		57 (100.0%)	57 (100.0%)	114 (100.0%)
Number of patients with events		5 (8.8%)	3 (5.3%)	8 (7.0%)
Number of patients without events		52 (91.2%)	54 (94.7%)	106 (93.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.731 [0.394, 7.612]			
Stratified OR, 95% CI	1.386 [0.291, 6.610]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.667 [0.418, 6.648]			
Stratified RR, 95% CI	1.342 [0.340, 5.293]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.035 [-0.058, 0.129]			
Stratified ARR, 95% CI (CMH method)	0.022 [-0.068, 0.112]			
Test on Differences [c]				
Unstratified p-value	0.7165			
Stratified p-value	0.6374			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TESAE by Gender
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.1599
Female vs. Male		0.2215	0.1566	0.1726	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Table 1002FDC.053b.202.2.2
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Age
Safety Population

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 48)	Total (N= 105)
Number of patients at risk		57 (100.0%)	48 (100.0%)	105 (100.0%)
Number of patients with events		6 (10.5%)	3 (6.3%)	9 (8.6%)
Number of patients without events		51 (89.5%)	45 (93.8%)	96 (91.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.765 [0.417, 7.469]			
Stratified OR, 95% CI	1.495 [0.354, 6.317]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.684 [0.445, 6.379]			
Stratified RR, 95% CI	1.406 [0.400, 4.939]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.043 [-0.062, 0.148]			
Stratified ARR, 95% CI (CMH method)	0.037 [-0.067, 0.141]			
Test on Differences [c]				
Unstratified p-value	0.5038			
Stratified p-value	0.4900			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Age
Safety Population

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		2 (4.0%)	7 (11.5%)	9 (8.1%)
Number of patients without events		48 (96.0%)	54 (88.5%)	102 (91.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.321 [0.064, 1.622]			
Stratified OR, 95% CI	0.381 [0.078, 1.859]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.349 [0.076, 1.604]			
Stratified RR, 95% CI	0.449 [0.114, 1.765]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.075 [-0.171, 0.022]			
Stratified ARR, 95% CI (CMH method)	-0.073 [-0.165, 0.020]			
Test on Differences [c]				
Unstratified p-value	0.1815			
Stratified p-value	0.1543			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Table 1002FDC.053b.202.2.2.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TESAE by Age
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.1059
>= 65 vs. < 65		0.4429	0.3591	0.1275	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Table 1002FDC.053b.202.2.3
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by CVD Risk Category
Safety Population

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 62)	Total (N= 121)
Number of patients at risk		59 (100.0%)	62 (100.0%)	121 (100.0%)
Number of patients with events		7 (11.9%)	10 (16.1%)	17 (14.0%)
Number of patients without events		52 (88.1%)	52 (83.9%)	104 (86.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.700 [0.248, 1.980]			
Stratified OR, 95% CI	0.783 [0.240, 2.553]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.736 [0.300, 1.805]			
Stratified RR, 95% CI	0.874 [0.323, 2.367]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.043 [-0.166, 0.081]			
Stratified ARR, 95% CI (CMH method)	-0.048 [-0.170, 0.074]			
Test on Differences [c]				
Unstratified p-value	0.4998			
Stratified p-value	0.4455			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by CVD Risk Category
Safety Population

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		1 (2.1%)	0	1 (1.1%)
Number of patients without events		47 (97.9%)	47 (100.0%)	94 (98.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.000 [0.119, 75.519]			
Stratified OR, 95% CI	3.000 [0.113, 79.499]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.939 [0.123, 70.369]			
Stratified RR, 95% CI	2.824 [0.124, 64.389]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.021 [-0.020, 0.061]			
Stratified ARR, 95% CI (CMH method)	0.020 [-0.020, 0.060]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3329			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TESAE by CVD Risk Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.2002
Multiple CV risk factors vs. ASCVD and/or HeFH		0.5026	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 65)	Ezetimibe (N= 70)	Total (N= 135)
Number of patients at risk		65 (100.0%)	70 (100.0%)	135 (100.0%)
Number of patients with events		1 (1.5%)	6 (8.6%)	7 (5.2%)
Number of patients without events		64 (98.5%)	64 (91.4%)	128 (94.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.167 [0.020, 1.424]			
Stratified OR, 95% CI	0.167 [0.019, 1.464]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.179 [0.022, 1.451]			
Stratified RR, 95% CI	0.192 [0.024, 1.513]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.070 [-0.142, 0.002]			
Stratified ARR, 95% CI (CMH method)	-0.067 [-0.137, 0.004]			
Test on Differences [c]				
Unstratified p-value	0.1170			
Stratified p-value	0.0741			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		7 (16.7%)	4 (10.3%)	11 (13.6%)
Number of patients without events		35 (83.3%)	35 (89.7%)	70 (86.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.750 [0.470, 6.517]			
Stratified OR, 95% CI	1.671 [0.458, 6.097]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.625 [0.515, 5.125]			
Stratified RR, 95% CI	1.505 [0.517, 4.381]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.064 [-0.083, 0.212]			
Stratified ARR, 95% CI (CMH method)	0.063 [-0.080, 0.207]			
Test on Differences [c]				
Unstratified p-value	0.5220			
Stratified p-value	0.3959			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Table 1002FDC.053b.202.2.4.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TESAE by Baseline Statin Intensity I
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.0382
High Intensity Statin vs. Other		0.1072	0.7700	0.0702	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 32)	Ezetimibe (N= 38)	Total (N= 70)
Number of patients at risk		32 (100.0%)	38 (100.0%)	70 (100.0%)
Number of patients with events		0	3 (7.9%)	3 (4.3%)
Number of patients without events		32 (100.0%)	35 (92.1%)	67 (95.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.156 [0.008, 3.138]			
Stratified OR, 95% CI	0.151 [0.007, 3.140]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.169 [0.009, 3.151]			
Stratified RR, 95% CI	0.175 [0.010, 3.164]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.079 [-0.165, 0.007]			
Stratified ARR, 95% CI (CMH method)	-0.077 [-0.162, 0.008]			
Test on Differences [c]				
Unstratified p-value	0.2447			
Stratified p-value	0.1091			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		7 (16.7%)	4 (10.3%)	11 (13.6%)
Number of patients without events		35 (83.3%)	35 (89.7%)	70 (86.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.750 [0.470, 6.517]			
Stratified OR, 95% CI	1.671 [0.458, 6.097]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.625 [0.515, 5.125]			
Stratified RR, 95% CI	1.505 [0.517, 4.381]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.064 [-0.083, 0.212]			
Stratified ARR, 95% CI (CMH method)	0.063 [-0.080, 0.207]			
Test on Differences [c]				
Unstratified p-value	0.5220			
Stratified p-value	0.3959			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		1 (3.0%)	3 (9.4%)	4 (6.2%)
Number of patients without events		32 (97.0%)	29 (90.6%)	61 (93.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.302 [0.030, 3.069]			
Stratified OR, 95% CI	0.311 [0.029, 3.353]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.323 [0.035, 2.947]			
Stratified RR, 95% CI	0.354 [0.041, 3.064]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.063 [-0.180, 0.053]			
Stratified ARR, 95% CI (CMH method)	-0.058 [-0.171, 0.055]			
Test on Differences [c]				
Unstratified p-value	0.3553			
Stratified p-value	0.3235			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TESAE by Baseline Statin Intensity II
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.0651
High Intensity Statin vs. Other Intensity Statin		<.0001	0.7196	<.0001	
None vs. Other Intensity Statin		<.0001	0.8257	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Race
Safety Population

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 84)	Ezetimibe (N= 91)	Total (N= 175)
Number of patients at risk		84 (100.0%)	91 (100.0%)	175 (100.0%)
Number of patients with events		5 (6.0%)	9 (9.9%)	14 (8.0%)
Number of patients without events		79 (94.0%)	82 (90.1%)	161 (92.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.577 [0.185, 1.796]			
Stratified OR, 95% CI	0.592 [0.183, 1.913]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.602 [0.210, 1.724]			
Stratified RR, 95% CI	0.627 [0.220, 1.782]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.039 [-0.119, 0.040]			
Stratified ARR, 95% CI (CMH method)	-0.036 [-0.114, 0.042]			
Test on Differences [c]				
Unstratified p-value	0.3374			
Stratified p-value	0.3782			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Race
Safety Population

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		3 (13.0%)	1 (5.6%)	4 (9.8%)
Number of patients without events		20 (87.0%)	17 (94.4%)	37 (90.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.550 [0.242, 26.838]			
Stratified OR, 95% CI	0.600 [0.027, 13.582]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.348 [0.266, 20.718]			
Stratified RR, 95% CI	0.750 [0.144, 3.903]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.075 [-0.099, 0.248]			
Stratified ARR, 95% CI (CMH method)	-0.022 [-0.160, 0.116]			
Test on Differences [c]				
Unstratified p-value	0.6178			
Stratified p-value	0.7595			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TESAE by Race
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.2374
non-White vs. White		0.3443	0.5726	0.2699	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 38)	Total (N= 76)
Number of patients at risk		38 (100.0%)	38 (100.0%)	76 (100.0%)
Number of patients with events		3 (7.9%)	4 (10.5%)	7 (9.2%)
Number of patients without events		35 (92.1%)	34 (89.5%)	69 (90.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.729 [0.152, 3.501]			
Stratified OR, 95% CI	0.720 [0.150, 3.455]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.750 [0.180, 3.127]			
Stratified RR, 95% CI	0.769 [0.209, 2.832]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.026 [-0.156, 0.104]			
Stratified ARR, 95% CI (CMH method)	-0.037 [-0.165, 0.092]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.5880			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		2 (6.5%)	3 (6.7%)	5 (6.6%)
Number of patients without events		29 (93.5%)	42 (93.3%)	71 (93.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.966 [0.152, 6.145]			
Stratified OR, 95% CI	1.055 [0.142, 7.811]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.968 [0.172, 5.457]			
Stratified RR, 95% CI	1.058 [0.204, 5.490]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.002 [-0.115, 0.111]			
Stratified ARR, 95% CI (CMH method)	0.002 [-0.106, 0.110]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9709			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		3 (7.9%)	3 (11.5%)	6 (9.4%)
Number of patients without events		35 (92.1%)	23 (88.5%)	58 (90.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.657 [0.122, 3.542]			
Stratified OR, 95% CI	0.568 [0.101, 3.181]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.684 [0.150, 3.130]			
Stratified RR, 95% CI	0.625 [0.147, 2.664]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.036 [-0.186, 0.113]			
Stratified ARR, 95% CI (CMH method)	-0.045 [-0.197, 0.107]			
Test on Differences [c]				
Unstratified p-value	0.6800			
Stratified p-value	0.5443			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TESAE by Baseline LDL-C Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.9560
130 - < 160 vs. < 130		0.6929	0.5322	0.8237	
>= 160 vs. < 130		0.6929	0.8986	0.9313	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by History of Diabetes
Safety Population

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 61)	Total (N= 109)
Number of patients at risk		48 (100.0%)	61 (100.0%)	109 (100.0%)
Number of patients with events		3 (6.3%)	6 (9.8%)	9 (8.3%)
Number of patients without events		45 (93.8%)	55 (90.2%)	100 (91.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.611 [0.145, 2.581]			
Stratified OR, 95% CI	0.743 [0.159, 3.470]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.635 [0.167, 2.411]			
Stratified RR, 95% CI	0.796 [0.222, 2.856]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.036 [-0.137, 0.066]			
Stratified ARR, 95% CI (CMH method)	-0.020 [-0.116, 0.076]			
Test on Differences [c]				
Unstratified p-value	0.7285			
Stratified p-value	0.6909			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by History of Diabetes
Safety Population

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		5 (8.5%)	4 (8.3%)	9 (8.4%)
Number of patients without events		54 (91.5%)	44 (91.7%)	98 (91.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.019 [0.258, 4.023]			
Stratified OR, 95% CI	1.043 [0.238, 4.564]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.017 [0.289, 3.579]			
Stratified RR, 95% CI	1.082 [0.319, 3.676]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.001 [-0.104, 0.107]			
Stratified ARR, 95% CI (CMH method)	-0.007 [-0.110, 0.096]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8940			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TESAE by History of Diabetes
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.6118
No vs. Yes		0.5050	0.7878	0.6151	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by BMI
Safety Population

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		13 (100.0%)	13 (100.0%)	26 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by BMI
Safety Population

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		3 (11.1%)	4 (10.8%)	7 (10.9%)
Number of patients without events		24 (88.9%)	33 (89.2%)	57 (89.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.031 [0.211, 5.040]			
Stratified OR, 95% CI	1.212 [0.244, 6.028]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.028 [0.250, 4.220]			
Stratified RR, 95% CI	1.191 [0.312, 4.545]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.003 [-0.152, 0.158]			
Stratified ARR, 95% CI (CMH method)	0.009 [-0.143, 0.160]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9112			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE by BMI
Safety Population

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 67)	Ezetimibe (N= 59)	Total (N= 126)
Number of patients at risk		67 (100.0%)	59 (100.0%)	126 (100.0%)
Number of patients with events		5 (7.5%)	6 (10.2%)	11 (8.7%)
Number of patients without events		62 (92.5%)	53 (89.8%)	115 (91.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.712 [0.206, 2.467]			
Stratified OR, 95% CI	0.847 [0.203, 3.533]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.734 [0.236, 2.281]			
Stratified RR, 95% CI	0.948 [0.297, 3.028]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.027 [-0.127, 0.072]			
Stratified ARR, 95% CI (CMH method)	-0.031 [-0.127, 0.065]			
Test on Differences [c]				
Unstratified p-value	0.5912			
Stratified p-value	0.5230			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Table 1002FDC.053b.202.2.9.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TESAE by BMI
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.9362
25 - < 30 vs. < 25		0.9998	<.0001	0.9765	
>= 30 vs. < 25		0.9998	-	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		9 (8.4%)	9 (8.3%)	18 (8.3%)
Number of patients without events		98 (91.6%)	100 (91.7%)	198 (91.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.020 [0.389, 2.678]			
Stratified OR, 95% CI	1.154 [0.403, 3.306]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.019 [0.421, 2.467]			
Stratified RR, 95% CI	1.165 [0.467, 2.906]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.002 [-0.072, 0.075]			
Stratified ARR, 95% CI (CMH method)	0.002 [-0.070, 0.074]			
Test on Differences [c]				
Unstratified p-value	0.9673			
Stratified p-value	0.9508			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Gender
Safety Population

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		3 (6.0%)	6 (11.5%)	9 (8.8%)
Number of patients without events		47 (94.0%)	46 (88.5%)	93 (91.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.489 [0.115, 2.074]			
Stratified OR, 95% CI	0.727 [0.159, 3.335]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.520 [0.137, 1.967]			
Stratified RR, 95% CI	0.808 [0.220, 2.966]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.055 [-0.164, 0.054]			
Stratified ARR, 95% CI (CMH method)	-0.043 [-0.150, 0.064]			
Test on Differences [c]				
Unstratified p-value	0.4882			
Stratified p-value	0.4430			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Gender
Safety Population

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 57)	Total (N= 114)
Number of patients at risk		57 (100.0%)	57 (100.0%)	114 (100.0%)
Number of patients with events		6 (10.5%)	3 (5.3%)	9 (7.9%)
Number of patients without events		51 (89.5%)	54 (94.7%)	105 (92.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.118 [0.503, 8.918]			
Stratified OR, 95% CI	1.664 [0.407, 6.806]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.000 [0.526, 7.611]			
Stratified RR, 95% CI	1.563 [0.444, 5.496]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.053 [-0.046, 0.151]			
Stratified ARR, 95% CI (CMH method)	0.041 [-0.056, 0.138]			
Test on Differences [c]				
Unstratified p-value	0.4897			
Stratified p-value	0.4106			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Severe TEAE by Gender
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.1478
Female vs. Male		0.3354	0.2488	0.1615	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Table 1002FDC.053b.202.3.2
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Age
Safety Population

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 48)	Total (N= 105)
Number of patients at risk		57 (100.0%)	48 (100.0%)	105 (100.0%)
Number of patients with events		6 (10.5%)	3 (6.3%)	9 (8.6%)
Number of patients without events		51 (89.5%)	45 (93.8%)	96 (91.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.765 [0.417, 7.469]			
Stratified OR, 95% CI	1.531 [0.375, 6.253]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.684 [0.445, 6.379]			
Stratified RR, 95% CI	1.466 [0.415, 5.177]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.043 [-0.062, 0.148]			
Stratified ARR, 95% CI (CMH method)	0.041 [-0.066, 0.148]			
Test on Differences [c]				
Unstratified p-value	0.5038			
Stratified p-value	0.4522			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Age
Safety Population

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		3 (6.0%)	6 (9.8%)	9 (8.1%)
Number of patients without events		47 (94.0%)	55 (90.2%)	102 (91.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.585 [0.139, 2.468]			
Stratified OR, 95% CI	0.724 [0.157, 3.343]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.610 [0.161, 2.317]			
Stratified RR, 95% CI	0.796 [0.218, 2.902]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.038 [-0.138, 0.061]			
Stratified ARR, 95% CI (CMH method)	-0.036 [-0.131, 0.059]			
Test on Differences [c]				
Unstratified p-value	0.5100			
Stratified p-value	0.4835			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Severe TEAE by Age
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.2780
>= 65 vs. < 65		0.4429	0.5050	0.2910	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by CVD Risk Category
Safety Population

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 62)	Total (N= 121)
Number of patients at risk		59 (100.0%)	62 (100.0%)	121 (100.0%)
Number of patients with events		7 (11.9%)	9 (14.5%)	16 (13.2%)
Number of patients without events		52 (88.1%)	53 (85.5%)	105 (86.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.793 [0.275, 2.286]			
Stratified OR, 95% CI	0.917 [0.265, 3.177]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.817 [0.325, 2.053]			
Stratified RR, 95% CI	0.992 [0.336, 2.926]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.027 [-0.147, 0.094]			
Stratified ARR, 95% CI (CMH method)	-0.031 [-0.151, 0.089]			
Test on Differences [c]				
Unstratified p-value	0.6669			
Stratified p-value	0.6164			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by CVD Risk Category
Safety Population

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		2 (4.2%)	0	2 (2.1%)
Number of patients without events		46 (95.8%)	47 (100.0%)	93 (97.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.108 [0.239, 109.28]			
Stratified OR, 95% CI	3.048 [0.305, 30.500]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.898 [0.241, 99.383]			
Stratified RR, 95% CI	2.909 [0.315, 26.897]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.042 [-0.015, 0.098]			
Stratified ARR, 95% CI (CMH method)	0.041 [-0.015, 0.098]			
Test on Differences [c]				
Unstratified p-value	0.4947			
Stratified p-value	0.1640			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Severe TEAE by CVD Risk Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.0855
Multiple CV risk factors vs. ASCVD and/or HeFH		0.6678	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 65)	Ezetimibe (N= 70)	Total (N= 135)
Number of patients at risk		65 (100.0%)	70 (100.0%)	135 (100.0%)
Number of patients with events		2 (3.1%)	6 (8.6%)	8 (5.9%)
Number of patients without events		63 (96.9%)	64 (91.4%)	127 (94.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.339 [0.066, 1.742]			
Stratified OR, 95% CI	0.413 [0.068, 2.509]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.359 [0.075, 1.716]			
Stratified RR, 95% CI	0.436 [0.077, 2.459]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.055 [-0.133, 0.023]			
Stratified ARR, 95% CI (CMH method)	-0.052 [-0.129, 0.025]			
Test on Differences [c]				
Unstratified p-value	0.2769			
Stratified p-value	0.1964			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		7 (16.7%)	3 (7.7%)	10 (12.3%)
Number of patients without events		35 (83.3%)	36 (92.3%)	71 (87.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.400 [0.574, 10.032]			
Stratified OR, 95% CI	2.236 [0.565, 8.847]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.167 [0.602, 7.795]			
Stratified RR, 95% CI	1.961 [0.604, 6.359]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.090 [-0.051, 0.230]			
Stratified ARR, 95% CI (CMH method)	0.089 [-0.048, 0.226]			
Test on Differences [c]				
Unstratified p-value	0.3151			
Stratified p-value	0.2164			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Table 1002FDC.053b.202.3.4.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Severe TEAE by Baseline Statin Intensity I
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.0628
High Intensity Statin vs. Other		0.1993	0.8732	0.0813	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 32)	Ezetimibe (N= 38)	Total (N= 70)
Number of patients at risk		32 (100.0%)	38 (100.0%)	70 (100.0%)
Number of patients with events		1 (3.1%)	4 (10.5%)	5 (7.1%)
Number of patients without events		31 (96.9%)	34 (89.5%)	65 (92.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.274 [0.029, 2.588]			
Stratified OR, 95% CI	0.543 [0.060, 4.955]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.297 [0.035, 2.524]			
Stratified RR, 95% CI	0.584 [0.071, 4.815]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.074 [-0.189, 0.041]			
Stratified ARR, 95% CI (CMH method)	-0.072 [-0.189, 0.044]			
Test on Differences [c]				
Unstratified p-value	0.3662			
Stratified p-value	0.2423			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		7 (16.7%)	3 (7.7%)	10 (12.3%)
Number of patients without events		35 (83.3%)	36 (92.3%)	71 (87.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.400 [0.574, 10.032]			
Stratified OR, 95% CI	2.236 [0.565, 8.847]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.167 [0.602, 7.795]			
Stratified RR, 95% CI	1.961 [0.604, 6.359]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.090 [-0.051, 0.230]			
Stratified ARR, 95% CI (CMH method)	0.089 [-0.048, 0.226]			
Test on Differences [c]				
Unstratified p-value	0.3151			
Stratified p-value	0.2164			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		1 (3.0%)	2 (6.3%)	3 (4.6%)
Number of patients without events		32 (97.0%)	30 (93.8%)	62 (95.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.469 [0.040, 5.441]			
Stratified OR, 95% CI	0.500 [0.041, 6.121]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.485 [0.046, 5.087]			
Stratified RR, 95% CI	0.531 [0.053, 5.306]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.032 [-0.134, 0.070]			
Stratified ARR, 95% CI (CMH method)	-0.028 [-0.128, 0.072]			
Test on Differences [c]				
Unstratified p-value	0.6132			
Stratified p-value	0.5876			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Severe TEAE by Baseline Statin Intensity II
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.1751
High Intensity Statin vs. Other Intensity Statin		0.2661	0.6670	0.1183	
None vs. Other Intensity Statin		0.2661	0.5310	0.7623	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Race
Safety Population

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 84)	Ezetimibe (N= 91)	Total (N= 175)
Number of patients at risk		84 (100.0%)	91 (100.0%)	175 (100.0%)
Number of patients with events		5 (6.0%)	7 (7.7%)	12 (6.9%)
Number of patients without events		79 (94.0%)	84 (92.3%)	163 (93.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.759 [0.232, 2.492]			
Stratified OR, 95% CI	0.877 [0.247, 3.118]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.774 [0.255, 2.345]			
Stratified RR, 95% CI	0.916 [0.295, 2.838]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.017 [-0.092, 0.057]			
Stratified ARR, 95% CI (CMH method)	-0.013 [-0.087, 0.061]			
Test on Differences [c]				
Unstratified p-value	0.6491			
Stratified p-value	0.7290			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Race
Safety Population

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		4 (17.4%)	2 (11.1%)	6 (14.6%)
Number of patients without events		19 (82.6%)	16 (88.9%)	35 (85.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.684 [0.272, 10.426]			
Stratified OR, 95% CI	0.773 [0.115, 5.205]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.565 [0.322, 7.609]			
Stratified RR, 95% CI	0.809 [0.220, 2.980]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.063 [-0.150, 0.275]			
Stratified ARR, 95% CI (CMH method)	-0.028 [-0.223, 0.166]			
Test on Differences [c]				
Unstratified p-value	0.6786			
Stratified p-value	0.7898			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Severe TEAE by Race
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.4654
non-White vs. White		0.6503	0.6281	0.4747	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 38)	Total (N= 76)
Number of patients at risk		38 (100.0%)	38 (100.0%)	76 (100.0%)
Number of patients with events		4 (10.5%)	5 (13.2%)	9 (11.8%)
Number of patients without events		34 (89.5%)	33 (86.8%)	67 (88.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.776 [0.192, 3.147]			
Stratified OR, 95% CI	0.837 [0.188, 3.723]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.800 [0.233, 2.752]			
Stratified RR, 95% CI	0.900 [0.270, 3.002]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.026 [-0.171, 0.119]			
Stratified ARR, 95% CI (CMH method)	-0.032 [-0.174, 0.110]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.6728			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		1 (3.2%)	2 (4.4%)	3 (3.9%)
Number of patients without events		30 (96.8%)	43 (95.6%)	73 (96.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.717 [0.062, 8.266]			
Stratified OR, 95% CI	1.063 [0.102, 11.045]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.726 [0.069, 7.660]			
Stratified RR, 95% CI	1.093 [0.136, 8.781]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.012 [-0.099, 0.074]			
Stratified ARR, 95% CI (CMH method)	-0.010 [-0.101, 0.081]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8212			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		4 (10.5%)	2 (7.7%)	6 (9.4%)
Number of patients without events		34 (89.5%)	24 (92.3%)	58 (90.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.412 [0.239, 8.338]			
Stratified OR, 95% CI	1.175 [0.240, 5.745]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.368 [0.270, 6.932]			
Stratified RR, 95% CI	1.132 [0.284, 4.506]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.028 [-0.113, 0.170]			
Stratified ARR, 95% CI (CMH method)	0.032 [-0.113, 0.176]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.6806			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Severe TEAE by Baseline LDL-C Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.8486
130 - < 160 vs. < 130		0.7233	0.1787	0.9428	
>= 160 vs. < 130		0.7233	0.5006	0.6059	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by History of Diabetes
Safety Population

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 61)	Total (N= 109)
Number of patients at risk		48 (100.0%)	61 (100.0%)	109 (100.0%)
Number of patients with events		4 (8.3%)	6 (9.8%)	10 (9.2%)
Number of patients without events		44 (91.7%)	55 (90.2%)	99 (90.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.833 [0.221, 3.138]			
Stratified OR, 95% CI	1.012 [0.251, 4.075]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.847 [0.253, 2.834]			
Stratified RR, 95% CI	0.998 [0.305, 3.263]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.015 [-0.123, 0.093]			
Stratified ARR, 95% CI (CMH method)	0.001 [-0.104, 0.105]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9891			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by History of Diabetes
Safety Population

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		5 (8.5%)	3 (6.3%)	8 (7.5%)
Number of patients without events		54 (91.5%)	45 (93.8%)	99 (92.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.389 [0.315, 6.132]			
Stratified OR, 95% CI	1.461 [0.281, 7.600]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.356 [0.341, 5.388]			
Stratified RR, 95% CI	1.452 [0.335, 6.291]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.022 [-0.076, 0.121]			
Stratified ARR, 95% CI (CMH method)	0.017 [-0.081, 0.114]			
Test on Differences [c]				
Unstratified p-value	0.7283			
Stratified p-value	0.7418			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Severe TEAE by History of Diabetes
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.6118
No vs. Yes		0.7878	0.5050	0.6151	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by BMI
Safety Population

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		0	1 (7.7%)	1 (3.8%)
Number of patients without events		13 (100.0%)	12 (92.3%)	25 (96.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.309 [0.011, 8.300]			
Stratified OR, 95% CI	0.407 [0.013, 12.636]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.333 [0.015, 7.501]			
Stratified RR, 95% CI	0.467 [0.024, 9.259]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.077 [-0.222, 0.068]			
Stratified ARR, 95% CI (CMH method)	-0.073 [-0.224, 0.078]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4142			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by BMI
Safety Population

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		2 (7.4%)	3 (8.1%)	5 (7.8%)
Number of patients without events		25 (92.6%)	34 (91.9%)	59 (92.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.907 [0.141, 5.837]			
Stratified OR, 95% CI	0.972 [0.167, 5.660]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.914 [0.164, 5.097]			
Stratified RR, 95% CI	0.972 [0.208, 4.539]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.007 [-0.139, 0.125]			
Stratified ARR, 95% CI (CMH method)	-0.006 [-0.135, 0.123]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9321			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE by BMI
Safety Population

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 67)	Ezetimibe (N= 59)	Total (N= 126)
Number of patients at risk		67 (100.0%)	59 (100.0%)	126 (100.0%)
Number of patients with events		7 (10.4%)	5 (8.5%)	12 (9.5%)
Number of patients without events		60 (89.6%)	54 (91.5%)	114 (90.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.260 [0.378, 4.205]			
Stratified OR, 95% CI	1.372 [0.376, 5.015]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.233 [0.413, 3.678]			
Stratified RR, 95% CI	1.345 [0.466, 3.880]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.020 [-0.082, 0.122]			
Stratified ARR, 95% CI (CMH method)	0.017 [-0.081, 0.115]			
Test on Differences [c]				
Unstratified p-value	0.7065			
Stratified p-value	0.7329			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Severe TEAE by BMI
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.4540
25 - < 30 vs. < 25		<.0001	0.9621	<.0001	
>= 30 vs. < 25		<.0001	0.9266	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		23 (21.5%)	14 (12.8%)	37 (17.1%)
Number of patients without events		84 (78.5%)	95 (87.2%)	179 (82.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.858 [0.899, 3.841]			
Stratified OR, 95% CI	1.869 [0.882, 3.957]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.674 [0.911, 3.075]			
Stratified RR, 95% CI	1.681 [0.903, 3.127]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.087 [-0.014, 0.187]			
Stratified ARR, 95% CI (CMH method)	0.089 [-0.011, 0.189]			
Test on Differences [c]				
Unstratified p-value	0.0916			
Stratified p-value	0.0801			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Gender
Safety Population

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		10 (20.0%)	3 (5.8%)	13 (12.7%)
Number of patients without events		40 (80.0%)	49 (94.2%)	89 (87.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.083 [1.052, 15.848]			
Stratified OR, 95% CI	3.161 [0.802, 12.458]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.467 [1.013, 11.865]			
Stratified RR, 95% CI	2.609 [0.763, 8.919]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.142 [0.015, 0.270]			
Stratified ARR, 95% CI (CMH method)	0.156 [0.026, 0.286]			
Test on Differences [c]				
Unstratified p-value	0.0394			
Stratified p-value	0.0185			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Gender
Safety Population

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 57)	Total (N= 114)
Number of patients at risk		57 (100.0%)	57 (100.0%)	114 (100.0%)
Number of patients with events		13 (22.8%)	11 (19.3%)	24 (21.1%)
Number of patients without events		44 (77.2%)	46 (80.7%)	90 (78.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.236 [0.501, 3.048]			
Stratified OR, 95% CI	1.239 [0.488, 3.145]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.182 [0.579, 2.414]			
Stratified RR, 95% CI	1.183 [0.581, 2.408]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.035 [-0.114, 0.185]			
Stratified ARR, 95% CI (CMH method)	0.034 [-0.113, 0.181]			
Test on Differences [c]				
Unstratified p-value	0.6459			
Stratified p-value	0.6537			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Moderate TEAE by Gender
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.1187
Female vs. Male		0.0477	0.0524	0.1382	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Age
Safety Population

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 48)	Total (N= 105)
Number of patients at risk		57 (100.0%)	48 (100.0%)	105 (100.0%)
Number of patients with events		15 (26.3%)	1 (2.1%)	16 (15.2%)
Number of patients without events		42 (73.7%)	47 (97.9%)	89 (84.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	16.786 [2.125, 132.57]			
Stratified OR, 95% CI	5.467 [1.207, 24.772]			
Relative Risk [a]				
Unstratified RR, 95% CI	12.632 [1.731, 92.175]			
Stratified RR, 95% CI	4.138 [1.027, 16.675]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.242 [0.121, 0.364]			
Stratified ARR, 95% CI (CMH method)	0.231 [0.109, 0.354]			
Test on Differences [c]				
Unstratified p-value	0.0006			
Stratified p-value	0.0010			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Age
Safety Population

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		8 (16.0%)	13 (21.3%)	21 (18.9%)
Number of patients without events		42 (84.0%)	48 (78.7%)	90 (81.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.703 [0.266, 1.861]			
Stratified OR, 95% CI	0.790 [0.294, 2.126]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.751 [0.338, 1.667]			
Stratified RR, 95% CI	0.870 [0.402, 1.884]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.053 [-0.198, 0.091]			
Stratified ARR, 95% CI (CMH method)	-0.045 [-0.191, 0.102]			
Test on Differences [c]				
Unstratified p-value	0.4772			
Stratified p-value	0.5516			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Moderate TEAE by Age
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.0006
>= 65 vs. < 65		0.0124	0.0226	0.0098	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by CVD Risk Category
Safety Population

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 62)	Total (N= 121)
Number of patients at risk		59 (100.0%)	62 (100.0%)	121 (100.0%)
Number of patients with events		16 (27.1%)	8 (12.9%)	24 (19.8%)
Number of patients without events		43 (72.9%)	54 (87.1%)	97 (80.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.512 [0.983, 6.420]			
Stratified OR, 95% CI	2.613 [0.995, 6.864]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.102 [0.973, 4.540]			
Stratified RR, 95% CI	2.171 [0.991, 4.757]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.142 [0.001, 0.283]			
Stratified ARR, 95% CI (CMH method)	0.150 [0.008, 0.291]			
Test on Differences [c]				
Unstratified p-value	0.0500			
Stratified p-value	0.0380			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by CVD Risk Category
Safety Population

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		7 (14.6%)	6 (12.8%)	13 (13.7%)
Number of patients without events		41 (85.4%)	41 (87.2%)	82 (86.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.167 [0.361, 3.771]			
Stratified OR, 95% CI	1.168 [0.356, 3.835]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.142 [0.415, 3.148]			
Stratified RR, 95% CI	1.132 [0.408, 3.140]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.018 [-0.120, 0.156]			
Stratified ARR, 95% CI (CMH method)	0.019 [-0.119, 0.157]			
Test on Differences [c]				
Unstratified p-value	0.7966			
Stratified p-value	0.7888			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Moderate TEAE by CVD Risk Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.3487
Multiple CV risk factors vs. ASCVD and/or HeFH		0.0587	0.9831	0.3479	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 65)	Ezetimibe (N= 70)	Total (N= 135)
Number of patients at risk		65 (100.0%)	70 (100.0%)	135 (100.0%)
Number of patients with events		18 (27.7%)	10 (14.3%)	28 (20.7%)
Number of patients without events		47 (72.3%)	60 (85.7%)	107 (79.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.298 [0.970, 5.442]			
Stratified OR, 95% CI	2.294 [0.947, 5.557]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.938 [0.967, 3.886]			
Stratified RR, 95% CI	1.942 [0.949, 3.971]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.134 [-0.002, 0.270]			
Stratified ARR, 95% CI (CMH method)	0.138 [0.000, 0.275]			
Test on Differences [c]				
Unstratified p-value	0.0549			
Stratified p-value	0.0488			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		5 (11.9%)	4 (10.3%)	9 (11.1%)
Number of patients without events		37 (88.1%)	35 (89.7%)	72 (88.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.182 [0.293, 4.765]			
Stratified OR, 95% CI	1.169 [0.285, 4.797]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.161 [0.336, 4.013]			
Stratified RR, 95% CI	1.141 [0.325, 4.009]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.016 [-0.120, 0.153]			
Stratified ARR, 95% CI (CMH method)	0.016 [-0.120, 0.153]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8166			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Moderate TEAE by Baseline Statin Intensity I
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.4833
High Intensity Statin vs. Other		0.0621	0.5518	0.4797	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 32)	Ezetimibe (N= 38)	Total (N= 70)
Number of patients at risk		32 (100.0%)	38 (100.0%)	70 (100.0%)
Number of patients with events		6 (18.8%)	2 (5.3%)	8 (11.4%)
Number of patients without events		26 (81.3%)	36 (94.7%)	62 (88.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.154 [0.776, 22.241]			
Stratified OR, 95% CI	3.878 [0.805, 18.679]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.562 [0.772, 16.447]			
Stratified RR, 95% CI	3.140 [0.806, 12.235]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.135 [-0.018, 0.288]			
Stratified ARR, 95% CI (CMH method)	0.138 [-0.011, 0.287]			
Test on Differences [c]				
Unstratified p-value	0.1301			
Stratified p-value	0.0656			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		5 (11.9%)	4 (10.3%)	9 (11.1%)
Number of patients without events		37 (88.1%)	35 (89.7%)	72 (88.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.182 [0.293, 4.765]			
Stratified OR, 95% CI	1.169 [0.285, 4.797]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.161 [0.336, 4.013]			
Stratified RR, 95% CI	1.141 [0.325, 4.009]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.016 [-0.120, 0.153]			
Stratified ARR, 95% CI (CMH method)	0.016 [-0.120, 0.153]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8166			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		12 (36.4%)	8 (25.0%)	20 (30.8%)
Number of patients without events		21 (63.6%)	24 (75.0%)	45 (69.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.714 [0.588, 4.994]			
Stratified OR, 95% CI	1.658 [0.547, 5.026]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.455 [0.686, 3.082]			
Stratified RR, 95% CI	1.396 [0.629, 3.097]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.114 [-0.109, 0.336]			
Stratified ARR, 95% CI (CMH method)	0.116 [-0.113, 0.345]			
Test on Differences [c]				
Unstratified p-value	0.3210			
Stratified p-value	0.3171			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Moderate TEAE by Baseline Statin Intensity II
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.4684
High Intensity Statin vs. Other Intensity Statin		0.1036	0.4246	0.2644	
None vs. Other Intensity Statin		0.1036	0.0386	0.3029	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Race
Safety Population

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 84)	Ezetimibe (N= 91)	Total (N= 175)
Number of patients at risk		84 (100.0%)	91 (100.0%)	175 (100.0%)
Number of patients with events		21 (25.0%)	13 (14.3%)	34 (19.4%)
Number of patients without events		63 (75.0%)	78 (85.7%)	141 (80.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.000 [0.929, 4.308]			
Stratified OR, 95% CI	1.988 [0.906, 4.362]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.750 [0.937, 3.269]			
Stratified RR, 95% CI	1.725 [0.920, 3.232]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.107 [-0.010, 0.224]			
Stratified ARR, 95% CI (CMH method)	0.105 [-0.012, 0.222]			
Test on Differences [c]				
Unstratified p-value	0.0735			
Stratified p-value	0.0793			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Race
Safety Population

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		2 (8.7%)	1 (5.6%)	3 (7.3%)
Number of patients without events		21 (91.3%)	17 (94.4%)	38 (92.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.619 [0.135, 19.414]			
Stratified OR, 95% CI	1.032 [0.090, 11.856]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.565 [0.154, 15.925]			
Stratified RR, 95% CI	0.908 [0.118, 6.976]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.031 [-0.125, 0.188]			
Stratified ARR, 95% CI (CMH method)	0.041 [-0.175, 0.257]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.6365			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Table 1002FDC.053b.202.4.6.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Moderate TEAE by Race
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.9279
non-White vs. White		0.0792	0.3474	0.9275	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 38)	Total (N= 76)
Number of patients at risk		38 (100.0%)	38 (100.0%)	76 (100.0%)
Number of patients with events		8 (21.1%)	4 (10.5%)	12 (15.8%)
Number of patients without events		30 (78.9%)	34 (89.5%)	64 (84.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.267 [0.620, 8.290]			
Stratified OR, 95% CI	2.625 [0.679, 10.148]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.000 [0.657, 6.086]			
Stratified RR, 95% CI	2.154 [0.734, 6.315]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.105 [-0.057, 0.268]			
Stratified ARR, 95% CI (CMH method)	0.135 [-0.028, 0.298]			
Test on Differences [c]				
Unstratified p-value	0.3459			
Stratified p-value	0.1113			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		7 (22.6%)	3 (6.7%)	10 (13.2%)
Number of patients without events		24 (77.4%)	42 (93.3%)	66 (86.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.083 [0.965, 17.278]			
Stratified OR, 95% CI	2.663 [0.586, 12.102]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.387 [0.949, 12.095]			
Stratified RR, 95% CI	2.190 [0.570, 8.416]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.159 [-0.005, 0.323]			
Stratified ARR, 95% CI (CMH method)	0.160 [-0.013, 0.334]			
Test on Differences [c]				
Unstratified p-value	0.0804			
Stratified p-value	0.0453			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		8 (21.1%)	7 (26.9%)	15 (23.4%)
Number of patients without events		30 (78.9%)	19 (73.1%)	49 (76.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.724 [0.226, 2.322]			
Stratified OR, 95% CI	0.676 [0.188, 2.434]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.782 [0.323, 1.891]			
Stratified RR, 95% CI	0.781 [0.289, 2.112]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.059 [-0.273, 0.155]			
Stratified ARR, 95% CI (CMH method)	-0.076 [-0.293, 0.141]			
Test on Differences [c]				
Unstratified p-value	0.5861			
Stratified p-value	0.4950			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Moderate TEAE by Baseline LDL-C Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.1364
130 - < 160 vs. < 130		0.2222	0.5322	0.5414	
>= 160 vs. < 130		0.2222	0.1011	0.1951	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by History of Diabetes
Safety Population

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 61)	Total (N= 109)
Number of patients at risk		48 (100.0%)	61 (100.0%)	109 (100.0%)
Number of patients with events		6 (12.5%)	5 (8.2%)	11 (10.1%)
Number of patients without events		42 (87.5%)	56 (91.8%)	98 (89.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.600 [0.457, 5.598]			
Stratified OR, 95% CI	1.747 [0.488, 6.252]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.525 [0.495, 4.697]			
Stratified RR, 95% CI	1.660 [0.534, 5.159]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.043 [-0.073, 0.159]			
Stratified ARR, 95% CI (CMH method)	0.046 [-0.070, 0.162]			
Test on Differences [c]				
Unstratified p-value	0.4590			
Stratified p-value	0.4353			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by History of Diabetes
Safety Population

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		17 (28.8%)	9 (18.8%)	26 (24.3%)
Number of patients without events		42 (71.2%)	39 (81.3%)	81 (75.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.754 [0.700, 4.393]			
Stratified OR, 95% CI	1.873 [0.711, 4.932]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.537 [0.754, 3.134]			
Stratified RR, 95% CI	1.620 [0.771, 3.407]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.101 [-0.059, 0.260]			
Stratified ARR, 95% CI (CMH method)	0.113 [-0.048, 0.274]			
Test on Differences [c]				
Unstratified p-value	0.2274			
Stratified p-value	0.1794			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Moderate TEAE by History of Diabetes
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.9910
No vs. Yes		0.4622	0.1139	0.9910	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by BMI
Safety Population

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		4 (30.8%)	3 (23.1%)	7 (26.9%)
Number of patients without events		9 (69.2%)	10 (76.9%)	19 (73.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.481 [0.258, 8.499]			
Stratified OR, 95% CI	3.402 [0.379, 30.508]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.333 [0.369, 4.817]			
Stratified RR, 95% CI	1.612 [0.637, 4.076]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.077 [-0.263, 0.417]			
Stratified ARR, 95% CI (CMH method)	0.201 [-0.100, 0.502]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.2436			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by BMI
Safety Population

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		6 (22.2%)	4 (10.8%)	10 (15.6%)
Number of patients without events		21 (77.8%)	33 (89.2%)	54 (84.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.357 [0.594, 9.354]			
Stratified OR, 95% CI	2.152 [0.554, 8.360]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.056 [0.642, 6.582]			
Stratified RR, 95% CI	1.856 [0.595, 5.787]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.114 [-0.072, 0.300]			
Stratified ARR, 95% CI (CMH method)	0.115 [-0.077, 0.308]			
Test on Differences [c]				
Unstratified p-value	0.2995			
Stratified p-value	0.2225			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Moderate TEAE by BMI
Safety Population

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 67)	Ezetimibe (N= 59)	Total (N= 126)
Number of patients at risk		67 (100.0%)	59 (100.0%)	126 (100.0%)
Number of patients with events		13 (19.4%)	7 (11.9%)	20 (15.9%)
Number of patients without events		54 (80.6%)	52 (88.1%)	106 (84.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.788 [0.661, 4.835]			
Stratified OR, 95% CI	1.532 [0.503, 4.670]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.635 [0.699, 3.825]			
Stratified RR, 95% CI	1.387 [0.523, 3.676]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.075 [-0.050, 0.201]			
Stratified ARR, 95% CI (CMH method)	0.076 [-0.052, 0.205]			
Test on Differences [c]				
Unstratified p-value	0.2479			
Stratified p-value	0.2460			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Moderate TEAE by BMI
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.8861
25 - < 30 vs. < 25		0.6607	0.2734	0.6245	
>= 30 vs. < 25		0.6607	0.2819	0.7950	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		31 (29.0%)	35 (32.1%)	66 (30.6%)
Number of patients without events		76 (71.0%)	74 (67.9%)	150 (69.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.862 [0.483, 1.540]			
Stratified OR, 95% CI	0.864 [0.478, 1.562]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.902 [0.603, 1.350]			
Stratified RR, 95% CI	0.915 [0.602, 1.391]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.031 [-0.154, 0.091]			
Stratified ARR, 95% CI (CMH method)	-0.032 [-0.155, 0.092]			
Test on Differences [c]				
Unstratified p-value	0.6167			
Stratified p-value	0.6161			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Table 1002FDC.053b.202.5.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Gender
Safety Population

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		15 (30.0%)	18 (34.6%)	33 (32.4%)
Number of patients without events		35 (70.0%)	34 (65.4%)	69 (67.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.810 [0.352, 1.860]			
Stratified OR, 95% CI	0.810 [0.336, 1.956]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.867 [0.493, 1.524]			
Stratified RR, 95% CI	0.871 [0.464, 1.633]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.046 [-0.227, 0.135]			
Stratified ARR, 95% CI (CMH method)	-0.047 [-0.231, 0.138]			
Test on Differences [c]				
Unstratified p-value	0.6184			
Stratified p-value	0.6243			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Gender
Safety Population

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 57)	Total (N= 114)
Number of patients at risk		57 (100.0%)	57 (100.0%)	114 (100.0%)
Number of patients with events		16 (28.1%)	17 (29.8%)	33 (28.9%)
Number of patients without events		41 (71.9%)	40 (70.2%)	81 (71.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.918 [0.409, 2.064]			
Stratified OR, 95% CI	0.968 [0.425, 2.205]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.941 [0.529, 1.674]			
Stratified RR, 95% CI	1.003 [0.564, 1.782]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.018 [-0.184, 0.149]			
Stratified ARR, 95% CI (CMH method)	-0.009 [-0.177, 0.159]			
Test on Differences [c]				
Unstratified p-value	0.8364			
Stratified p-value	0.9213			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Table 1002FDC.053b.202.5.1.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Mild TEAE by Gender
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.8410
Female vs. Male		0.6194	0.5928	0.8411	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Table 1002FDC.053b.202.5.2
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Age
Safety Population

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 48)	Total (N= 105)
Number of patients at risk		57 (100.0%)	48 (100.0%)	105 (100.0%)
Number of patients with events		14 (24.6%)	18 (37.5%)	32 (30.5%)
Number of patients without events		43 (75.4%)	30 (62.5%)	73 (69.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.543 [0.234, 1.257]			
Stratified OR, 95% CI	0.546 [0.233, 1.276]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.655 [0.365, 1.174]			
Stratified RR, 95% CI	0.658 [0.365, 1.186]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.129 [-0.306, 0.047]			
Stratified ARR, 95% CI (CMH method)	-0.132 [-0.311, 0.048]			
Test on Differences [c]				
Unstratified p-value	0.1513			
Stratified p-value	0.1537			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Age
Safety Population

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		17 (34.0%)	17 (27.9%)	34 (30.6%)
Number of patients without events		33 (66.0%)	44 (72.1%)	77 (69.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.333 [0.593, 2.996]			
Stratified OR, 95% CI	1.296 [0.549, 3.057]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.220 [0.698, 2.133]			
Stratified RR, 95% CI	1.218 [0.659, 2.251]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.061 [-0.112, 0.234]			
Stratified ARR, 95% CI (CMH method)	0.058 [-0.118, 0.234]			
Test on Differences [c]				
Unstratified p-value	0.4857			
Stratified p-value	0.5175			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Table 1002FDC.053b.202.5.2.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Mild TEAE by Age
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.1304
>= 65 vs. < 65		0.1551	0.2852	0.1312	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by CVD Risk Category
Safety Population

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 62)	Total (N= 121)
Number of patients at risk		59 (100.0%)	62 (100.0%)	121 (100.0%)
Number of patients with events		13 (22.0%)	22 (35.5%)	35 (28.9%)
Number of patients without events		46 (78.0%)	40 (64.5%)	86 (71.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.514 [0.229, 1.150]			
Stratified OR, 95% CI	0.516 [0.230, 1.158]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.621 [0.346, 1.115]			
Stratified RR, 95% CI	0.623 [0.346, 1.123]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.134 [-0.294, 0.025]			
Stratified ARR, 95% CI (CMH method)	-0.134 [-0.294, 0.025]			
Test on Differences [c]				
Unstratified p-value	0.1029			
Stratified p-value	0.1074			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by CVD Risk Category
Safety Population

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		18 (37.5%)	13 (27.7%)	31 (32.6%)
Number of patients without events		30 (62.5%)	34 (72.3%)	64 (67.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.569 [0.660, 3.731]			
Stratified OR, 95% CI	1.576 [0.662, 3.752]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.356 [0.752, 2.444]			
Stratified RR, 95% CI	1.362 [0.756, 2.454]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.098 [-0.089, 0.286]			
Stratified ARR, 95% CI (CMH method)	0.099 [-0.088, 0.286]			
Test on Differences [c]				
Unstratified p-value	0.3064			
Stratified p-value	0.3070			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Table 1002FDC.053b.202.5.3.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Mild TEAE by CVD Risk Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.0606
Multiple CV risk factors vs. ASCVD and/or HeFH		0.1108	0.3928	0.0654	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 65)	Ezetimibe (N= 70)	Total (N= 135)
Number of patients at risk		65 (100.0%)	70 (100.0%)	135 (100.0%)
Number of patients with events		20 (30.8%)	23 (32.9%)	43 (31.9%)
Number of patients without events		45 (69.2%)	47 (67.1%)	92 (68.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.908 [0.440, 1.876]			
Stratified OR, 95% CI	0.909 [0.431, 1.915]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.936 [0.571, 1.536]			
Stratified RR, 95% CI	0.961 [0.572, 1.613]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.021 [-0.178, 0.136]			
Stratified ARR, 95% CI (CMH method)	-0.023 [-0.181, 0.136]			
Test on Differences [c]				
Unstratified p-value	0.7947			
Stratified p-value	0.7798			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		11 (26.2%)	12 (30.8%)	23 (28.4%)
Number of patients without events		31 (73.8%)	27 (69.2%)	58 (71.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.798 [0.303, 2.100]			
Stratified OR, 95% CI	0.799 [0.302, 2.114]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.851 [0.426, 1.701]			
Stratified RR, 95% CI	0.853 [0.424, 1.718]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.046 [-0.242, 0.151]			
Stratified ARR, 95% CI (CMH method)	-0.046 [-0.243, 0.152]			
Test on Differences [c]				
Unstratified p-value	0.6479			
Stratified p-value	0.6523			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Mild TEAE by Baseline Statin Intensity I
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.8260
High Intensity Statin vs. Other		0.7949	0.8237	0.8260	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 32)	Ezetimibe (N= 38)	Total (N= 70)
Number of patients at risk		32 (100.0%)	38 (100.0%)	70 (100.0%)
Number of patients with events		8 (25.0%)	11 (28.9%)	19 (27.1%)
Number of patients without events		24 (75.0%)	27 (71.1%)	51 (72.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.818 [0.282, 2.371]			
Stratified OR, 95% CI	0.831 [0.278, 2.481]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.864 [0.396, 1.884]			
Stratified RR, 95% CI	0.894 [0.396, 2.020]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.039 [-0.248, 0.169]			
Stratified ARR, 95% CI (CMH method)	-0.040 [-0.250, 0.170]			
Test on Differences [c]				
Unstratified p-value	0.7114			
Stratified p-value	0.7126			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		11 (26.2%)	12 (30.8%)	23 (28.4%)
Number of patients without events		31 (73.8%)	27 (69.2%)	58 (71.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.798 [0.303, 2.100]			
Stratified OR, 95% CI	0.799 [0.302, 2.114]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.851 [0.426, 1.701]			
Stratified RR, 95% CI	0.853 [0.424, 1.718]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.046 [-0.242, 0.151]			
Stratified ARR, 95% CI (CMH method)	-0.046 [-0.243, 0.152]			
Test on Differences [c]				
Unstratified p-value	0.6479			
Stratified p-value	0.6523			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		12 (36.4%)	12 (37.5%)	24 (36.9%)
Number of patients without events		21 (63.6%)	20 (62.5%)	41 (63.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.952 [0.348, 2.609]			
Stratified OR, 95% CI	0.942 [0.335, 2.647]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.970 [0.514, 1.831]			
Stratified RR, 95% CI	0.988 [0.508, 1.920]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.011 [-0.246, 0.223]			
Stratified ARR, 95% CI (CMH method)	-0.015 [-0.251, 0.222]			
Test on Differences [c]				
Unstratified p-value	0.9244			
Stratified p-value	0.9031			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Mild TEAE by Baseline Statin Intensity II
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.9567
High Intensity Statin vs. Other Intensity Statin		0.7126	0.8614	0.9782	
None vs. Other Intensity Statin		0.7126	0.4485	0.8215	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Race
Safety Population

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 84)	Ezetimibe (N= 91)	Total (N= 175)
Number of patients at risk		84 (100.0%)	91 (100.0%)	175 (100.0%)
Number of patients with events		26 (31.0%)	29 (31.9%)	55 (31.4%)
Number of patients without events		58 (69.0%)	62 (68.1%)	120 (68.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.958 [0.506, 1.816]			
Stratified OR, 95% CI	0.958 [0.499, 1.838]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.971 [0.626, 1.506]			
Stratified RR, 95% CI	0.990 [0.632, 1.553]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.009 [-0.147, 0.128]			
Stratified ARR, 95% CI (CMH method)	-0.010 [-0.148, 0.129]			
Test on Differences [c]				
Unstratified p-value	0.8963			
Stratified p-value	0.8918			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Race
Safety Population

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		5 (21.7%)	6 (33.3%)	11 (26.8%)
Number of patients without events		18 (78.3%)	12 (66.7%)	30 (73.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.556 [0.138, 2.238]			
Stratified OR, 95% CI	0.773 [0.156, 3.841]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.652 [0.237, 1.798]			
Stratified RR, 95% CI	0.866 [0.253, 2.957]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.116 [-0.391, 0.159]			
Stratified ARR, 95% CI (CMH method)	-0.074 [-0.372, 0.223]			
Test on Differences [c]				
Unstratified p-value	0.4057			
Stratified p-value	0.6307			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Mild TEAE by Race
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.4782
non-White vs. White		0.8963	0.9025	0.4798	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 38)	Total (N= 76)
Number of patients at risk		38 (100.0%)	38 (100.0%)	76 (100.0%)
Number of patients with events		7 (18.4%)	12 (31.6%)	19 (25.0%)
Number of patients without events		31 (81.6%)	26 (68.4%)	57 (75.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.489 [0.168, 1.423]			
Stratified OR, 95% CI	0.462 [0.140, 1.523]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.583 [0.258, 1.320]			
Stratified RR, 95% CI	0.503 [0.213, 1.190]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.132 [-0.324, 0.061]			
Stratified ARR, 95% CI (CMH method)	-0.142 [-0.336, 0.053]			
Test on Differences [c]				
Unstratified p-value	0.1853			
Stratified p-value	0.1715			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		9 (29.0%)	14 (31.1%)	23 (30.3%)
Number of patients without events		22 (71.0%)	31 (68.9%)	53 (69.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.906 [0.333, 2.462]			
Stratified OR, 95% CI	0.968 [0.329, 2.844]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.933 [0.463, 1.882]			
Stratified RR, 95% CI	1.097 [0.523, 2.300]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.021 [-0.230, 0.189]			
Stratified ARR, 95% CI (CMH method)	-0.034 [-0.246, 0.177]			
Test on Differences [c]				
Unstratified p-value	0.8463			
Stratified p-value	0.7519			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		15 (39.5%)	9 (34.6%)	24 (37.5%)
Number of patients without events		23 (60.5%)	17 (65.4%)	40 (62.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.232 [0.437, 3.476]			
Stratified OR, 95% CI	1.176 [0.406, 3.407]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.140 [0.590, 2.204]			
Stratified RR, 95% CI	1.062 [0.552, 2.043]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.049 [-0.191, 0.289]			
Stratified ARR, 95% CI (CMH method)	0.046 [-0.201, 0.294]			
Test on Differences [c]				
Unstratified p-value	0.6934			
Stratified p-value	0.7186			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Mild TEAE by Baseline LDL-C Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.4358
130 - < 160 vs. < 130		0.1957	0.9635	0.3923	
>= 160 vs. < 130		0.1957	0.7988	0.2105	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by History of Diabetes
Safety Population

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 61)	Total (N= 109)
Number of patients at risk		48 (100.0%)	61 (100.0%)	109 (100.0%)
Number of patients with events		16 (33.3%)	20 (32.8%)	36 (33.0%)
Number of patients without events		32 (66.7%)	41 (67.2%)	73 (67.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.025 [0.459, 2.290]			
Stratified OR, 95% CI	1.169 [0.495, 2.763]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.017 [0.594, 1.741]			
Stratified RR, 95% CI	1.165 [0.665, 2.041]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.005 [-0.172, 0.183]			
Stratified ARR, 95% CI (CMH method)	0.013 [-0.166, 0.192]			
Test on Differences [c]				
Unstratified p-value	0.9520			
Stratified p-value	0.8853			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by History of Diabetes
Safety Population

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		15 (25.4%)	15 (31.3%)	30 (28.0%)
Number of patients without events		44 (74.6%)	33 (68.8%)	77 (72.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.750 [0.322, 1.748]			
Stratified OR, 95% CI	0.771 [0.308, 1.930]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.814 [0.444, 1.491]			
Stratified RR, 95% CI	0.816 [0.423, 1.575]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.058 [-0.230, 0.114]			
Stratified ARR, 95% CI (CMH method)	-0.041 [-0.214, 0.132]			
Test on Differences [c]				
Unstratified p-value	0.5046			
Stratified p-value	0.6361			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Mild TEAE by History of Diabetes
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.5905
No vs. Yes		0.9520	0.8647	0.5897	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by BMI
Safety Population

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		4 (30.8%)	2 (15.4%)	6 (23.1%)
Number of patients without events		9 (69.2%)	11 (84.6%)	20 (76.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.444 [0.361, 16.547]			
Stratified OR, 95% CI	1.208 [0.151, 9.671]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.000 [0.440, 9.083]			
Stratified RR, 95% CI	0.667 [0.340, 1.309]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.154 [-0.165, 0.472]			
Stratified ARR, 95% CI (CMH method)	0.003 [-0.272, 0.278]			
Test on Differences [c]				
Unstratified p-value	0.6447			
Stratified p-value	0.9835			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by BMI
Safety Population

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		6 (22.2%)	17 (45.9%)	23 (35.9%)
Number of patients without events		21 (77.8%)	20 (54.1%)	41 (64.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.336 [0.110, 1.024]			
Stratified OR, 95% CI	0.536 [0.159, 1.810]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.484 [0.220, 1.063]			
Stratified RR, 95% CI	0.821 [0.368, 1.831]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.237 [-0.462, -0.013]			
Stratified ARR, 95% CI (CMH method)	-0.242 [-0.476, -0.007]			
Test on Differences [c]				
Unstratified p-value	0.0508			
Stratified p-value	0.0545			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Mild TEAE by BMI
Safety Population

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 67)	Ezetimibe (N= 59)	Total (N= 126)
Number of patients at risk		67 (100.0%)	59 (100.0%)	126 (100.0%)
Number of patients with events		21 (31.3%)	16 (27.1%)	37 (29.4%)
Number of patients without events		46 (68.7%)	43 (72.9%)	89 (70.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.227 [0.567, 2.655]			
Stratified OR, 95% CI	1.207 [0.550, 2.648]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.156 [0.668, 2.000]			
Stratified RR, 95% CI	1.108 [0.636, 1.928]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.042 [-0.117, 0.201]			
Stratified ARR, 95% CI (CMH method)	0.040 [-0.119, 0.200]			
Test on Differences [c]				
Unstratified p-value	0.6034			
Stratified p-value	0.6235			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Mild TEAE by BMI
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.0905
25 - < 30 vs. < 25		0.3693	0.1048	0.1029	
>= 30 vs. < 25		0.3693	0.4076	0.5043	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		7 (6.5%)	10 (9.2%)	17 (7.9%)
Number of patients without events		100 (93.5%)	99 (90.8%)	199 (92.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.693 [0.254, 1.893]			
Stratified OR, 95% CI	0.754 [0.267, 2.124]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.713 [0.282, 1.804]			
Stratified RR, 95% CI	0.775 [0.306, 1.964]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.026 [-0.098, 0.045]			
Stratified ARR, 95% CI (CMH method)	-0.024 [-0.095, 0.047]			
Test on Differences [c]				
Unstratified p-value	0.4726			
Stratified p-value	0.5063			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Gender
Safety Population

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		2 (4.0%)	4 (7.7%)	6 (5.9%)
Number of patients without events		48 (96.0%)	48 (92.3%)	96 (94.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.500 [0.087, 2.860]			
Stratified OR, 95% CI	0.664 [0.126, 3.483]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.520 [0.100, 2.714]			
Stratified RR, 95% CI	0.706 [0.162, 3.070]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.037 [-0.127, 0.054]			
Stratified ARR, 95% CI (CMH method)	-0.027 [-0.115, 0.061]			
Test on Differences [c]				
Unstratified p-value	0.6783			
Stratified p-value	0.5575			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Gender
Safety Population

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 57)	Total (N= 114)
Number of patients at risk		57 (100.0%)	57 (100.0%)	114 (100.0%)
Number of patients with events		5 (8.8%)	6 (10.5%)	11 (9.6%)
Number of patients without events		52 (91.2%)	51 (89.5%)	103 (90.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.817 [0.235, 2.847]			
Stratified OR, 95% CI	0.861 [0.242, 3.069]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.833 [0.270, 2.576]			
Stratified RR, 95% CI	0.871 [0.279, 2.714]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.018 [-0.126, 0.091]			
Stratified ARR, 95% CI (CMH method)	-0.018 [-0.127, 0.091]			
Test on Differences [c]				
Unstratified p-value	0.7511			
Stratified p-value	0.7487			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Gender
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.6406
Female vs. Male		0.4380	0.6108	0.6441	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Age
Safety Population

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 48)	Total (N= 105)
Number of patients at risk		57 (100.0%)	48 (100.0%)	105 (100.0%)
Number of patients with events		5 (8.8%)	2 (4.2%)	7 (6.7%)
Number of patients without events		52 (91.2%)	46 (95.8%)	98 (93.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.212 [0.409, 11.951]			
Stratified OR, 95% CI	1.648 [0.372, 7.302]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.105 [0.428, 10.368]			
Stratified RR, 95% CI	1.571 [0.397, 6.227]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.046 [-0.047, 0.139]			
Stratified ARR, 95% CI (CMH method)	0.040 [-0.053, 0.133]			
Test on Differences [c]				
Unstratified p-value	0.4497			
Stratified p-value	0.4125			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Age
Safety Population

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		2 (4.0%)	8 (13.1%)	10 (9.0%)
Number of patients without events		48 (96.0%)	53 (86.9%)	101 (91.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.276 [0.056, 1.364]			
Stratified OR, 95% CI	0.416 [0.101, 1.719]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.305 [0.068, 1.372]			
Stratified RR, 95% CI	0.456 [0.124, 1.673]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.091 [-0.192, 0.009]			
Stratified ARR, 95% CI (CMH method)	-0.078 [-0.177, 0.021]			
Test on Differences [c]				
Unstratified p-value	0.1805			
Stratified p-value	0.1507			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Age
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.0627
>= 65 vs. < 65		0.3601	0.1348	0.0840	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by CVD Risk Category
Safety Population

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 62)	Total (N= 121)
Number of patients at risk		59 (100.0%)	62 (100.0%)	121 (100.0%)
Number of patients with events		5 (8.5%)	7 (11.3%)	12 (9.9%)
Number of patients without events		54 (91.5%)	55 (88.7%)	109 (90.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.728 [0.217, 2.434]			
Stratified OR, 95% CI	0.767 [0.225, 2.616]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.751 [0.252, 2.234]			
Stratified RR, 95% CI	0.790 [0.269, 2.325]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.028 [-0.134, 0.078]			
Stratified ARR, 95% CI (CMH method)	-0.023 [-0.128, 0.082]			
Test on Differences [c]				
Unstratified p-value	0.6045			
Stratified p-value	0.6730			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by CVD Risk Category
Safety Population

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		2 (4.2%)	3 (6.4%)	5 (5.3%)
Number of patients without events		46 (95.8%)	44 (93.6%)	90 (94.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.638 [0.102, 4.000]			
Stratified OR, 95% CI	0.712 [0.127, 3.988]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.653 [0.114, 3.732]			
Stratified RR, 95% CI	0.732 [0.145, 3.707]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.022 [-0.112, 0.068]			
Stratified ARR, 95% CI (CMH method)	-0.022 [-0.112, 0.068]			
Test on Differences [c]				
Unstratified p-value	0.6773			
Stratified p-value	0.6378			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by CVD Risk Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.8939
Multiple CV risk factors vs. ASCVD and/or HeFH		0.6063	0.3893	0.8941	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 65)	Ezetimibe (N= 70)	Total (N= 135)
Number of patients at risk		65 (100.0%)	70 (100.0%)	135 (100.0%)
Number of patients with events		6 (9.2%)	8 (11.4%)	14 (10.4%)
Number of patients without events		59 (90.8%)	62 (88.6%)	121 (89.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.788 [0.258, 2.408]			
Stratified OR, 95% CI	0.809 [0.262, 2.505]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.808 [0.296, 2.203]			
Stratified RR, 95% CI	0.826 [0.304, 2.245]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.022 [-0.124, 0.081]			
Stratified ARR, 95% CI (CMH method)	-0.019 [-0.121, 0.082]			
Test on Differences [c]				
Unstratified p-value	0.6756			
Stratified p-value	0.7138			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline Statin Intensity I
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		1 (2.4%)	2 (5.1%)	3 (3.7%)
Number of patients without events		41 (97.6%)	37 (94.9%)	78 (96.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.451 [0.039, 5.183]			
Stratified OR, 95% CI	0.564 [0.066, 4.804]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.464 [0.044, 4.920]			
Stratified RR, 95% CI	0.580 [0.075, 4.510]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.027 [-0.111, 0.056]			
Stratified ARR, 95% CI (CMH method)	-0.028 [-0.111, 0.056]			
Test on Differences [c]				
Unstratified p-value	0.6064			
Stratified p-value	0.5176			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline Statin Intensity I
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.6662
High Intensity Statin vs. Other		0.6765	0.2948	0.6722	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 32)	Ezetimibe (N= 38)	Total (N= 70)
Number of patients at risk		32 (100.0%)	38 (100.0%)	70 (100.0%)
Number of patients with events		3 (9.4%)	4 (10.5%)	7 (10.0%)
Number of patients without events		29 (90.6%)	34 (89.5%)	63 (90.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.879 [0.182, 4.255]			
Stratified OR, 95% CI	0.882 [0.178, 4.370]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.891 [0.215, 3.689]			
Stratified RR, 95% CI	0.870 [0.213, 3.545]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.012 [-0.152, 0.129]			
Stratified ARR, 95% CI (CMH method)	-0.009 [-0.147, 0.129]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9016			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		1 (2.4%)	2 (5.1%)	3 (3.7%)
Number of patients without events		41 (97.6%)	37 (94.9%)	78 (96.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.451 [0.039, 5.183]			
Stratified OR, 95% CI	0.564 [0.066, 4.804]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.464 [0.044, 4.920]			
Stratified RR, 95% CI	0.580 [0.075, 4.510]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.027 [-0.111, 0.056]			
Stratified ARR, 95% CI (CMH method)	-0.028 [-0.111, 0.056]			
Test on Differences [c]				
Unstratified p-value	0.6064			
Stratified p-value	0.5176			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline Statin Intensity II
Safety Population

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		3 (9.1%)	4 (12.5%)	7 (10.8%)
Number of patients without events		30 (90.9%)	28 (87.5%)	58 (89.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.700 [0.144, 3.409]			
Stratified OR, 95% CI	0.720 [0.144, 3.590]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.727 [0.177, 2.996]			
Stratified RR, 95% CI	0.754 [0.180, 3.167]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.034 [-0.185, 0.117]			
Stratified ARR, 95% CI (CMH method)	-0.033 [-0.185, 0.119]			
Test on Differences [c]				
Unstratified p-value	0.7085			
Stratified p-value	0.6738			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline Statin Intensity II
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.8950
High Intensity Statin vs. Other Intensity Statin		0.8731	0.3894	0.6431	
None vs. Other Intensity Statin		0.8731	0.7961	0.8431	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Race
Safety Population

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 84)	Ezetimibe (N= 91)	Total (N= 175)
Number of patients at risk		84 (100.0%)	91 (100.0%)	175 (100.0%)
Number of patients with events		6 (7.1%)	9 (9.9%)	15 (8.6%)
Number of patients without events		78 (92.9%)	82 (90.1%)	160 (91.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.701 [0.238, 2.061]			
Stratified OR, 95% CI	0.734 [0.246, 2.188]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.722 [0.268, 1.943]			
Stratified RR, 95% CI	0.768 [0.292, 2.016]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.027 [-0.110, 0.055]			
Stratified ARR, 95% CI (CMH method)	-0.030 [-0.113, 0.052]			
Test on Differences [c]				
Unstratified p-value	0.5166			
Stratified p-value	0.4711			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Race
Safety Population

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		1 (4.3%)	1 (5.6%)	2 (4.9%)
Number of patients without events		22 (95.7%)	17 (94.4%)	39 (95.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.773 [0.045, 13.268]			
Stratified OR, 95% CI	0.900 [0.081, 10.009]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.783 [0.052, 11.672]			
Stratified RR, 95% CI	0.918 [0.109, 7.707]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.012 [-0.147, 0.123]			
Stratified ARR, 95% CI (CMH method)	-0.006 [-0.143, 0.131]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9386			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Race
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.9564
non-White vs. White		0.5192	0.5726	0.9564	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 38)	Total (N= 76)
Number of patients at risk		38 (100.0%)	38 (100.0%)	76 (100.0%)
Number of patients with events		2 (5.3%)	5 (13.2%)	7 (9.2%)
Number of patients without events		36 (94.7%)	33 (86.8%)	69 (90.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.367 [0.067, 2.020]			
Stratified OR, 95% CI	0.583 [0.099, 3.445]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.400 [0.083, 1.936]			
Stratified RR, 95% CI	0.640 [0.125, 3.277]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.079 [-0.208, 0.050]			
Stratified ARR, 95% CI (CMH method)	-0.067 [-0.194, 0.060]			
Test on Differences [c]				
Unstratified p-value	0.4303			
Stratified p-value	0.3341			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		2 (6.5%)	2 (4.4%)	4 (5.3%)
Number of patients without events		29 (93.5%)	43 (95.6%)	72 (94.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.483 [0.198, 11.130]			
Stratified OR, 95% CI	1.738 [0.219, 13.799]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.452 [0.216, 9.762]			
Stratified RR, 95% CI	1.653 [0.277, 9.855]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.020 [-0.085, 0.125]			
Stratified ARR, 95% CI (CMH method)	0.023 [-0.078, 0.124]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.6578			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline LDL-C Category
Safety Population

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		3 (7.9%)	3 (11.5%)	6 (9.4%)
Number of patients without events		35 (92.1%)	23 (88.5%)	58 (90.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.657 [0.122, 3.542]			
Stratified OR, 95% CI	0.597 [0.110, 3.225]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.684 [0.150, 3.130]			
Stratified RR, 95% CI	0.643 [0.146, 2.822]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.036 [-0.186, 0.113]			
Stratified ARR, 95% CI (CMH method)	-0.048 [-0.201, 0.104]			
Test on Differences [c]				
Unstratified p-value	0.6800			
Stratified p-value	0.5214			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by Baseline LDL-C Category
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.5894
130 - < 160 vs. < 130		0.2548	0.1787	0.3071	
>= 160 vs. < 130		0.2548	0.8478	0.6310	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by History of Diabetes
Safety Population

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 61)	Total (N= 109)
Number of patients at risk		48 (100.0%)	61 (100.0%)	109 (100.0%)
Number of patients with events		3 (6.3%)	5 (8.2%)	8 (7.3%)
Number of patients without events		45 (93.8%)	56 (91.8%)	101 (92.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.747 [0.169, 3.294]			
Stratified OR, 95% CI	0.883 [0.190, 4.114]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.763 [0.192, 3.032]			
Stratified RR, 95% CI	0.889 [0.220, 3.583]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.019 [-0.117, 0.078]			
Stratified ARR, 95% CI (CMH method)	-0.013 [-0.109, 0.082]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7894			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by History of Diabetes
Safety Population

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		4 (6.8%)	5 (10.4%)	9 (8.4%)
Number of patients without events		55 (93.2%)	43 (89.6%)	98 (91.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.625 [0.158, 2.471]			
Stratified OR, 95% CI	0.768 [0.192, 3.080]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.651 [0.185, 2.291]			
Stratified RR, 95% CI	0.797 [0.238, 2.671]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.036 [-0.144, 0.071]			
Stratified ARR, 95% CI (CMH method)	-0.024 [-0.129, 0.080]			
Test on Differences [c]				
Unstratified p-value	0.7283			
Stratified p-value	0.6499			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by History of Diabetes
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.8683
No vs. Yes		0.7003	0.6907	0.8681	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by BMI
Safety Population

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		1 (7.7%)	3 (23.1%)	4 (15.4%)
Number of patients without events		12 (92.3%)	10 (76.9%)	22 (84.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.278 [0.025, 3.104]			
Stratified OR, 95% CI	0.625 [0.065, 6.023]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.333 [0.040, 2.801]			
Stratified RR, 95% CI	0.719 [0.141, 3.671]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.154 [-0.425, 0.117]			
Stratified ARR, 95% CI (CMH method)	-0.082 [-0.361, 0.197]			
Test on Differences [c]				
Unstratified p-value	0.5930			
Stratified p-value	0.6027			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by BMI
Safety Population

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		1 (3.7%)	5 (13.5%)	6 (9.4%)
Number of patients without events		26 (96.3%)	32 (86.5%)	58 (90.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.246 [0.027, 2.241]			
Stratified OR, 95% CI	0.389 [0.069, 2.174]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.274 [0.034, 2.214]			
Stratified RR, 95% CI	0.451 [0.102, 2.001]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.098 [-0.229, 0.033]			
Stratified ARR, 95% CI (CMH method)	-0.097 [-0.225, 0.032]			
Test on Differences [c]				
Unstratified p-value	0.3877			
Stratified p-value	0.1900			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by BMI
Safety Population

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 67)	Ezetimibe (N= 59)	Total (N= 126)
Number of patients at risk		67 (100.0%)	59 (100.0%)	126 (100.0%)
Number of patients with events		5 (7.5%)	2 (3.4%)	7 (5.6%)
Number of patients without events		62 (92.5%)	57 (96.6%)	119 (94.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.298 [0.429, 12.317]			
Stratified OR, 95% CI	2.089 [0.442, 9.863]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.201 [0.444, 10.926]			
Stratified RR, 95% CI	1.976 [0.464, 8.416]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.041 [-0.037, 0.119]			
Stratified ARR, 95% CI (CMH method)	0.043 [-0.035, 0.120]			
Test on Differences [c]				
Unstratified p-value	0.4466			
Stratified p-value	0.2998			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE Resulting in Discontinuation of Investigational Medicinal Product by BMI
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.1553
25 - < 30 vs. < 25		0.3117	0.4141	0.8976	
>= 30 vs. < 25		0.3117	0.0257	0.1649	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

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Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Gastrointestinal disorders (SOC)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		11 (10.3%)	8 (7.3%)	19 (8.8%)
Number of patients without events		96 (89.7%)	101 (92.7%)	197 (91.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.447 [0.558, 3.750]			
Stratified OR, 95% CI	1.421 [0.512, 3.945]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.401 [0.586, 3.346]			
Stratified RR, 95% CI	1.342 [0.540, 3.337]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.029 [-0.046, 0.105]			
Stratified ARR, 95% CI (CMH method)	0.031 [-0.044, 0.106]			
Test on Differences [c]				
Unstratified p-value	0.4455			
Stratified p-value	0.4195			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Gastrointestinal disorders (SOC)
Safety Population

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		4 (8.0%)	2 (3.8%)	6 (5.9%)
Number of patients without events		46 (92.0%)	50 (96.2%)	96 (94.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.174 [0.380, 12.435]			
Stratified OR, 95% CI	2.139 [0.405, 11.292]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.080 [0.399, 10.856]			
Stratified RR, 95% CI	1.943 [0.448, 8.423]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.042 [-0.050, 0.133]			
Stratified ARR, 95% CI (CMH method)	0.048 [-0.041, 0.136]			
Test on Differences [c]				
Unstratified p-value	0.4320			
Stratified p-value	0.3015			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Gastrointestinal disorders (SOC)
Safety Population

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 57)	Total (N= 114)
Number of patients at risk		57 (100.0%)	57 (100.0%)	114 (100.0%)
Number of patients with events		7 (12.3%)	6 (10.5%)	13 (11.4%)
Number of patients without events		50 (87.7%)	51 (89.5%)	101 (88.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.190 [0.374, 3.789]			
Stratified OR, 95% CI	1.150 [0.332, 3.984]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.167 [0.418, 3.257]			
Stratified RR, 95% CI	1.109 [0.366, 3.360]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.018 [-0.099, 0.134]			
Stratified ARR, 95% CI (CMH method)	0.020 [-0.099, 0.139]			
Test on Differences [c]				
Unstratified p-value	0.7683			
Stratified p-value	0.7397			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Gender - Gastrointestinal disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.5544
Female vs. Male		0.3850	0.2046	0.5602	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Gastrointestinal disorders (SOC)
Safety Population

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 48)	Total (N= 105)
Number of patients at risk		57 (100.0%)	48 (100.0%)	105 (100.0%)
Number of patients with events		7 (12.3%)	4 (8.3%)	11 (10.5%)
Number of patients without events		50 (87.7%)	44 (91.7%)	94 (89.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.540 [0.422, 5.614]			
Stratified OR, 95% CI	1.016 [0.225, 4.593]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.474 [0.459, 4.734]			
Stratified RR, 95% CI	0.960 [0.246, 3.741]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.039 [-0.076, 0.155]			
Stratified ARR, 95% CI (CMH method)	0.040 [-0.082, 0.163]			
Test on Differences [c]				
Unstratified p-value	0.7506			
Stratified p-value	0.5051			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Gastrointestinal disorders (SOC)
Safety Population

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		4 (8.0%)	4 (6.6%)	8 (7.2%)
Number of patients without events		46 (92.0%)	57 (93.4%)	103 (92.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.239 [0.294, 5.226]			
Stratified OR, 95% CI	1.595 [0.388, 6.565]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.220 [0.321, 4.634]			
Stratified RR, 95% CI	1.528 [0.458, 5.099]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.014 [-0.083, 0.112]			
Stratified ARR, 95% CI (CMH method)	0.033 [-0.064, 0.129]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4947			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Age - Gastrointestinal disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.8343
>= 65 vs. < 65		0.5149	0.7246	0.8346	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Gastrointestinal disorders (SOC)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 62)	Total (N= 121)
Number of patients at risk		59 (100.0%)	62 (100.0%)	121 (100.0%)
Number of patients with events		6 (10.2%)	5 (8.1%)	11 (9.1%)
Number of patients without events		53 (89.8%)	57 (91.9%)	110 (90.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.291 [0.372, 4.479]			
Stratified OR, 95% CI	1.342 [0.389, 4.624]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.261 [0.407, 3.912]			
Stratified RR, 95% CI	1.277 [0.434, 3.756]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.021 [-0.082, 0.124]			
Stratified ARR, 95% CI (CMH method)	0.028 [-0.073, 0.128]			
Test on Differences [c]				
Unstratified p-value	0.6872			
Stratified p-value	0.5925			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Gastrointestinal disorders (SOC)
Safety Population

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		5 (10.4%)	3 (6.4%)	8 (8.4%)
Number of patients without events		43 (89.6%)	44 (93.6%)	87 (91.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.705 [0.384, 7.581]			
Stratified OR, 95% CI	1.709 [0.373, 7.838]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.632 [0.413, 6.446]			
Stratified RR, 95% CI	1.650 [0.407, 6.686]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.040 [-0.071, 0.151]			
Stratified ARR, 95% CI (CMH method)	0.041 [-0.070, 0.153]			
Test on Differences [c]				
Unstratified p-value	0.7145			
Stratified p-value	0.4674			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by CVD Risk Category - Gastrointestinal disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.7758
Multiple CV risk factors vs. ASCVD and/or HeFH		0.6880	0.7398	0.7765	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Gastrointestinal disorders (SOC)
Safety Population

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 65)	Ezetimibe (N= 70)	Total (N= 135)
Number of patients at risk		65 (100.0%)	70 (100.0%)	135 (100.0%)
Number of patients with events		10 (15.4%)	7 (10.0%)	17 (12.6%)
Number of patients without events		55 (84.6%)	63 (90.0%)	118 (87.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.636 [0.583, 4.590]			
Stratified OR, 95% CI	1.628 [0.566, 4.681]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.538 [0.622, 3.803]			
Stratified RR, 95% CI	1.511 [0.598, 3.813]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.054 [-0.059, 0.166]			
Stratified ARR, 95% CI (CMH method)	0.055 [-0.057, 0.167]			
Test on Differences [c]				
Unstratified p-value	0.3461			
Stratified p-value	0.3389			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Gastrointestinal disorders (SOC)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		1 (2.4%)	1 (2.6%)	2 (2.5%)
Number of patients without events		41 (97.6%)	38 (97.4%)	79 (97.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.927 [0.056, 15.344]			
Stratified OR, 95% CI	0.928 [0.092, 9.325]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.929 [0.060, 14.342]			
Stratified RR, 95% CI	0.925 [0.100, 8.520]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.002 [-0.070, 0.066]			
Stratified ARR, 95% CI (CMH method)	-0.002 [-0.070, 0.067]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9592			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity I - Gastrointestinal disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.7324
High Intensity Statin vs. Other		0.3508	0.1950	0.7314	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Gastrointestinal disorders (SOC)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 32)	Ezetimibe (N= 38)	Total (N= 70)
Number of patients at risk		32 (100.0%)	38 (100.0%)	70 (100.0%)
Number of patients with events		5 (15.6%)	4 (10.5%)	9 (12.9%)
Number of patients without events		27 (84.4%)	34 (89.5%)	61 (87.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.574 [0.385, 6.438]			
Stratified OR, 95% CI	1.129 [0.182, 7.009]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.484 [0.435, 5.067]			
Stratified RR, 95% CI	1.055 [0.195, 5.703]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.051 [-0.108, 0.210]			
Stratified ARR, 95% CI (CMH method)	0.051 [-0.114, 0.216]			
Test on Differences [c]				
Unstratified p-value	0.7225			
Stratified p-value	0.5302			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Gastrointestinal disorders (SOC)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		1 (2.4%)	1 (2.6%)	2 (2.5%)
Number of patients without events		41 (97.6%)	38 (97.4%)	79 (97.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.927 [0.056, 15.344]			
Stratified OR, 95% CI	0.928 [0.092, 9.325]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.929 [0.060, 14.342]			
Stratified RR, 95% CI	0.925 [0.100, 8.520]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.002 [-0.070, 0.066]			
Stratified ARR, 95% CI (CMH method)	-0.002 [-0.070, 0.067]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9592			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Gastrointestinal disorders (SOC)
Safety Population

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		5 (15.2%)	3 (9.4%)	8 (12.3%)
Number of patients without events		28 (84.8%)	29 (90.6%)	57 (87.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.726 [0.377, 7.913]			
Stratified OR, 95% CI	1.632 [0.298, 8.951]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.616 [0.421, 6.211]			
Stratified RR, 95% CI	1.530 [0.327, 7.160]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.058 [-0.101, 0.216]			
Stratified ARR, 95% CI (CMH method)	0.061 [-0.102, 0.224]			
Test on Differences [c]				
Unstratified p-value	0.7085			
Stratified p-value	0.4632			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity II - Gastrointestinal disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.9386
High Intensity Statin vs. Other Intensity Statin		0.5283	0.1970	0.7592	
None vs. Other Intensity Statin		0.5283	0.8731	0.9271	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Gastrointestinal disorders (SOC)
Safety Population

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 84)	Ezetimibe (N= 91)	Total (N= 175)
Number of patients at risk		84 (100.0%)	91 (100.0%)	175 (100.0%)
Number of patients with events		8 (9.5%)	6 (6.6%)	14 (8.0%)
Number of patients without events		76 (90.5%)	85 (93.4%)	161 (92.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.491 [0.495, 4.492]			
Stratified OR, 95% CI	1.422 [0.477, 4.237]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.444 [0.523, 3.990]			
Stratified RR, 95% CI	1.356 [0.516, 3.561]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.029 [-0.052, 0.110]			
Stratified ARR, 95% CI (CMH method)	0.027 [-0.054, 0.107]			
Test on Differences [c]				
Unstratified p-value	0.4753			
Stratified p-value	0.5104			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Gastrointestinal disorders (SOC)
Safety Population

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		3 (13.0%)	2 (11.1%)	5 (12.2%)
Number of patients without events		20 (87.0%)	16 (88.9%)	36 (87.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.200 [0.178, 8.073]			
Stratified OR, 95% CI	1.143 [0.163, 8.002]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.174 [0.219, 6.296]			
Stratified RR, 95% CI	1.078 [0.203, 5.733]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.019 [-0.181, 0.219]			
Stratified ARR, 95% CI (CMH method)	0.033 [-0.178, 0.245]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7684			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Race - Gastrointestinal disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.8367
non-White vs. White		0.4781	0.5005	0.8360	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Gastrointestinal disorders (SOC)
Safety Population

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 38)	Total (N= 76)
Number of patients at risk		38 (100.0%)	38 (100.0%)	76 (100.0%)
Number of patients with events		2 (5.3%)	4 (10.5%)	6 (7.9%)
Number of patients without events		36 (94.7%)	34 (89.5%)	70 (92.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.472 [0.081, 2.747]			
Stratified OR, 95% CI	0.682 [0.074, 6.295]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.500 [0.097, 2.569]			
Stratified RR, 95% CI	0.764 [0.103, 5.646]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.053 [-0.173, 0.068]			
Stratified ARR, 95% CI (CMH method)	-0.041 [-0.155, 0.073]			
Test on Differences [c]				
Unstratified p-value	0.6745			
Stratified p-value	0.5083			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Gastrointestinal disorders (SOC)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		4 (12.9%)	2 (4.4%)	6 (7.9%)
Number of patients without events		27 (87.1%)	43 (95.6%)	70 (92.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.185 [0.546, 18.593]			
Stratified OR, 95% CI	2.730 [0.573, 13.004]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.903 [0.566, 14.886]			
Stratified RR, 95% CI	2.407 [0.607, 9.542]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.085 [-0.048, 0.217]			
Stratified ARR, 95% CI (CMH method)	0.088 [-0.044, 0.219]			
Test on Differences [c]				
Unstratified p-value	0.2181			
Stratified p-value	0.1684			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Gastrointestinal disorders (SOC)
Safety Population

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		5 (13.2%)	2 (7.7%)	7 (10.9%)
Number of patients without events		33 (86.8%)	24 (92.3%)	57 (89.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.818 [0.325, 10.175]			
Stratified OR, 95% CI	1.332 [0.239, 7.405]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.711 [0.359, 8.157]			
Stratified RR, 95% CI	1.259 [0.276, 5.743]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.055 [-0.094, 0.203]			
Stratified ARR, 95% CI (CMH method)	0.050 [-0.103, 0.202]			
Test on Differences [c]				
Unstratified p-value	0.6911			
Stratified p-value	0.5412			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline LDL-C Category - Gastrointestinal disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.2821
130 - < 160 vs. < 130		0.4065	0.3033	0.1361	
>= 160 vs. < 130		0.4065	0.7048	0.2867	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Gastrointestinal disorders (SOC)
Safety Population

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 61)	Total (N= 109)
Number of patients at risk		48 (100.0%)	61 (100.0%)	109 (100.0%)
Number of patients with events		3 (6.3%)	2 (3.3%)	5 (4.6%)
Number of patients without events		45 (93.8%)	59 (96.7%)	104 (95.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.967 [0.315, 12.269]			
Stratified OR, 95% CI	1.709 [0.192, 15.211]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.906 [0.332, 10.956]			
Stratified RR, 95% CI	1.589 [0.202, 12.479]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.030 [-0.052, 0.111]			
Stratified ARR, 95% CI (CMH method)	0.031 [-0.051, 0.113]			
Test on Differences [c]				
Unstratified p-value	0.6525			
Stratified p-value	0.4418			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Gastrointestinal disorders (SOC)
Safety Population

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		8 (13.6%)	6 (12.5%)	14 (13.1%)
Number of patients without events		51 (86.4%)	42 (87.5%)	93 (86.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.098 [0.353, 3.415]			
Stratified OR, 95% CI	1.267 [0.397, 4.046]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.085 [0.404, 2.912]			
Stratified RR, 95% CI	1.232 [0.456, 3.328]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.011 [-0.117, 0.139]			
Stratified ARR, 95% CI (CMH method)	0.023 [-0.104, 0.150]			
Test on Differences [c]				
Unstratified p-value	0.8716			
Stratified p-value	0.7301			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by History of Diabetes - Gastrointestinal disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.5794
No vs. Yes		0.4697	0.0916	0.5822	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Gastrointestinal disorders (SOC)
Safety Population

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		2 (15.4%)	2 (15.4%)	4 (15.4%)
Number of patients without events		11 (84.6%)	11 (84.6%)	22 (84.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.000 [0.119, 8.421]			
Stratified OR, 95% CI	1.635 [0.221, 12.073]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.000 [0.165, 6.067]			
Stratified RR, 95% CI	1.407 [0.301, 6.579]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.000 [-0.277, 0.277]			
Stratified ARR, 95% CI (CMH method)	0.082 [-0.229, 0.393]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.6283			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Gastrointestinal disorders (SOC)
Safety Population

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		3 (11.1%)	3 (8.1%)	6 (9.4%)
Number of patients without events		24 (88.9%)	34 (91.9%)	58 (90.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.417 [0.263, 7.628]			
Stratified OR, 95% CI	1.464 [0.237, 9.038]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.370 [0.299, 6.275]			
Stratified RR, 95% CI	1.390 [0.285, 6.785]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.030 [-0.118, 0.178]			
Stratified ARR, 95% CI (CMH method)	0.031 [-0.114, 0.177]			
Test on Differences [c]				
Unstratified p-value	0.6908			
Stratified p-value	0.6713			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Gastrointestinal disorders (SOC)
Safety Population

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 67)	Ezetimibe (N= 59)	Total (N= 126)
Number of patients at risk		67 (100.0%)	59 (100.0%)	126 (100.0%)
Number of patients with events		6 (9.0%)	3 (5.1%)	9 (7.1%)
Number of patients without events		61 (91.0%)	56 (94.9%)	117 (92.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.836 [0.438, 7.692]			
Stratified OR, 95% CI	1.457 [0.339, 6.270]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.761 [0.461, 6.733]			
Stratified RR, 95% CI	1.366 [0.369, 5.055]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.039 [-0.050, 0.127]			
Stratified ARR, 95% CI (CMH method)	0.040 [-0.050, 0.129]			
Test on Differences [c]				
Unstratified p-value	0.5000			
Stratified p-value	0.3867			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by BMI - Gastrointestinal disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.8835
25 - < 30 vs. < 25		1.0000	0.4533	0.7935	
>= 30 vs. < 25		1.0000	0.1979	0.6215	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Infections and infestations (SOC)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		27 (25.2%)	16 (14.7%)	43 (19.9%)
Number of patients without events		80 (74.8%)	93 (85.3%)	173 (80.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.962 [0.987, 3.899]			
Stratified OR, 95% CI	1.936 [0.967, 3.877]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.719 [0.984, 3.003]			
Stratified RR, 95% CI	1.681 [0.959, 2.946]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.106 [0.000, 0.211]			
Stratified ARR, 95% CI (CMH method)	0.106 [0.000, 0.212]			
Test on Differences [c]				
Unstratified p-value	0.0521			
Stratified p-value	0.0529			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Infections and infestations (SOC)
Safety Population

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		11 (22.0%)	2 (3.8%)	13 (12.7%)
Number of patients without events		39 (78.0%)	50 (96.2%)	89 (87.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	7.051 [1.476, 33.682]			
Stratified OR, 95% CI	4.645 [1.176, 18.342]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.720 [1.334, 24.526]			
Stratified RR, 95% CI	3.710 [1.084, 12.693]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.182 [0.055, 0.308]			
Stratified ARR, 95% CI (CMH method)	0.174 [0.048, 0.300]			
Test on Differences [c]				
Unstratified p-value	0.0072			
Stratified p-value	0.0099			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Infections and infestations (SOC)
Safety Population

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 57)	Total (N= 114)
Number of patients at risk		57 (100.0%)	57 (100.0%)	114 (100.0%)
Number of patients with events		16 (28.1%)	14 (24.6%)	30 (26.3%)
Number of patients without events		41 (71.9%)	43 (75.4%)	84 (73.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.199 [0.520, 2.763]			
Stratified OR, 95% CI	1.135 [0.477, 2.697]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.143 [0.617, 2.116]			
Stratified RR, 95% CI	1.077 [0.588, 1.972]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.035 [-0.126, 0.197]			
Stratified ARR, 95% CI (CMH method)	0.025 [-0.135, 0.184]			
Test on Differences [c]				
Unstratified p-value	0.6706			
Stratified p-value	0.7653			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Gender - Infections and infestations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.0235
Female vs. Male		0.0189	0.0112	0.0459	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Table 1002FDC.053b.203.2.2
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Infections and infestations (SOC)
Safety Population

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 48)	Total (N= 105)
Number of patients at risk		57 (100.0%)	48 (100.0%)	105 (100.0%)
Number of patients with events		11 (19.3%)	7 (14.6%)	18 (17.1%)
Number of patients without events		46 (80.7%)	41 (85.4%)	87 (82.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.401 [0.497, 3.950]			
Stratified OR, 95% CI	1.329 [0.447, 3.952]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.323 [0.556, 3.147]			
Stratified RR, 95% CI	1.275 [0.508, 3.205]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.047 [-0.096, 0.190]			
Stratified ARR, 95% CI (CMH method)	0.040 [-0.103, 0.183]			
Test on Differences [c]				
Unstratified p-value	0.5231			
Stratified p-value	0.5939			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Infections and infestations (SOC)
Safety Population

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		16 (32.0%)	9 (14.8%)	25 (22.5%)
Number of patients without events		34 (68.0%)	52 (85.2%)	86 (77.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.719 [1.079, 6.850]			
Stratified OR, 95% CI	2.539 [0.986, 6.538]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.169 [1.049, 4.483]			
Stratified RR, 95% CI	1.987 [0.955, 4.135]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.172 [0.015, 0.329]			
Stratified ARR, 95% CI (CMH method)	0.169 [0.011, 0.326]			
Test on Differences [c]				
Unstratified p-value	0.0305			
Stratified p-value	0.0379			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Age - Infections and infestations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.3942
>= 65 vs. < 65		0.5262	0.9801	0.3916	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Infections and infestations (SOC)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 62)	Total (N= 121)
Number of patients at risk		59 (100.0%)	62 (100.0%)	121 (100.0%)
Number of patients with events		15 (25.4%)	10 (16.1%)	25 (20.7%)
Number of patients without events		44 (74.6%)	52 (83.9%)	96 (79.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.773 [0.724, 4.339]			
Stratified OR, 95% CI	1.763 [0.719, 4.323]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.576 [0.770, 3.227]			
Stratified RR, 95% CI	1.569 [0.765, 3.217]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.093 [-0.051, 0.237]			
Stratified ARR, 95% CI (CMH method)	0.092 [-0.052, 0.236]			
Test on Differences [c]				
Unstratified p-value	0.2069			
Stratified p-value	0.2159			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Infections and infestations (SOC)
Safety Population

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		12 (25.0%)	6 (12.8%)	18 (18.9%)
Number of patients without events		36 (75.0%)	41 (87.2%)	77 (81.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.278 [0.776, 6.690]			
Stratified OR, 95% CI	1.907 [0.628, 5.791]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.958 [0.801, 4.786]			
Stratified RR, 95% CI	1.599 [0.656, 3.898]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.122 [-0.033, 0.278]			
Stratified ARR, 95% CI (CMH method)	0.124 [-0.031, 0.279]			
Test on Differences [c]				
Unstratified p-value	0.1282			
Stratified p-value	0.1258			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by CVD Risk Category - Infections and infestations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.7092
Multiple CV risk factors vs. ASCVD and/or HeFH		0.2131	0.6253	0.7103	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Infections and infestations (SOC)
Safety Population

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 65)	Ezetimibe (N= 70)	Total (N= 135)
Number of patients at risk		65 (100.0%)	70 (100.0%)	135 (100.0%)
Number of patients with events		16 (24.6%)	12 (17.1%)	28 (20.7%)
Number of patients without events		49 (75.4%)	58 (82.9%)	107 (79.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.578 [0.682, 3.654]			
Stratified OR, 95% CI	1.572 [0.679, 3.640]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.436 [0.736, 2.801]			
Stratified RR, 95% CI	1.430 [0.733, 2.787]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.075 [-0.062, 0.212]			
Stratified ARR, 95% CI (CMH method)	0.074 [-0.063, 0.211]			
Test on Differences [c]				
Unstratified p-value	0.2846			
Stratified p-value	0.2927			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Infections and infestations (SOC)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		11 (26.2%)	4 (10.3%)	15 (18.5%)
Number of patients without events		31 (73.8%)	35 (89.7%)	66 (81.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.105 [0.896, 10.754]			
Stratified OR, 95% CI	2.516 [0.718, 8.823]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.554 [0.886, 7.357]			
Stratified RR, 95% CI	2.002 [0.720, 5.567]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.159 [-0.004, 0.323]			
Stratified ARR, 95% CI (CMH method)	0.159 [-0.004, 0.322]			
Test on Differences [c]				
Unstratified p-value	0.0877			
Stratified p-value	0.0671			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity I - Infections and infestations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.3550
High Intensity Statin vs. Other		0.2885	0.3430	0.3672	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Infections and infestations (SOC)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 32)	Ezetimibe (N= 38)	Total (N= 70)
Number of patients at risk		32 (100.0%)	38 (100.0%)	70 (100.0%)
Number of patients with events		5 (15.6%)	5 (13.2%)	10 (14.3%)
Number of patients without events		27 (84.4%)	33 (86.8%)	60 (85.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.222 [0.320, 4.667]			
Stratified OR, 95% CI	1.230 [0.322, 4.705]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.188 [0.377, 3.739]			
Stratified RR, 95% CI	1.194 [0.380, 3.755]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.025 [-0.141, 0.190]			
Stratified ARR, 95% CI (CMH method)	0.025 [-0.140, 0.191]			
Test on Differences [c]				
Unstratified p-value	0.7689			
Stratified p-value	0.7654			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Infections and infestations (SOC)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		11 (26.2%)	4 (10.3%)	15 (18.5%)
Number of patients without events		31 (73.8%)	35 (89.7%)	66 (81.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.105 [0.896, 10.754]			
Stratified OR, 95% CI	2.516 [0.718, 8.823]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.554 [0.886, 7.357]			
Stratified RR, 95% CI	2.002 [0.720, 5.567]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.159 [-0.004, 0.323]			
Stratified ARR, 95% CI (CMH method)	0.159 [-0.004, 0.322]			
Test on Differences [c]				
Unstratified p-value	0.0877			
Stratified p-value	0.0671			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Infections and infestations (SOC)
Safety Population

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		11 (33.3%)	7 (21.9%)	18 (27.7%)
Number of patients without events		22 (66.7%)	25 (78.1%)	47 (72.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.786 [0.590, 5.404]			
Stratified OR, 95% CI	1.761 [0.579, 5.352]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.524 [0.676, 3.437]			
Stratified RR, 95% CI	1.493 [0.665, 3.355]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.115 [-0.101, 0.330]			
Stratified ARR, 95% CI (CMH method)	0.112 [-0.104, 0.327]			
Test on Differences [c]				
Unstratified p-value	0.3020			
Stratified p-value	0.3215			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity II - Infections and infestations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.5898
High Intensity Statin vs. Other Intensity Statin		0.7690	0.6929	0.3362	
None vs. Other Intensity Statin		0.7690	0.3413	0.7281	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Infections and infestations (SOC)
Safety Population

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 84)	Ezetimibe (N= 91)	Total (N= 175)
Number of patients at risk		84 (100.0%)	91 (100.0%)	175 (100.0%)
Number of patients with events		24 (28.6%)	15 (16.5%)	39 (22.3%)
Number of patients without events		60 (71.4%)	76 (83.5%)	136 (77.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.027 [0.978, 4.199]			
Stratified OR, 95% CI	2.051 [0.984, 4.276]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.733 [0.977, 3.074]			
Stratified RR, 95% CI	1.737 [0.978, 3.085]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.121 [-0.002, 0.244]			
Stratified ARR, 95% CI (CMH method)	0.123 [0.000, 0.246]			
Test on Differences [c]				
Unstratified p-value	0.0549			
Stratified p-value	0.0539			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Infections and infestations (SOC)
Safety Population

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		3 (13.0%)	1 (5.6%)	4 (9.8%)
Number of patients without events		20 (87.0%)	17 (94.4%)	37 (90.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.550 [0.242, 26.838]			
Stratified OR, 95% CI	2.063 [0.300, 14.173]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.348 [0.266, 20.718]			
Stratified RR, 95% CI	1.789 [0.361, 8.875]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.075 [-0.099, 0.248]			
Stratified ARR, 95% CI (CMH method)	0.111 [-0.076, 0.298]			
Test on Differences [c]				
Unstratified p-value	0.6178			
Stratified p-value	0.2782			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Race - Infections and infestations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.7866
non-White vs. White		0.0599	0.2768	0.7917	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Infections and infestations (SOC)
Safety Population

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 38)	Total (N= 76)
Number of patients at risk		38 (100.0%)	38 (100.0%)	76 (100.0%)
Number of patients with events		9 (23.7%)	7 (18.4%)	16 (21.1%)
Number of patients without events		29 (76.3%)	31 (81.6%)	60 (78.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.374 [0.453, 4.170]			
Stratified OR, 95% CI	1.490 [0.455, 4.874]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.286 [0.534, 3.098]			
Stratified RR, 95% CI	1.276 [0.514, 3.168]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.053 [-0.130, 0.236]			
Stratified ARR, 95% CI (CMH method)	0.088 [-0.092, 0.267]			
Test on Differences [c]				
Unstratified p-value	0.5736			
Stratified p-value	0.3646			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Infections and infestations (SOC)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		9 (29.0%)	3 (6.7%)	12 (15.8%)
Number of patients without events		22 (71.0%)	42 (93.3%)	64 (84.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.727 [1.406, 23.336]			
Stratified OR, 95% CI	4.953 [1.211, 20.254]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.355 [1.281, 14.809]			
Stratified RR, 95% CI	3.384 [1.091, 10.493]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.224 [0.048, 0.399]			
Stratified ARR, 95% CI (CMH method)	0.218 [0.043, 0.392]			
Test on Differences [c]				
Unstratified p-value	0.0117			
Stratified p-value	0.0110			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Infections and infestations (SOC)
Safety Population

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		9 (23.7%)	6 (23.1%)	15 (23.4%)
Number of patients without events		29 (76.3%)	20 (76.9%)	49 (76.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.034 [0.318, 3.365]			
Stratified OR, 95% CI	1.060 [0.294, 3.815]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.026 [0.415, 2.536]			
Stratified RR, 95% CI	1.047 [0.399, 2.749]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.006 [-0.205, 0.217]			
Stratified ARR, 95% CI (CMH method)	0.018 [-0.193, 0.228]			
Test on Differences [c]				
Unstratified p-value	0.9551			
Stratified p-value	0.8737			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline LDL-C Category - Infections and infestations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.1247
130 - < 160 vs. < 130		0.5754	0.1201	0.1126	
>= 160 vs. < 130		0.5754	0.6488	0.7263	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Infections and infestations (SOC)
Safety Population

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 61)	Total (N= 109)
Number of patients at risk		48 (100.0%)	61 (100.0%)	109 (100.0%)
Number of patients with events		12 (25.0%)	4 (6.6%)	16 (14.7%)
Number of patients without events		36 (75.0%)	57 (93.4%)	93 (85.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.750 [1.422, 15.866]			
Stratified OR, 95% CI	4.408 [1.349, 14.405]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.813 [1.312, 11.076]			
Stratified RR, 95% CI	3.455 [1.233, 9.686]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.184 [0.047, 0.322]			
Stratified ARR, 95% CI (CMH method)	0.194 [0.056, 0.332]			
Test on Differences [c]				
Unstratified p-value	0.0123			
Stratified p-value	0.0053			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Infections and infestations (SOC)
Safety Population

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		15 (25.4%)	12 (25.0%)	27 (25.2%)
Number of patients without events		44 (74.6%)	36 (75.0%)	80 (74.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.023 [0.425, 2.460]			
Stratified OR, 95% CI	1.051 [0.430, 2.569]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.017 [0.527, 1.961]			
Stratified RR, 95% CI	1.056 [0.543, 2.057]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.004 [-0.161, 0.170]			
Stratified ARR, 95% CI (CMH method)	0.010 [-0.158, 0.179]			
Test on Differences [c]				
Unstratified p-value	0.9600			
Stratified p-value	0.9055			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by History of Diabetes - Infections and infestations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.0298
No vs. Yes		0.0139	0.0139	0.0386	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Infections and infestations (SOC)
Safety Population

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		6 (46.2%)	3 (23.1%)	9 (34.6%)
Number of patients without events		7 (53.8%)	10 (76.9%)	17 (65.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.857 [0.528, 15.473]			
Stratified OR, 95% CI	2.746 [0.506, 14.886]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.000 [0.631, 6.336]			
Stratified RR, 95% CI	1.897 [0.709, 5.080]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.231 [-0.124, 0.586]			
Stratified ARR, 95% CI (CMH method)	0.289 [-0.068, 0.645]			
Test on Differences [c]				
Unstratified p-value	0.4110			
Stratified p-value	0.1692			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Infections and infestations (SOC)
Safety Population

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		6 (22.2%)	7 (18.9%)	13 (20.3%)
Number of patients without events		21 (77.8%)	30 (81.1%)	51 (79.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.224 [0.360, 4.167]			
Stratified OR, 95% CI	1.324 [0.388, 4.516]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.175 [0.445, 3.102]			
Stratified RR, 95% CI	1.260 [0.487, 3.256]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.033 [-0.168, 0.234]			
Stratified ARR, 95% CI (CMH method)	0.036 [-0.164, 0.237]			
Test on Differences [c]				
Unstratified p-value	0.7456			
Stratified p-value	0.7259			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Infections and infestations (SOC)
Safety Population

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 67)	Ezetimibe (N= 59)	Total (N= 126)
Number of patients at risk		67 (100.0%)	59 (100.0%)	126 (100.0%)
Number of patients with events		15 (22.4%)	6 (10.2%)	21 (16.7%)
Number of patients without events		52 (77.6%)	53 (89.8%)	105 (83.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.548 [0.918, 7.074]			
Stratified OR, 95% CI	2.286 [0.832, 6.285]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.201 [0.913, 5.306]			
Stratified RR, 95% CI	1.977 [0.832, 4.696]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.122 [-0.004, 0.248]			
Stratified ARR, 95% CI (CMH method)	0.121 [-0.005, 0.247]			
Test on Differences [c]				
Unstratified p-value	0.0663			
Stratified p-value	0.0732			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by BMI - Infections and infestations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.6143
25 - < 30 vs. < 25		0.2387	0.7447	0.4890	
>= 30 vs. < 25		0.2387	0.1985	0.8968	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Investigations (SOC)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		14 (13.1%)	9 (8.3%)	23 (10.6%)
Number of patients without events		93 (86.9%)	100 (91.7%)	193 (89.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.673 [0.691, 4.048]			
Stratified OR, 95% CI	1.409 [0.538, 3.686]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.585 [0.716, 3.505]			
Stratified RR, 95% CI	1.333 [0.563, 3.155]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.048 [-0.034, 0.130]			
Stratified ARR, 95% CI (CMH method)	0.048 [-0.034, 0.131]			
Test on Differences [c]				
Unstratified p-value	0.2502			
Stratified p-value	0.2523			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Investigations (SOC)
Safety Population

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		7 (14.0%)	5 (9.6%)	12 (11.8%)
Number of patients without events		43 (86.0%)	47 (90.4%)	90 (88.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.530 [0.452, 5.183]			
Stratified OR, 95% CI	1.504 [0.444, 5.096]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.456 [0.494, 4.287]			
Stratified RR, 95% CI	1.376 [0.481, 3.935]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.044 [-0.081, 0.169]			
Stratified ARR, 95% CI (CMH method)	0.053 [-0.075, 0.180]			
Test on Differences [c]				
Unstratified p-value	0.4920			
Stratified p-value	0.4168			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Investigations (SOC)
Safety Population

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 57)	Total (N= 114)
Number of patients at risk		57 (100.0%)	57 (100.0%)	114 (100.0%)
Number of patients with events		7 (12.3%)	4 (7.0%)	11 (9.6%)
Number of patients without events		50 (87.7%)	53 (93.0%)	103 (90.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.855 [0.512, 6.724]			
Stratified OR, 95% CI	1.279 [0.318, 5.153]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.750 [0.542, 5.652]			
Stratified RR, 95% CI	1.194 [0.333, 4.289]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.053 [-0.055, 0.161]			
Stratified ARR, 95% CI (CMH method)	0.056 [-0.056, 0.167]			
Test on Differences [c]				
Unstratified p-value	0.5277			
Stratified p-value	0.3221			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Gender - Investigations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.8209
Female vs. Male		0.4954	0.6242	0.8211	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Investigations (SOC)
Safety Population

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 48)	Total (N= 105)
Number of patients at risk		57 (100.0%)	48 (100.0%)	105 (100.0%)
Number of patients with events		6 (10.5%)	2 (4.2%)	8 (7.6%)
Number of patients without events		51 (89.5%)	46 (95.8%)	97 (92.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.706 [0.520, 14.078]			
Stratified OR, 95% CI	1.823 [0.401, 8.297]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.526 [0.534, 11.945]			
Stratified RR, 95% CI	1.680 [0.415, 6.806]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.064 [-0.034, 0.161]			
Stratified ARR, 95% CI (CMH method)	0.066 [-0.035, 0.167]			
Test on Differences [c]				
Unstratified p-value	0.2849			
Stratified p-value	0.2119			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Investigations (SOC)
Safety Population

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		8 (16.0%)	7 (11.5%)	15 (13.5%)
Number of patients without events		42 (84.0%)	54 (88.5%)	96 (86.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.469 [0.493, 4.377]			
Stratified OR, 95% CI	1.548 [0.499, 4.802]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.394 [0.543, 3.580]			
Stratified RR, 95% CI	1.448 [0.554, 3.787]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.045 [-0.084, 0.175]			
Stratified ARR, 95% CI (CMH method)	0.050 [-0.082, 0.183]			
Test on Differences [c]				
Unstratified p-value	0.4878			
Stratified p-value	0.4485			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Age - Investigations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.5107
>= 65 vs. < 65		0.2423	0.1930	0.5215	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Investigations (SOC)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 62)	Total (N= 121)
Number of patients at risk		59 (100.0%)	62 (100.0%)	121 (100.0%)
Number of patients with events		8 (13.6%)	6 (9.7%)	14 (11.6%)
Number of patients without events		51 (86.4%)	56 (90.3%)	107 (88.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.464 [0.476, 4.507]			
Stratified OR, 95% CI	1.435 [0.465, 4.428]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.401 [0.517, 3.796]			
Stratified RR, 95% CI	1.371 [0.507, 3.706]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.039 [-0.075, 0.153]			
Stratified ARR, 95% CI (CMH method)	0.037 [-0.078, 0.151]			
Test on Differences [c]				
Unstratified p-value	0.5046			
Stratified p-value	0.5314			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Investigations (SOC)
Safety Population

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		6 (12.5%)	3 (6.4%)	9 (9.5%)
Number of patients without events		42 (87.5%)	44 (93.6%)	86 (90.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.095 [0.492, 8.923]			
Stratified OR, 95% CI	1.250 [0.196, 7.972]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.958 [0.520, 7.377]			
Stratified RR, 95% CI	1.135 [0.204, 6.323]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.061 [-0.056, 0.178]			
Stratified ARR, 95% CI (CMH method)	0.060 [-0.060, 0.181]			
Test on Differences [c]				
Unstratified p-value	0.4860			
Stratified p-value	0.3184			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by CVD Risk Category - Investigations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.6905
Multiple CV risk factors vs. ASCVD and/or HeFH		0.5072	0.5406	0.6924	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Investigations (SOC)
Safety Population

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 65)	Ezetimibe (N= 70)	Total (N= 135)
Number of patients at risk		65 (100.0%)	70 (100.0%)	135 (100.0%)
Number of patients with events		9 (13.8%)	3 (4.3%)	12 (8.9%)
Number of patients without events		56 (86.2%)	67 (95.7%)	123 (91.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.589 [0.927, 13.901]			
Stratified OR, 95% CI	2.566 [0.640, 10.288]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.231 [0.914, 11.416]			
Stratified RR, 95% CI	2.272 [0.636, 8.114]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.096 [-0.001, 0.192]			
Stratified ARR, 95% CI (CMH method)	0.096 [0.000, 0.193]			
Test on Differences [c]				
Unstratified p-value	0.0697			
Stratified p-value	0.0508			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Investigations (SOC)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		5 (11.9%)	6 (15.4%)	11 (13.6%)
Number of patients without events		37 (88.1%)	33 (84.6%)	70 (86.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.743 [0.207, 2.663]			
Stratified OR, 95% CI	0.780 [0.205, 2.967]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.774 [0.257, 2.334]			
Stratified RR, 95% CI	0.822 [0.256, 2.641]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.035 [-0.185, 0.115]			
Stratified ARR, 95% CI (CMH method)	-0.035 [-0.186, 0.116]			
Test on Differences [c]				
Unstratified p-value	0.6478			
Stratified p-value	0.6515			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity I - Investigations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.0839
High Intensity Statin vs. Other		0.0686	0.0595	0.0948	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Investigations (SOC)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 32)	Ezetimibe (N= 38)	Total (N= 70)
Number of patients at risk		32 (100.0%)	38 (100.0%)	70 (100.0%)
Number of patients with events		4 (12.5%)	2 (5.3%)	6 (8.6%)
Number of patients without events		28 (87.5%)	36 (94.7%)	64 (91.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.571 [0.439, 15.063]			
Stratified OR, 95% CI	2.090 [0.372, 11.747]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.375 [0.465, 12.133]			
Stratified RR, 95% CI	1.892 [0.393, 9.101]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.072 [-0.062, 0.207]			
Stratified ARR, 95% CI (CMH method)	0.073 [-0.061, 0.208]			
Test on Differences [c]				
Unstratified p-value	0.4016			
Stratified p-value	0.2804			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Investigations (SOC)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		5 (11.9%)	6 (15.4%)	11 (13.6%)
Number of patients without events		37 (88.1%)	33 (84.6%)	70 (86.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.743 [0.207, 2.663]			
Stratified OR, 95% CI	0.780 [0.205, 2.967]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.774 [0.257, 2.334]			
Stratified RR, 95% CI	0.822 [0.256, 2.641]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.035 [-0.185, 0.115]			
Stratified ARR, 95% CI (CMH method)	-0.035 [-0.186, 0.116]			
Test on Differences [c]				
Unstratified p-value	0.6478			
Stratified p-value	0.6515			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Investigations (SOC)
Safety Population

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		5 (15.2%)	1 (3.1%)	6 (9.2%)
Number of patients without events		28 (84.8%)	31 (96.9%)	59 (90.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.536 [0.609, 50.311]			
Stratified OR, 95% CI	3.687 [0.532, 25.542]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.848 [0.599, 39.248]			
Stratified RR, 95% CI	3.227 [0.534, 19.505]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.120 [-0.016, 0.257]			
Stratified ARR, 95% CI (CMH method)	0.120 [-0.016, 0.257]			
Test on Differences [c]				
Unstratified p-value	0.1968			
Stratified p-value	0.0992			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity II - Investigations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.1949
High Intensity Statin vs. Other Intensity Statin		0.2986	0.1713	0.2644	
None vs. Other Intensity Statin		0.2986	0.6643	0.5979	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Investigations (SOC)
Safety Population

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 84)	Ezetimibe (N= 91)	Total (N= 175)
Number of patients at risk		84 (100.0%)	91 (100.0%)	175 (100.0%)
Number of patients with events		11 (13.1%)	7 (7.7%)	18 (10.3%)
Number of patients without events		73 (86.9%)	84 (92.3%)	157 (89.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.808 [0.666, 4.906]			
Stratified OR, 95% CI	1.470 [0.510, 4.233]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.702 [0.692, 4.187]			
Stratified RR, 95% CI	1.375 [0.533, 3.548]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.054 [-0.037, 0.145]			
Stratified ARR, 95% CI (CMH method)	0.053 [-0.039, 0.145]			
Test on Differences [c]				
Unstratified p-value	0.2398			
Stratified p-value	0.2556			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Investigations (SOC)
Safety Population

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		3 (13.0%)	2 (11.1%)	5 (12.2%)
Number of patients without events		20 (87.0%)	16 (88.9%)	36 (87.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.200 [0.178, 8.073]			
Stratified OR, 95% CI	0.650 [0.093, 4.533]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.174 [0.219, 6.296]			
Stratified RR, 95% CI	0.662 [0.166, 2.633]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.019 [-0.181, 0.219]			
Stratified ARR, 95% CI (CMH method)	-0.046 [-0.237, 0.145]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.6534			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Race - Investigations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.7052
non-White vs. White		0.2466	0.6281	0.7022	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Investigations (SOC)
Safety Population

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 38)	Total (N= 76)
Number of patients at risk		38 (100.0%)	38 (100.0%)	76 (100.0%)
Number of patients with events		5 (13.2%)	3 (7.9%)	8 (10.5%)
Number of patients without events		33 (86.8%)	35 (92.1%)	68 (89.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.768 [0.391, 7.988]			
Stratified OR, 95% CI	1.200 [0.242, 5.948]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.667 [0.428, 6.486]			
Stratified RR, 95% CI	1.004 [0.260, 3.876]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.053 [-0.085, 0.190]			
Stratified ARR, 95% CI (CMH method)	0.028 [-0.120, 0.177]			
Test on Differences [c]				
Unstratified p-value	0.7110			
Stratified p-value	0.6927			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Investigations (SOC)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		2 (6.5%)	2 (4.4%)	4 (5.3%)
Number of patients without events		29 (93.5%)	43 (95.6%)	72 (94.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.483 [0.198, 11.130]			
Stratified OR, 95% CI	1.672 [0.259, 10.781]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.452 [0.216, 9.762]			
Stratified RR, 95% CI	1.581 [0.303, 8.254]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.020 [-0.085, 0.125]			
Stratified ARR, 95% CI (CMH method)	0.025 [-0.080, 0.131]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.6305			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Investigations (SOC)
Safety Population

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		7 (18.4%)	4 (15.4%)	11 (17.2%)
Number of patients without events		31 (81.6%)	22 (84.6%)	53 (82.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.242 [0.324, 4.764]			
Stratified OR, 95% CI	1.186 [0.292, 4.813]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.197 [0.390, 3.679]			
Stratified RR, 95% CI	1.084 [0.381, 3.083]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.030 [-0.155, 0.216]			
Stratified ARR, 95% CI (CMH method)	0.042 [-0.142, 0.226]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.6651			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline LDL-C Category - Investigations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.9333
130 - < 160 vs. < 130		0.4613	0.5166	0.9079	
>= 160 vs. < 130		0.4613	0.3542	0.7131	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Investigations (SOC)
Safety Population

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 61)	Total (N= 109)
Number of patients at risk		48 (100.0%)	61 (100.0%)	109 (100.0%)
Number of patients with events		5 (10.4%)	6 (9.8%)	11 (10.1%)
Number of patients without events		43 (89.6%)	55 (90.2%)	98 (89.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.066 [0.305, 3.728]			
Stratified OR, 95% CI	0.853 [0.214, 3.396]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.059 [0.344, 3.262]			
Stratified RR, 95% CI	0.835 [0.240, 2.909]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.006 [-0.108, 0.120]			
Stratified ARR, 95% CI (CMH method)	0.005 [-0.111, 0.120]			
Test on Differences [c]				
Unstratified p-value	0.9204			
Stratified p-value	0.9365			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Investigations (SOC)
Safety Population

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		9 (15.3%)	3 (6.3%)	12 (11.2%)
Number of patients without events		50 (84.7%)	45 (93.8%)	95 (88.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.700 [0.688, 10.597]			
Stratified OR, 95% CI	2.120 [0.581, 7.740]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.441 [0.699, 8.518]			
Stratified RR, 95% CI	1.885 [0.592, 6.005]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.090 [-0.024, 0.205]			
Stratified ARR, 95% CI (CMH method)	0.093 [-0.021, 0.206]			
Test on Differences [c]				
Unstratified p-value	0.2185			
Stratified p-value	0.1388			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by History of Diabetes - Investigations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.3191
No vs. Yes		0.9204	0.5050	0.3305	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Investigations (SOC)
Safety Population

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		2 (15.4%)	0	2 (7.7%)
Number of patients without events		11 (84.6%)	13 (100.0%)	24 (92.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.870 [0.255, 135.15]			
Stratified OR, 95% CI	4.863 [0.404, 58.583]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.000 [0.263, 95.016]			
Stratified RR, 95% CI	3.529 [0.443, 28.116]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.154 [-0.042, 0.350]			
Stratified ARR, 95% CI (CMH method)	0.201 [-0.041, 0.442]			
Test on Differences [c]				
Unstratified p-value	0.4800			
Stratified p-value	0.1161			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Investigations (SOC)
Safety Population

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		1 (3.7%)	4 (10.8%)	5 (7.8%)
Number of patients without events		26 (96.3%)	33 (89.2%)	59 (92.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.317 [0.033, 3.013]			
Stratified OR, 95% CI	0.502 [0.076, 3.296]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.343 [0.041, 2.896]			
Stratified RR, 95% CI	0.548 [0.100, 2.988]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.071 [-0.194, 0.052]			
Stratified ARR, 95% CI (CMH method)	-0.080 [-0.210, 0.050]			
Test on Differences [c]				
Unstratified p-value	0.3868			
Stratified p-value	0.2449			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Investigations (SOC)
Safety Population

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 67)	Ezetimibe (N= 59)	Total (N= 126)
Number of patients at risk		67 (100.0%)	59 (100.0%)	126 (100.0%)
Number of patients with events		11 (16.4%)	5 (8.5%)	16 (12.7%)
Number of patients without events		56 (83.6%)	54 (91.5%)	110 (87.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.121 [0.691, 6.510]			
Stratified OR, 95% CI	1.641 [0.508, 5.295]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.937 [0.714, 5.253]			
Stratified RR, 95% CI	1.451 [0.521, 4.040]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.079 [-0.034, 0.193]			
Stratified ARR, 95% CI (CMH method)	0.079 [-0.037, 0.194]			
Test on Differences [c]				
Unstratified p-value	0.1815			
Stratified p-value	0.1906			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by BMI - Investigations (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.0909
25 - < 30 vs. < 25		<.0001	<.0001	<.0001	
>= 30 vs. < 25		<.0001	<.0001	-	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		13 (12.1%)	18 (16.5%)	31 (14.4%)
Number of patients without events		94 (87.9%)	91 (83.5%)	185 (85.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.699 [0.324, 1.509]			
Stratified OR, 95% CI	0.712 [0.321, 1.579]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.736 [0.380, 1.426]			
Stratified RR, 95% CI	0.766 [0.396, 1.481]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.044 [-0.137, 0.050]			
Stratified ARR, 95% CI (CMH method)	-0.042 [-0.134, 0.050]			
Test on Differences [c]				
Unstratified p-value	0.3604			
Stratified p-value	0.3759			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		8 (16.0%)	10 (19.2%)	18 (17.6%)
Number of patients without events		42 (84.0%)	42 (80.8%)	84 (82.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.800 [0.288, 2.226]			
Stratified OR, 95% CI	0.967 [0.327, 2.860]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.832 [0.357, 1.936]			
Stratified RR, 95% CI	1.044 [0.449, 2.427]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.032 [-0.180, 0.115]			
Stratified ARR, 95% CI (CMH method)	-0.009 [-0.157, 0.139]			
Test on Differences [c]				
Unstratified p-value	0.6687			
Stratified p-value	0.9032			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 57)	Total (N= 114)
Number of patients at risk		57 (100.0%)	57 (100.0%)	114 (100.0%)
Number of patients with events		5 (8.8%)	8 (14.0%)	13 (11.4%)
Number of patients without events		52 (91.2%)	49 (86.0%)	101 (88.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.589 [0.180, 1.923]			
Stratified OR, 95% CI	0.580 [0.168, 2.002]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.625 [0.218, 1.796]			
Stratified RR, 95% CI	0.639 [0.221, 1.853]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.053 [-0.169, 0.064]			
Stratified ARR, 95% CI (CMH method)	-0.056 [-0.173, 0.060]			
Test on Differences [c]				
Unstratified p-value	0.3767			
Stratified p-value	0.3437			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Gender - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.6773
Female vs. Male		0.6696	0.4679	0.6783	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 48)	Total (N= 105)
Number of patients at risk		57 (100.0%)	48 (100.0%)	105 (100.0%)
Number of patients with events		6 (10.5%)	6 (12.5%)	12 (11.4%)
Number of patients without events		51 (89.5%)	42 (87.5%)	93 (88.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.824 [0.247, 2.743]			
Stratified OR, 95% CI	0.807 [0.184, 3.545]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.842 [0.290, 2.441]			
Stratified RR, 95% CI	0.843 [0.220, 3.235]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.020 [-0.143, 0.103]			
Stratified ARR, 95% CI (CMH method)	-0.026 [-0.150, 0.097]			
Test on Differences [c]				
Unstratified p-value	0.7515			
Stratified p-value	0.6736			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		7 (14.0%)	12 (19.7%)	19 (17.1%)
Number of patients without events		43 (86.0%)	49 (80.3%)	92 (82.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.665 [0.240, 1.840]			
Stratified OR, 95% CI	0.701 [0.243, 2.021]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.712 [0.303, 1.672]			
Stratified RR, 95% CI	0.751 [0.317, 1.775]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.057 [-0.195, 0.082]			
Stratified ARR, 95% CI (CMH method)	-0.048 [-0.184, 0.089]			
Test on Differences [c]				
Unstratified p-value	0.4299			
Stratified p-value	0.5066			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Age - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.8088
>= 65 vs. < 65		0.7517	0.3256	0.8090	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 62)	Total (N= 121)
Number of patients at risk		59 (100.0%)	62 (100.0%)	121 (100.0%)
Number of patients with events		10 (16.9%)	14 (22.6%)	24 (19.8%)
Number of patients without events		49 (83.1%)	48 (77.4%)	97 (80.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.700 [0.283, 1.728]			
Stratified OR, 95% CI	0.716 [0.288, 1.784]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.751 [0.362, 1.556]			
Stratified RR, 95% CI	0.776 [0.372, 1.618]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.056 [-0.198, 0.085]			
Stratified ARR, 95% CI (CMH method)	-0.055 [-0.197, 0.088]			
Test on Differences [c]				
Unstratified p-value	0.4374			
Stratified p-value	0.4539			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		3 (6.3%)	4 (8.5%)	7 (7.4%)
Number of patients without events		45 (93.8%)	43 (91.5%)	88 (92.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.717 [0.151, 3.391]			
Stratified OR, 95% CI	0.724 [0.148, 3.531]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.734 [0.174, 3.105]			
Stratified RR, 95% CI	0.750 [0.182, 3.086]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.023 [-0.128, 0.083]			
Stratified ARR, 95% CI (CMH method)	-0.021 [-0.124, 0.082]			
Test on Differences [c]				
Unstratified p-value	0.7145			
Stratified p-value	0.6911			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by CVD Risk Category - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.9788
Multiple CV risk factors vs. ASCVD and/or HeFH		0.4406	0.0671	0.9788	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 65)	Ezetimibe (N= 70)	Total (N= 135)
Number of patients at risk		65 (100.0%)	70 (100.0%)	135 (100.0%)
Number of patients with events		10 (15.4%)	12 (17.1%)	22 (16.3%)
Number of patients without events		55 (84.6%)	58 (82.9%)	113 (83.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.879 [0.351, 2.198]			
Stratified OR, 95% CI	0.901 [0.357, 2.276]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.897 [0.416, 1.935]			
Stratified RR, 95% CI	0.925 [0.433, 1.978]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.018 [-0.142, 0.107]			
Stratified ARR, 95% CI (CMH method)	-0.014 [-0.138, 0.109]			
Test on Differences [c]				
Unstratified p-value	0.7823			
Stratified p-value	0.8253			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		3 (7.1%)	6 (15.4%)	9 (11.1%)
Number of patients without events		39 (92.9%)	33 (84.6%)	72 (88.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.423 [0.098, 1.824]			
Stratified OR, 95% CI	0.391 [0.086, 1.784]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.464 [0.125, 1.730]			
Stratified RR, 95% CI	0.462 [0.130, 1.643]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.082 [-0.220, 0.055]			
Stratified ARR, 95% CI (CMH method)	-0.083 [-0.216, 0.050]			
Test on Differences [c]				
Unstratified p-value	0.3010			
Stratified p-value	0.2204			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity I - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.3875
High Intensity Statin vs. Other		0.7825	0.8134	0.3965	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 32)	Ezetimibe (N= 38)	Total (N= 70)
Number of patients at risk		32 (100.0%)	38 (100.0%)	70 (100.0%)
Number of patients with events		3 (9.4%)	4 (10.5%)	7 (10.0%)
Number of patients without events		29 (90.6%)	34 (89.5%)	63 (90.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.879 [0.182, 4.255]			
Stratified OR, 95% CI	0.882 [0.178, 4.370]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.891 [0.215, 3.689]			
Stratified RR, 95% CI	0.870 [0.213, 3.545]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.012 [-0.152, 0.129]			
Stratified ARR, 95% CI (CMH method)	-0.009 [-0.147, 0.129]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9016			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		3 (7.1%)	6 (15.4%)	9 (11.1%)
Number of patients without events		39 (92.9%)	33 (84.6%)	72 (88.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.423 [0.098, 1.824]			
Stratified OR, 95% CI	0.391 [0.086, 1.784]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.464 [0.125, 1.730]			
Stratified RR, 95% CI	0.462 [0.130, 1.643]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.082 [-0.220, 0.055]			
Stratified ARR, 95% CI (CMH method)	-0.083 [-0.216, 0.050]			
Test on Differences [c]				
Unstratified p-value	0.3010			
Stratified p-value	0.2204			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		7 (21.2%)	8 (25.0%)	15 (23.1%)
Number of patients without events		26 (78.8%)	24 (75.0%)	50 (76.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.808 [0.254, 2.567]			
Stratified OR, 95% CI	0.840 [0.256, 2.757]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.848 [0.348, 2.067]			
Stratified RR, 95% CI	0.908 [0.366, 2.255]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.038 [-0.243, 0.167]			
Stratified ARR, 95% CI (CMH method)	-0.034 [-0.241, 0.173]			
Test on Differences [c]				
Unstratified p-value	0.7171			
Stratified p-value	0.7478			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity II - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.7182
High Intensity Statin vs. Other Intensity Statin		0.8731	0.5298	0.5097	
None vs. Other Intensity Statin		0.8731	0.1247	0.9548	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 84)	Ezetimibe (N= 91)	Total (N= 175)
Number of patients at risk		84 (100.0%)	91 (100.0%)	175 (100.0%)
Number of patients with events		9 (10.7%)	17 (18.7%)	26 (14.9%)
Number of patients without events		75 (89.3%)	74 (81.3%)	149 (85.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.522 [0.219, 1.246]			
Stratified OR, 95% CI	0.539 [0.220, 1.320]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.574 [0.270, 1.216]			
Stratified RR, 95% CI	0.607 [0.288, 1.280]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.080 [-0.184, 0.024]			
Stratified ARR, 95% CI (CMH method)	-0.074 [-0.176, 0.028]			
Test on Differences [c]				
Unstratified p-value	0.1388			
Stratified p-value	0.1669			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		4 (17.4%)	1 (5.6%)	5 (12.2%)
Number of patients without events		19 (82.6%)	17 (94.4%)	36 (87.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.579 [0.364, 35.233]			
Stratified OR, 95% CI	1.587 [0.224, 11.246]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.130 [0.382, 25.633]			
Stratified RR, 95% CI	1.103 [0.238, 5.125]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.118 [-0.069, 0.306]			
Stratified ARR, 95% CI (CMH method)	0.104 [-0.127, 0.335]			
Test on Differences [c]				
Unstratified p-value	0.3629			
Stratified p-value	0.3418			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Race - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.0924
non-White vs. White		0.1471	0.2234	0.1363	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 38)	Total (N= 76)
Number of patients at risk		38 (100.0%)	38 (100.0%)	76 (100.0%)
Number of patients with events		6 (15.8%)	8 (21.1%)	14 (18.4%)
Number of patients without events		32 (84.2%)	30 (78.9%)	62 (81.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.703 [0.218, 2.265]			
Stratified OR, 95% CI	0.804 [0.241, 2.689]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.750 [0.288, 1.955]			
Stratified RR, 95% CI	0.856 [0.325, 2.256]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.053 [-0.227, 0.121]			
Stratified ARR, 95% CI (CMH method)	-0.038 [-0.223, 0.148]			
Test on Differences [c]				
Unstratified p-value	0.5540			
Stratified p-value	0.6851			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		3 (9.7%)	4 (8.9%)	7 (9.2%)
Number of patients without events		28 (90.3%)	41 (91.1%)	69 (90.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.098 [0.228, 5.290]			
Stratified OR, 95% CI	1.087 [0.213, 5.542]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.089 [0.262, 4.528]			
Stratified RR, 95% CI	1.102 [0.268, 4.532]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.008 [-0.125, 0.141]			
Stratified ARR, 95% CI (CMH method)	0.005 [-0.127, 0.138]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9399			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		4 (10.5%)	6 (23.1%)	10 (15.6%)
Number of patients without events		34 (89.5%)	20 (76.9%)	54 (84.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.392 [0.099, 1.559]			
Stratified OR, 95% CI	0.340 [0.082, 1.408]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.456 [0.143, 1.459]			
Stratified RR, 95% CI	0.445 [0.153, 1.291]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.126 [-0.315, 0.064]			
Stratified ARR, 95% CI (CMH method)	-0.144 [-0.326, 0.039]			
Test on Differences [c]				
Unstratified p-value	0.2929			
Stratified p-value	0.1182			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline LDL-C Category - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.6350
130 - < 160 vs. < 130		0.5563	0.1313	0.6706	
>= 160 vs. < 130		0.5563	0.8472	0.5177	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 61)	Total (N= 109)
Number of patients at risk		48 (100.0%)	61 (100.0%)	109 (100.0%)
Number of patients with events		5 (10.4%)	12 (19.7%)	17 (15.6%)
Number of patients without events		43 (89.6%)	49 (80.3%)	92 (84.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.475 [0.155, 1.456]			
Stratified OR, 95% CI	0.565 [0.168, 1.895]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.530 [0.200, 1.400]			
Stratified RR, 95% CI	0.647 [0.232, 1.800]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.093 [-0.225, 0.039]			
Stratified ARR, 95% CI (CMH method)	-0.077 [-0.207, 0.053]			
Test on Differences [c]				
Unstratified p-value	0.1861			
Stratified p-value	0.2675			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		8 (13.6%)	6 (12.5%)	14 (13.1%)
Number of patients without events		51 (86.4%)	42 (87.5%)	93 (86.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.098 [0.353, 3.415]			
Stratified OR, 95% CI	1.148 [0.357, 3.688]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.085 [0.404, 2.912]			
Stratified RR, 95% CI	1.151 [0.443, 2.990]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.011 [-0.117, 0.139]			
Stratified ARR, 95% CI (CMH method)	0.014 [-0.112, 0.139]			
Test on Differences [c]				
Unstratified p-value	0.8716			
Stratified p-value	0.8340			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by History of Diabetes - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.3020
No vs. Yes		0.2000	0.3256	0.3105	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		3 (23.1%)	2 (15.4%)	5 (19.2%)
Number of patients without events		10 (76.9%)	11 (84.6%)	21 (80.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.650 [0.227, 11.993]			
Stratified OR, 95% CI	1.580 [0.213, 11.687]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.500 [0.298, 7.546]			
Stratified RR, 95% CI	1.251 [0.300, 5.217]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.077 [-0.225, 0.378]			
Stratified ARR, 95% CI (CMH method)	0.085 [-0.318, 0.488]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.6319			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		1 (3.7%)	6 (16.2%)	7 (10.9%)
Number of patients without events		26 (96.3%)	31 (83.8%)	57 (89.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.199 [0.022, 1.758]			
Stratified OR, 95% CI	0.352 [0.065, 1.900]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.228 [0.029, 1.789]			
Stratified RR, 95% CI	0.413 [0.095, 1.804]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.125 [-0.264, 0.013]			
Stratified ARR, 95% CI (CMH method)	-0.119 [-0.252, 0.015]			
Test on Differences [c]				
Unstratified p-value	0.2232			
Stratified p-value	0.1276			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 67)	Ezetimibe (N= 59)	Total (N= 126)
Number of patients at risk		67 (100.0%)	59 (100.0%)	126 (100.0%)
Number of patients with events		9 (13.4%)	10 (16.9%)	19 (15.1%)
Number of patients without events		58 (86.6%)	49 (83.1%)	107 (84.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.760 [0.286, 2.021]			
Stratified OR, 95% CI	0.797 [0.275, 2.311]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.793 [0.346, 1.817]			
Stratified RR, 95% CI	0.825 [0.336, 2.027]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.035 [-0.161, 0.091]			
Stratified ARR, 95% CI (CMH method)	-0.035 [-0.161, 0.092]			
Test on Differences [c]				
Unstratified p-value	0.5821			
Stratified p-value	0.5855			

Abbreviations: ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardiovascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, PT=preferred term, RR=relative risk, SOC=system organ class, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by BMI - Musculoskeletal and connective tissue disorders (SOC)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.2910
25 - < 30 vs. < 25		0.6228	0.9441	0.1586	
>= 30 vs. < 25		0.6228	0.8917	0.4912	

Abbreviations: ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
SOCs/PTs with incidence >=10 patients and >=1% in at least one treatment arm are presented.

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Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Creatine Kinase Elevations (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	2 (1.8%)	2 (0.9%)
Number of patients without events		107 (100.0%)	107 (98.2%)	214 (99.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.200 [0.009, 4.215]			
Stratified OR, 95% CI	0.185 [0.008, 4.046]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.204 [0.010, 4.194]			
Stratified RR, 95% CI	0.200 [0.010, 3.974]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.018 [-0.044, 0.007]			
Stratified ARR, 95% CI (CMH method)	-0.019 [-0.044, 0.007]			
Test on Differences [c]				
Unstratified p-value	0.4977			
Stratified p-value	0.1532			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Creatine Kinase Elevations (AESI)
Safety Population

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		0	2 (3.8%)	2 (2.0%)
Number of patients without events		50 (100.0%)	50 (96.2%)	100 (98.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.200 [0.009, 4.271]			
Stratified OR, 95% CI	0.212 [0.009, 4.756]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.208 [0.010, 4.225]			
Stratified RR, 95% CI	0.235 [0.012, 4.571]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.038 [-0.091, 0.014]			
Stratified ARR, 95% CI (CMH method)	-0.036 [-0.088, 0.015]			
Test on Differences [c]				
Unstratified p-value	0.4952			
Stratified p-value	0.1877			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Creatine Kinase Elevations (AESI)
Safety Population

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 57)	Total (N= 114)
Number of patients at risk		57 (100.0%)	57 (100.0%)	114 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		57 (100.0%)	57 (100.0%)	114 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Gender - Creatine Kinase Elevations (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	WARNING: Negative of Hessian not positive definite				-
Female vs. Male		1.0000	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Creatine Kinase Elevations (AESI)
Safety Population

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 48)	Total (N= 105)
Number of patients at risk		57 (100.0%)	48 (100.0%)	105 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		57 (100.0%)	48 (100.0%)	105 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Creatine Kinase Elevations (AESI)
Safety Population

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		0	2 (3.3%)	2 (1.8%)
Number of patients without events		50 (100.0%)	59 (96.7%)	109 (98.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.236 [0.011, 5.023]			
Stratified OR, 95% CI	0.188 [0.008, 4.231]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.243 [0.012, 4.951]			
Stratified RR, 95% CI	0.212 [0.011, 4.099]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.033 [-0.077, 0.012]			
Stratified ARR, 95% CI (CMH method)	-0.036 [-0.083, 0.011]			
Test on Differences [c]				
Unstratified p-value	0.5004			
Stratified p-value	0.1633			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Age - Creatine Kinase Elevations (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	WARNING: Negative of Hessian not positive definite				-
>= 65 vs. < 65		1.0000	-	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Creatine Kinase Elevations (AESI)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 62)	Total (N= 121)
Number of patients at risk		59 (100.0%)	62 (100.0%)	121 (100.0%)
Number of patients with events		0	2 (3.2%)	2 (1.7%)
Number of patients without events		59 (100.0%)	60 (96.8%)	119 (98.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.203 [0.010, 4.326]			
Stratified OR, 95% CI	0.170 [0.008, 3.724]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.210 [0.010, 4.285]			
Stratified RR, 95% CI	0.185 [0.009, 3.672]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.032 [-0.076, 0.012]			
Stratified ARR, 95% CI (CMH method)	-0.035 [-0.080, 0.011]			
Test on Differences [c]				
Unstratified p-value	0.4961			
Stratified p-value	0.1370			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Creatine Kinase Elevations (AESI)
Safety Population

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		48 (100.0%)	47 (100.0%)	95 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by CVD Risk Category - Creatine Kinase Elevations (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	WARNING: Negative of Hessian not positive definite				-
Multiple CV risk factors vs. ASCVD and/or HeFH		1.0000	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Creatine Kinase Elevations (AESI)
Safety Population

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 65)	Ezetimibe (N= 70)	Total (N= 135)
Number of patients at risk		65 (100.0%)	70 (100.0%)	135 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		65 (100.0%)	70 (100.0%)	135 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Creatine Kinase Elevations (AESI)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		0	2 (5.1%)	2 (2.5%)
Number of patients without events		42 (100.0%)	37 (94.9%)	79 (97.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.176 [0.008, 3.794]			
Stratified OR, 95% CI	0.170 [0.008, 3.724]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.186 [0.009, 3.758]			
Stratified RR, 95% CI	0.185 [0.009, 3.672]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.051 [-0.121, 0.018]			
Stratified ARR, 95% CI (CMH method)	-0.051 [-0.121, 0.018]			
Test on Differences [c]				
Unstratified p-value	0.2287			
Stratified p-value	0.1370			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity I - Creatine Kinase Elevations (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	WARNING: Negative of Hessian not positive definite				-
High Intensity Statin vs. Other		1.0000	-	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Creatine Kinase Elevations (AESI)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 32)	Ezetimibe (N= 38)	Total (N= 70)
Number of patients at risk		32 (100.0%)	38 (100.0%)	70 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		32 (100.0%)	38 (100.0%)	70 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Creatine Kinase Elevations (AESI)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		0	2 (5.1%)	2 (2.5%)
Number of patients without events		42 (100.0%)	37 (94.9%)	79 (97.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.176 [0.008, 3.794]			
Stratified OR, 95% CI	0.170 [0.008, 3.724]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.186 [0.009, 3.758]			
Stratified RR, 95% CI	0.185 [0.009, 3.672]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.051 [-0.121, 0.018]			
Stratified ARR, 95% CI (CMH method)	-0.051 [-0.121, 0.018]			
Test on Differences [c]				
Unstratified p-value	0.2287			
Stratified p-value	0.1370			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Creatine Kinase Elevations (AESI)
Safety Population

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		33 (100.0%)	32 (100.0%)	65 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity II - Creatine Kinase Elevations (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	WARNING: Negative of Hessian not positive definite				-
High Intensity Statin vs. Other Intensity Statin		1.0000	-	1.0000	
None vs. Other Intensity Statin		1.0000	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Creatine Kinase Elevations (AESI)
Safety Population

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 84)	Ezetimibe (N= 91)	Total (N= 175)
Number of patients at risk		84 (100.0%)	91 (100.0%)	175 (100.0%)
Number of patients with events		0	1 (1.1%)	1 (0.6%)
Number of patients without events		84 (100.0%)	90 (98.9%)	174 (99.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.357 [0.014, 8.884]			
Stratified OR, 95% CI	0.423 [0.016, 11.009]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.361 [0.015, 8.737]			
Stratified RR, 95% CI	0.439 [0.019, 10.179]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.011 [-0.032, 0.010]			
Stratified ARR, 95% CI (CMH method)	-0.010 [-0.030, 0.011]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3865			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Creatine Kinase Elevations (AESI)
Safety Population

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		0	1 (5.6%)	1 (2.4%)
Number of patients without events		23 (100.0%)	17 (94.4%)	40 (97.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.248 [0.010, 6.465]			
Stratified OR, 95% CI	0.059 [0.002, 2.243]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.264 [0.011, 6.118]			
Stratified RR, 95% CI	0.111 [0.006, 2.064]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.056 [-0.161, 0.050]			
Stratified ARR, 95% CI (CMH method)	-0.090 [-0.224, 0.045]			
Test on Differences [c]				
Unstratified p-value	0.4390			
Stratified p-value	0.0455			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Race - Creatine Kinase Elevations (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				1.0000
non-White vs. White		0.9999	0.2439	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Creatine Kinase Elevations (AESI)
Safety Population

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 38)	Total (N= 76)
Number of patients at risk		38 (100.0%)	38 (100.0%)	76 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		38 (100.0%)	38 (100.0%)	76 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Creatine Kinase Elevations (AESI)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		31 (100.0%)	45 (100.0%)	76 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Creatine Kinase Elevations (AESI)
Safety Population

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		0	2 (7.7%)	2 (3.1%)
Number of patients without events		38 (100.0%)	24 (92.3%)	62 (96.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.127 [0.006, 2.765]			
Stratified OR, 95% CI	0.127 [0.005, 3.517]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.138 [0.007, 2.771]			
Stratified RR, 95% CI	0.200 [0.012, 3.347]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.077 [-0.179, 0.026]			
Stratified ARR, 95% CI (CMH method)	-0.066 [-0.163, 0.031]			
Test on Differences [c]				
Unstratified p-value	0.1612			
Stratified p-value	0.1336			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline LDL-C Category - Creatine Kinase Elevations (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	WARNING: Negative of Hessian not positive definite				-
130 - < 160 vs. < 130		1.0000	1.0000	1.0000	
>= 160 vs. < 130		1.0000	-	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Creatine Kinase Elevations (AESI)
Safety Population

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 61)	Total (N= 109)
Number of patients at risk		48 (100.0%)	61 (100.0%)	109 (100.0%)
Number of patients with events		0	2 (3.3%)	2 (1.8%)
Number of patients without events		48 (100.0%)	59 (96.7%)	107 (98.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.245 [0.012, 5.233]			
Stratified OR, 95% CI	0.276 [0.012, 6.372]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.253 [0.012, 5.150]			
Stratified RR, 95% CI	0.309 [0.016, 5.847]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.033 [-0.077, 0.012]			
Stratified ARR, 95% CI (CMH method)	-0.029 [-0.071, 0.013]			
Test on Differences [c]				
Unstratified p-value	0.5025			
Stratified p-value	0.2538			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Creatine Kinase Elevations (AESI)
Safety Population

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		59 (100.0%)	48 (100.0%)	107 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by History of Diabetes - Creatine Kinase Elevations (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	WARNING: Negative of Hessian not positive definite				-
No vs. Yes		1.0000	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Creatine Kinase Elevations (AESI)
Safety Population

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		13 (100.0%)	13 (100.0%)	26 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Creatine Kinase Elevations (AESI)
Safety Population

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		27 (100.0%)	37 (100.0%)	64 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Creatine Kinase Elevations (AESI)
Safety Population

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 67)	Ezetimibe (N= 59)	Total (N= 126)
Number of patients at risk		67 (100.0%)	59 (100.0%)	126 (100.0%)
Number of patients with events		0	2 (3.4%)	2 (1.6%)
Number of patients without events		67 (100.0%)	57 (96.6%)	124 (98.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.170 [0.008, 3.621]			
Stratified OR, 95% CI	0.149 [0.007, 3.339]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.176 [0.009, 3.603]			
Stratified RR, 95% CI	0.170 [0.009, 3.303]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.034 [-0.080, 0.012]			
Stratified ARR, 95% CI (CMH method)	-0.035 [-0.081, 0.012]			
Test on Differences [c]				
Unstratified p-value	0.2173			
Stratified p-value	0.1178			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by BMI - Creatine Kinase Elevations (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	WARNING: Negative of Hessian not positive definite				-
25 - < 30 vs. < 25		1.0000	1.0000	1.0000	
>= 30 vs. < 25		1.0000	-	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE - Creatine Kinase Elevations (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE - Creatine Kinase Elevations (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE - Creatine Kinase Elevations (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	2 (1.8%)	2 (0.9%)
Number of patients without events		107 (100.0%)	107 (98.2%)	214 (99.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.200 [0.009, 4.215]			
Stratified OR, 95% CI	0.185 [0.008, 4.046]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.204 [0.010, 4.194]			
Stratified RR, 95% CI	0.200 [0.010, 3.974]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.018 [-0.044, 0.007]			
Stratified ARR, 95% CI (CMH method)	-0.019 [-0.044, 0.007]			
Test on Differences [c]				
Unstratified p-value	0.4977			
Stratified p-value	0.1532			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Gender - Creatine Kinase Elevations (AESI)
Safety Population

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		0	2 (3.8%)	2 (2.0%)
Number of patients without events		50 (100.0%)	50 (96.2%)	100 (98.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.200 [0.009, 4.271]			
Stratified OR, 95% CI	0.212 [0.009, 4.756]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.208 [0.010, 4.225]			
Stratified RR, 95% CI	0.235 [0.012, 4.571]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.038 [-0.091, 0.014]			
Stratified ARR, 95% CI (CMH method)	-0.036 [-0.088, 0.015]			
Test on Differences [c]				
Unstratified p-value	0.4952			
Stratified p-value	0.1877			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Gender - Creatine Kinase Elevations (AESI)
Safety Population

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 57)	Total (N= 114)
Number of patients at risk		57 (100.0%)	57 (100.0%)	114 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		57 (100.0%)	57 (100.0%)	114 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Gender - Creatine Kinase Elevations (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	WARNING: Negative of Hessian not positive definite				-
Female vs. Male		1.0000	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Age - Creatine Kinase Elevations (AESI)
Safety Population

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 48)	Total (N= 105)
Number of patients at risk		57 (100.0%)	48 (100.0%)	105 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		57 (100.0%)	48 (100.0%)	105 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Age - Creatine Kinase Elevations (AESI)
Safety Population

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		0	2 (3.3%)	2 (1.8%)
Number of patients without events		50 (100.0%)	59 (96.7%)	109 (98.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.236 [0.011, 5.023]			
Stratified OR, 95% CI	0.188 [0.008, 4.231]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.243 [0.012, 4.951]			
Stratified RR, 95% CI	0.212 [0.011, 4.099]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.033 [-0.077, 0.012]			
Stratified ARR, 95% CI (CMH method)	-0.036 [-0.083, 0.011]			
Test on Differences [c]				
Unstratified p-value	0.5004			
Stratified p-value	0.1633			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Age - Creatine Kinase Elevations (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	WARNING: Negative of Hessian not positive definite				-
>= 65 vs. < 65		1.0000	-	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by CVD Risk Category - Creatine Kinase Elevations (AESI)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 62)	Total (N= 121)
Number of patients at risk		59 (100.0%)	62 (100.0%)	121 (100.0%)
Number of patients with events		0	2 (3.2%)	2 (1.7%)
Number of patients without events		59 (100.0%)	60 (96.8%)	119 (98.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.203 [0.010, 4.326]			
Stratified OR, 95% CI	0.170 [0.008, 3.724]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.210 [0.010, 4.285]			
Stratified RR, 95% CI	0.185 [0.009, 3.672]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.032 [-0.076, 0.012]			
Stratified ARR, 95% CI (CMH method)	-0.035 [-0.080, 0.011]			
Test on Differences [c]				
Unstratified p-value	0.4961			
Stratified p-value	0.1370			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by CVD Risk Category - Creatine Kinase Elevations (AESI)
Safety Population

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		48 (100.0%)	47 (100.0%)	95 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by CVD Risk Category - Creatine Kinase Elevations (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	WARNING: Negative of Hessian not positive definite				-
Multiple CV risk factors vs. ASCVD and/or HeFH		1.0000	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Creatine Kinase Elevations (AESI)
Safety Population

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 65)	Ezetimibe (N= 70)	Total (N= 135)
Number of patients at risk		65 (100.0%)	70 (100.0%)	135 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		65 (100.0%)	70 (100.0%)	135 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Creatine Kinase Elevations (AESI)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		0	2 (5.1%)	2 (2.5%)
Number of patients without events		42 (100.0%)	37 (94.9%)	79 (97.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.176 [0.008, 3.794]			
Stratified OR, 95% CI	0.170 [0.008, 3.724]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.186 [0.009, 3.758]			
Stratified RR, 95% CI	0.185 [0.009, 3.672]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.051 [-0.121, 0.018]			
Stratified ARR, 95% CI (CMH method)	-0.051 [-0.121, 0.018]			
Test on Differences [c]				
Unstratified p-value	0.2287			
Stratified p-value	0.1370			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Creatine Kinase Elevations (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	WARNING: Negative of Hessian not positive definite				-
High Intensity Statin vs. Other		1.0000	-	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Creatine Kinase Elevations (AESI)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 32)	Ezetimibe (N= 38)	Total (N= 70)
Number of patients at risk		32 (100.0%)	38 (100.0%)	70 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		32 (100.0%)	38 (100.0%)	70 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Creatine Kinase Elevations (AESI)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		0	2 (5.1%)	2 (2.5%)
Number of patients without events		42 (100.0%)	37 (94.9%)	79 (97.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.176 [0.008, 3.794]			
Stratified OR, 95% CI	0.170 [0.008, 3.724]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.186 [0.009, 3.758]			
Stratified RR, 95% CI	0.185 [0.009, 3.672]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.051 [-0.121, 0.018]			
Stratified ARR, 95% CI (CMH method)	-0.051 [-0.121, 0.018]			
Test on Differences [c]				
Unstratified p-value	0.2287			
Stratified p-value	0.1370			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Creatine Kinase Elevations (AESI)
Safety Population

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		33 (100.0%)	32 (100.0%)	65 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Creatine Kinase Elevations (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	WARNING: Negative of Hessian not positive definite				-
High Intensity Statin vs. Other Intensity Statin		1.0000	-	1.0000	
None vs. Other Intensity Statin		1.0000	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Race - Creatine Kinase Elevations (AESI)
Safety Population

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 84)	Ezetimibe (N= 91)	Total (N= 175)
Number of patients at risk		84 (100.0%)	91 (100.0%)	175 (100.0%)
Number of patients with events		0	1 (1.1%)	1 (0.6%)
Number of patients without events		84 (100.0%)	90 (98.9%)	174 (99.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.357 [0.014, 8.884]			
Stratified OR, 95% CI	0.423 [0.016, 11.009]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.361 [0.015, 8.737]			
Stratified RR, 95% CI	0.439 [0.019, 10.179]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.011 [-0.032, 0.010]			
Stratified ARR, 95% CI (CMH method)	-0.010 [-0.030, 0.011]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3865			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Race - Creatine Kinase Elevations (AESI)
Safety Population

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		0	1 (5.6%)	1 (2.4%)
Number of patients without events		23 (100.0%)	17 (94.4%)	40 (97.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.248 [0.010, 6.465]			
Stratified OR, 95% CI	0.059 [0.002, 2.243]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.264 [0.011, 6.118]			
Stratified RR, 95% CI	0.111 [0.006, 2.064]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.056 [-0.161, 0.050]			
Stratified ARR, 95% CI (CMH method)	-0.090 [-0.224, 0.045]			
Test on Differences [c]				
Unstratified p-value	0.4390			
Stratified p-value	0.0455			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Race - Creatine Kinase Elevations (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				1.0000
non-White vs. White		0.9999	0.2439	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Creatine Kinase Elevations (AESI)
Safety Population

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 38)	Total (N= 76)
Number of patients at risk		38 (100.0%)	38 (100.0%)	76 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		38 (100.0%)	38 (100.0%)	76 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Creatine Kinase Elevations (AESI)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		31 (100.0%)	45 (100.0%)	76 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Creatine Kinase Elevations (AESI)
Safety Population

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		0	2 (7.7%)	2 (3.1%)
Number of patients without events		38 (100.0%)	24 (92.3%)	62 (96.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.127 [0.006, 2.765]			
Stratified OR, 95% CI	0.127 [0.005, 3.517]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.138 [0.007, 2.771]			
Stratified RR, 95% CI	0.200 [0.012, 3.347]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.077 [-0.179, 0.026]			
Stratified ARR, 95% CI (CMH method)	-0.066 [-0.163, 0.031]			
Test on Differences [c]				
Unstratified p-value	0.1612			
Stratified p-value	0.1336			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline LDL-C Category - Creatine Kinase Elevations (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	WARNING: Negative of Hessian not positive definite				-
130 - < 160 vs. < 130		1.0000	1.0000	1.0000	
>= 160 vs. < 130		1.0000	-	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by History of Diabetes - Creatine Kinase Elevations (AESI)
Safety Population

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 61)	Total (N= 109)
Number of patients at risk		48 (100.0%)	61 (100.0%)	109 (100.0%)
Number of patients with events		0	2 (3.3%)	2 (1.8%)
Number of patients without events		48 (100.0%)	59 (96.7%)	107 (98.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.245 [0.012, 5.233]			
Stratified OR, 95% CI	0.276 [0.012, 6.372]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.253 [0.012, 5.150]			
Stratified RR, 95% CI	0.309 [0.016, 5.847]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.033 [-0.077, 0.012]			
Stratified ARR, 95% CI (CMH method)	-0.029 [-0.071, 0.013]			
Test on Differences [c]				
Unstratified p-value	0.5025			
Stratified p-value	0.2538			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by History of Diabetes - Creatine Kinase Elevations (AESI)
Safety Population

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		59 (100.0%)	48 (100.0%)	107 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by History of Diabetes - Creatine Kinase Elevations (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	WARNING: Negative of Hessian not positive definite				-
No vs. Yes		1.0000	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Creatine Kinase Elevations (AESI)
Safety Population

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		13 (100.0%)	13 (100.0%)	26 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Creatine Kinase Elevations (AESI)
Safety Population

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		27 (100.0%)	37 (100.0%)	64 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Creatine Kinase Elevations (AESI)
Safety Population

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 67)	Ezetimibe (N= 59)	Total (N= 126)
Number of patients at risk		67 (100.0%)	59 (100.0%)	126 (100.0%)
Number of patients with events		0	2 (3.4%)	2 (1.6%)
Number of patients without events		67 (100.0%)	57 (96.6%)	124 (98.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.170 [0.008, 3.621]			
Stratified OR, 95% CI	0.149 [0.007, 3.339]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.176 [0.009, 3.603]			
Stratified RR, 95% CI	0.170 [0.009, 3.303]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.034 [-0.080, 0.012]			
Stratified ARR, 95% CI (CMH method)	-0.035 [-0.081, 0.012]			
Test on Differences [c]				
Unstratified p-value	0.2173			
Stratified p-value	0.1178			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by BMI - Creatine Kinase Elevations (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	WARNING: Negative of Hessian not positive definite				-
25 - < 30 vs. < 25		1.0000	1.0000	1.0000	
>= 30 vs. < 25		1.0000	-	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Hepatic Disorders (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		2 (1.9%)	0	2 (0.9%)
Number of patients without events		105 (98.1%)	109 (100.0%)	214 (99.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.190 [0.246, 109.37]			
Stratified OR, 95% CI	5.794 [0.268, 125.25]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.093 [0.247, 104.85]			
Stratified RR, 95% CI	5.441 [0.271, 109.34]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.019 [-0.007, 0.044]			
Stratified ARR, 95% CI (CMH method)	0.019 [-0.007, 0.045]			
Test on Differences [c]				
Unstratified p-value	0.2442			
Stratified p-value	0.1367			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Hepatic Disorders (AESI)
Safety Population

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		1 (2.0%)	0	1 (1.0%)
Number of patients without events		49 (98.0%)	52 (100.0%)	101 (99.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.182 [0.127, 79.960]			
Stratified OR, 95% CI	3.968 [0.151, 104.18]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.118 [0.130, 74.777]			
Stratified RR, 95% CI	3.706 [0.161, 85.285]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.020 [-0.019, 0.059]			
Stratified ARR, 95% CI (CMH method)	0.022 [-0.019, 0.063]			
Test on Differences [c]				
Unstratified p-value	0.4902			
Stratified p-value	0.2636			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Hepatic Disorders (AESI)
Safety Population

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 57)	Total (N= 114)
Number of patients at risk		57 (100.0%)	57 (100.0%)	114 (100.0%)
Number of patients with events		1 (1.8%)	0	1 (0.9%)
Number of patients without events		56 (98.2%)	57 (100.0%)	113 (99.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.053 [0.122, 76.535]			
Stratified OR, 95% CI	3.000 [0.114, 79.135]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.000 [0.125, 72.129]			
Stratified RR, 95% CI	2.833 [0.124, 64.888]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.018 [-0.017, 0.052]			
Stratified ARR, 95% CI (CMH method)	0.017 [-0.017, 0.051]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3320			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Gender - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				1.0000
Female vs. Male		-	1.0000	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Hepatic Disorders (AESI)
Safety Population

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 48)	Total (N= 105)
Number of patients at risk		57 (100.0%)	48 (100.0%)	105 (100.0%)
Number of patients with events		1 (1.8%)	0	1 (1.0%)
Number of patients without events		56 (98.2%)	48 (100.0%)	104 (99.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.575 [0.103, 64.680]			
Stratified OR, 95% CI	2.122 [0.081, 55.860]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.534 [0.106, 60.820]			
Stratified RR, 95% CI	2.045 [0.089, 46.909]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.018 [-0.017, 0.052]			
Stratified ARR, 95% CI (CMH method)	0.015 [-0.017, 0.048]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4142			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Hepatic Disorders (AESI)
Safety Population

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		1 (2.0%)	0	1 (0.9%)
Number of patients without events		49 (98.0%)	61 (100.0%)	110 (99.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.727 [0.149, 93.512]			
Stratified OR, 95% CI	5.870 [0.221, 155.76]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.647 [0.152, 87.620]			
Stratified RR, 95% CI	5.308 [0.233, 121.11]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.020 [-0.019, 0.059]			
Stratified ARR, 95% CI (CMH method)	0.024 [-0.019, 0.067]			
Test on Differences [c]				
Unstratified p-value	0.4505			
Stratified p-value	0.1757			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Age - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				1.0000
>= 65 vs. < 65		-	0.9999	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Hepatic Disorders (AESI)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 62)	Total (N= 121)
Number of patients at risk		59 (100.0%)	62 (100.0%)	121 (100.0%)
Number of patients with events		2 (3.4%)	0	2 (1.7%)
Number of patients without events		57 (96.6%)	62 (100.0%)	119 (98.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.435 [0.255, 115.61]			
Stratified OR, 95% CI	6.111 [0.283, 132.00]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.250 [0.257, 107.12]			
Stratified RR, 95% CI	5.735 [0.285, 115.35]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.034 [-0.012, 0.080]			
Stratified ARR, 95% CI (CMH method)	0.036 [-0.012, 0.083]			
Test on Differences [c]				
Unstratified p-value	0.2357			
Stratified p-value	0.1264			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Hepatic Disorders (AESI)
Safety Population

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		48 (100.0%)	47 (100.0%)	95 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by CVD Risk Category - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	WARNING: Negative of Hessian not positive definite				-
Multiple CV risk factors vs. ASCVD and/or HeFH		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Hepatic Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 65)	Ezetimibe (N= 70)	Total (N= 135)
Number of patients at risk		65 (100.0%)	70 (100.0%)	135 (100.0%)
Number of patients with events		2 (3.1%)	0	2 (1.5%)
Number of patients without events		63 (96.9%)	70 (100.0%)	133 (98.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.551 [0.262, 117.83]			
Stratified OR, 95% CI	6.111 [0.283, 132.00]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.379 [0.263, 109.98]			
Stratified RR, 95% CI	5.735 [0.285, 115.35]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.031 [-0.011, 0.073]			
Stratified ARR, 95% CI (CMH method)	0.032 [-0.011, 0.074]			
Test on Differences [c]				
Unstratified p-value	0.2300			
Stratified p-value	0.1264			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Hepatic Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		42 (100.0%)	39 (100.0%)	81 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity I - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	WARNING: Negative of Hessian not positive definite				-
High Intensity Statin vs. Other		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Hepatic Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 32)	Ezetimibe (N= 38)	Total (N= 70)
Number of patients at risk		32 (100.0%)	38 (100.0%)	70 (100.0%)
Number of patients with events		2 (6.3%)	0	2 (2.9%)
Number of patients without events		30 (93.8%)	38 (100.0%)	68 (97.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.311 [0.292, 136.41]			
Stratified OR, 95% CI	6.935 [0.311, 154.85]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.909 [0.294, 118.78]			
Stratified RR, 95% CI	6.111 [0.313, 119.33]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.063 [-0.021, 0.146]			
Stratified ARR, 95% CI (CMH method)	0.064 [-0.021, 0.148]			
Test on Differences [c]				
Unstratified p-value	0.2054			
Stratified p-value	0.1110			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Hepatic Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		42 (100.0%)	39 (100.0%)	81 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Hepatic Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		33 (100.0%)	32 (100.0%)	65 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity II - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	WARNING: Negative of Hessian not positive definite				-
High Intensity Statin vs. Other Intensity Statin		-	1.0000	1.0000	
None vs. Other Intensity Statin		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Hepatic Disorders (AESI)
Safety Population

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 84)	Ezetimibe (N= 91)	Total (N= 175)
Number of patients at risk		84 (100.0%)	91 (100.0%)	175 (100.0%)
Number of patients with events		2 (2.4%)	0	2 (1.1%)
Number of patients without events		82 (97.6%)	91 (100.0%)	173 (98.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.545 [0.262, 117.20]			
Stratified OR, 95% CI	5.566 [0.255, 121.27]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.412 [0.264, 111.12]			
Stratified RR, 95% CI	5.172 [0.259, 103.18]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.024 [-0.009, 0.056]			
Stratified ARR, 95% CI (CMH method)	0.023 [-0.009, 0.056]			
Test on Differences [c]				
Unstratified p-value	0.2290			
Stratified p-value	0.1464			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Hepatic Disorders (AESI)
Safety Population

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		23 (100.0%)	18 (100.0%)	41 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Race - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	WARNING: Negative of Hessian not positive definite				-
non-White vs. White		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Hepatic Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 38)	Total (N= 76)
Number of patients at risk		38 (100.0%)	38 (100.0%)	76 (100.0%)
Number of patients with events		1 (2.6%)	0	1 (1.3%)
Number of patients without events		37 (97.4%)	38 (100.0%)	75 (98.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.080 [0.122, 78.021]			
Stratified OR, 95% CI	5.571 [0.208, 149.16]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.000 [0.126, 71.400]			
Stratified RR, 95% CI	5.000 [0.221, 113.18]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.026 [-0.025, 0.077]			
Stratified ARR, 95% CI (CMH method)	0.035 [-0.025, 0.095]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.1888			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Hepatic Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		31 (100.0%)	45 (100.0%)	76 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Hepatic Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		1 (2.6%)	0	1 (1.6%)
Number of patients without events		37 (97.4%)	26 (100.0%)	63 (98.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.120 [0.083, 54.079]			
Stratified OR, 95% CI	1.552 [0.056, 42.912]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.077 [0.088, 49.090]			
Stratified RR, 95% CI	1.500 [0.069, 32.835]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.026 [-0.025, 0.077]			
Stratified ARR, 95% CI (CMH method)	0.021 [-0.026, 0.068]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4945			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline LDL-C Category - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	WARNING: Negative of Hessian not positive definite				-
130 - < 160 vs. < 130		-	1.0000	1.0000	
>= 160 vs. < 130		-	0.9995	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Hepatic Disorders (AESI)
Safety Population

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 61)	Total (N= 109)
Number of patients at risk		48 (100.0%)	61 (100.0%)	109 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		48 (100.0%)	61 (100.0%)	109 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Hepatic Disorders (AESI)
Safety Population

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		2 (3.4%)	0	2 (1.9%)
Number of patients without events		57 (96.6%)	48 (100.0%)	105 (98.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.217 [0.198, 89.975]			
Stratified OR, 95% CI	5.000 [0.226, 110.40]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.083 [0.201, 83.074]			
Stratified RR, 95% CI	4.583 [0.233, 90.303]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.034 [-0.012, 0.080]			
Stratified ARR, 95% CI (CMH method)	0.036 [-0.012, 0.084]			
Test on Differences [c]				
Unstratified p-value	0.5006			
Stratified p-value	0.1715			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by History of Diabetes - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	WARNING: Negative of Hessian not positive definite				-
No vs. Yes		-	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Hepatic Disorders (AESI)
Safety Population

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		13 (100.0%)	13 (100.0%)	26 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Hepatic Disorders (AESI)
Safety Population

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		27 (100.0%)	37 (100.0%)	64 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Hepatic Disorders (AESI)
Safety Population

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 67)	Ezetimibe (N= 59)	Total (N= 126)
Number of patients at risk		67 (100.0%)	59 (100.0%)	126 (100.0%)
Number of patients with events		2 (3.0%)	0	2 (1.6%)
Number of patients without events		65 (97.0%)	59 (100.0%)	124 (98.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.542 [0.214, 96.539]			
Stratified OR, 95% CI	4.730 [0.212, 105.61]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.412 [0.216, 90.083]			
Stratified RR, 95% CI	4.286 [0.220, 83.569]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.030 [-0.011, 0.071]			
Stratified ARR, 95% CI (CMH method)	0.029 [-0.011, 0.070]			
Test on Differences [c]				
Unstratified p-value	0.4980			
Stratified p-value	0.1861			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by BMI - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	WARNING: Negative of Hessian not positive definite				-
25 - < 30 vs. < 25		-	1.0000	1.0000	
>= 30 vs. < 25		-	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE - Hepatic Disorders (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE - Hepatic Disorders (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE - Hepatic Disorders (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		2 (1.9%)	0	2 (0.9%)
Number of patients without events		105 (98.1%)	109 (100.0%)	214 (99.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.190 [0.246, 109.37]			
Stratified OR, 95% CI	5.794 [0.268, 125.25]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.093 [0.247, 104.85]			
Stratified RR, 95% CI	5.441 [0.271, 109.34]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.019 [-0.007, 0.044]			
Stratified ARR, 95% CI (CMH method)	0.019 [-0.007, 0.045]			
Test on Differences [c]				
Unstratified p-value	0.2442			
Stratified p-value	0.1367			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Gender - Hepatic Disorders (AESI)
Safety Population

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		1 (2.0%)	0	1 (1.0%)
Number of patients without events		49 (98.0%)	52 (100.0%)	101 (99.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.182 [0.127, 79.960]			
Stratified OR, 95% CI	3.968 [0.151, 104.18]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.118 [0.130, 74.777]			
Stratified RR, 95% CI	3.706 [0.161, 85.285]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.020 [-0.019, 0.059]			
Stratified ARR, 95% CI (CMH method)	0.022 [-0.019, 0.063]			
Test on Differences [c]				
Unstratified p-value	0.4902			
Stratified p-value	0.2636			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Gender - Hepatic Disorders (AESI)
Safety Population

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 57)	Total (N= 114)
Number of patients at risk		57 (100.0%)	57 (100.0%)	114 (100.0%)
Number of patients with events		1 (1.8%)	0	1 (0.9%)
Number of patients without events		56 (98.2%)	57 (100.0%)	113 (99.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.053 [0.122, 76.535]			
Stratified OR, 95% CI	3.000 [0.114, 79.135]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.000 [0.125, 72.129]			
Stratified RR, 95% CI	2.833 [0.124, 64.888]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.018 [-0.017, 0.052]			
Stratified ARR, 95% CI (CMH method)	0.017 [-0.017, 0.051]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3320			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Gender - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				1.0000
Female vs. Male		-	1.0000	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Age - Hepatic Disorders (AESI)
Safety Population

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 48)	Total (N= 105)
Number of patients at risk		57 (100.0%)	48 (100.0%)	105 (100.0%)
Number of patients with events		1 (1.8%)	0	1 (1.0%)
Number of patients without events		56 (98.2%)	48 (100.0%)	104 (99.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.575 [0.103, 64.680]			
Stratified OR, 95% CI	2.122 [0.081, 55.860]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.534 [0.106, 60.820]			
Stratified RR, 95% CI	2.045 [0.089, 46.909]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.018 [-0.017, 0.052]			
Stratified ARR, 95% CI (CMH method)	0.015 [-0.017, 0.048]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4142			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Age - Hepatic Disorders (AESI)
Safety Population

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		1 (2.0%)	0	1 (0.9%)
Number of patients without events		49 (98.0%)	61 (100.0%)	110 (99.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.727 [0.149, 93.512]			
Stratified OR, 95% CI	5.870 [0.221, 155.76]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.647 [0.152, 87.620]			
Stratified RR, 95% CI	5.308 [0.233, 121.11]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.020 [-0.019, 0.059]			
Stratified ARR, 95% CI (CMH method)	0.024 [-0.019, 0.067]			
Test on Differences [c]				
Unstratified p-value	0.4505			
Stratified p-value	0.1757			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Age - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				1.0000
>= 65 vs. < 65		-	0.9999	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by CVD Risk Category - Hepatic Disorders (AESI)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 62)	Total (N= 121)
Number of patients at risk		59 (100.0%)	62 (100.0%)	121 (100.0%)
Number of patients with events		2 (3.4%)	0	2 (1.7%)
Number of patients without events		57 (96.6%)	62 (100.0%)	119 (98.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.435 [0.255, 115.61]			
Stratified OR, 95% CI	6.111 [0.283, 132.00]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.250 [0.257, 107.12]			
Stratified RR, 95% CI	5.735 [0.285, 115.35]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.034 [-0.012, 0.080]			
Stratified ARR, 95% CI (CMH method)	0.036 [-0.012, 0.083]			
Test on Differences [c]				
Unstratified p-value	0.2357			
Stratified p-value	0.1264			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by CVD Risk Category - Hepatic Disorders (AESI)
Safety Population

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		48 (100.0%)	47 (100.0%)	95 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by CVD Risk Category - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	WARNING: Negative of Hessian not positive definite				-
Multiple CV risk factors vs. ASCVD and/or HeFH		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Hepatic Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 65)	Ezetimibe (N= 70)	Total (N= 135)
Number of patients at risk		65 (100.0%)	70 (100.0%)	135 (100.0%)
Number of patients with events		2 (3.1%)	0	2 (1.5%)
Number of patients without events		63 (96.9%)	70 (100.0%)	133 (98.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.551 [0.262, 117.83]			
Stratified OR, 95% CI	6.111 [0.283, 132.00]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.379 [0.263, 109.98]			
Stratified RR, 95% CI	5.735 [0.285, 115.35]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.031 [-0.011, 0.073]			
Stratified ARR, 95% CI (CMH method)	0.032 [-0.011, 0.074]			
Test on Differences [c]				
Unstratified p-value	0.2300			
Stratified p-value	0.1264			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Hepatic Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		42 (100.0%)	39 (100.0%)	81 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	WARNING: Negative of Hessian not positive definite				-
High Intensity Statin vs. Other		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Hepatic Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 32)	Ezetimibe (N= 38)	Total (N= 70)
Number of patients at risk		32 (100.0%)	38 (100.0%)	70 (100.0%)
Number of patients with events		2 (6.3%)	0	2 (2.9%)
Number of patients without events		30 (93.8%)	38 (100.0%)	68 (97.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.311 [0.292, 136.41]			
Stratified OR, 95% CI	6.935 [0.311, 154.85]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.909 [0.294, 118.78]			
Stratified RR, 95% CI	6.111 [0.313, 119.33]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.063 [-0.021, 0.146]			
Stratified ARR, 95% CI (CMH method)	0.064 [-0.021, 0.148]			
Test on Differences [c]				
Unstratified p-value	0.2054			
Stratified p-value	0.1110			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Hepatic Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		42 (100.0%)	39 (100.0%)	81 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Hepatic Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		33 (100.0%)	32 (100.0%)	65 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	WARNING: Negative of Hessian not positive definite				-
High Intensity Statin vs. Other Intensity Statin		-	1.0000	1.0000	
None vs. Other Intensity Statin		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Race - Hepatic Disorders (AESI)
Safety Population

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 84)	Ezetimibe (N= 91)	Total (N= 175)
Number of patients at risk		84 (100.0%)	91 (100.0%)	175 (100.0%)
Number of patients with events		2 (2.4%)	0	2 (1.1%)
Number of patients without events		82 (97.6%)	91 (100.0%)	173 (98.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.545 [0.262, 117.20]			
Stratified OR, 95% CI	5.566 [0.255, 121.27]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.412 [0.264, 111.12]			
Stratified RR, 95% CI	5.172 [0.259, 103.18]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.024 [-0.009, 0.056]			
Stratified ARR, 95% CI (CMH method)	0.023 [-0.009, 0.056]			
Test on Differences [c]				
Unstratified p-value	0.2290			
Stratified p-value	0.1464			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Race - Hepatic Disorders (AESI)
Safety Population

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		23 (100.0%)	18 (100.0%)	41 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Race - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	WARNING: Negative of Hessian not positive definite				-
non-White vs. White		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Hepatic Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 38)	Total (N= 76)
Number of patients at risk		38 (100.0%)	38 (100.0%)	76 (100.0%)
Number of patients with events		1 (2.6%)	0	1 (1.3%)
Number of patients without events		37 (97.4%)	38 (100.0%)	75 (98.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.080 [0.122, 78.021]			
Stratified OR, 95% CI	5.571 [0.208, 149.16]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.000 [0.126, 71.400]			
Stratified RR, 95% CI	5.000 [0.221, 113.18]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.026 [-0.025, 0.077]			
Stratified ARR, 95% CI (CMH method)	0.035 [-0.025, 0.095]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.1888			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Hepatic Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		31 (100.0%)	45 (100.0%)	76 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Hepatic Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		1 (2.6%)	0	1 (1.6%)
Number of patients without events		37 (97.4%)	26 (100.0%)	63 (98.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.120 [0.083, 54.079]			
Stratified OR, 95% CI	1.552 [0.056, 42.912]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.077 [0.088, 49.090]			
Stratified RR, 95% CI	1.500 [0.069, 32.835]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.026 [-0.025, 0.077]			
Stratified ARR, 95% CI (CMH method)	0.021 [-0.026, 0.068]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4945			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline LDL-C Category - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	WARNING: Negative of Hessian not positive definite				-
130 - < 160 vs. < 130		-	1.0000	1.0000	
>= 160 vs. < 130		-	0.9995	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by History of Diabetes - Hepatic Disorders (AESI)
Safety Population

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 61)	Total (N= 109)
Number of patients at risk		48 (100.0%)	61 (100.0%)	109 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		48 (100.0%)	61 (100.0%)	109 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by History of Diabetes - Hepatic Disorders (AESI)
Safety Population

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		2 (3.4%)	0	2 (1.9%)
Number of patients without events		57 (96.6%)	48 (100.0%)	105 (98.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.217 [0.198, 89.975]			
Stratified OR, 95% CI	5.000 [0.226, 110.40]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.083 [0.201, 83.074]			
Stratified RR, 95% CI	4.583 [0.233, 90.303]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.034 [-0.012, 0.080]			
Stratified ARR, 95% CI (CMH method)	0.036 [-0.012, 0.084]			
Test on Differences [c]				
Unstratified p-value	0.5006			
Stratified p-value	0.1715			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by History of Diabetes - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	WARNING: Negative of Hessian not positive definite				-
No vs. Yes		-	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Hepatic Disorders (AESI)
Safety Population

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		13 (100.0%)	13 (100.0%)	26 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Hepatic Disorders (AESI)
Safety Population

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		27 (100.0%)	37 (100.0%)	64 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Hepatic Disorders (AESI)
Safety Population

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 67)	Ezetimibe (N= 59)	Total (N= 126)
Number of patients at risk		67 (100.0%)	59 (100.0%)	126 (100.0%)
Number of patients with events		2 (3.0%)	0	2 (1.6%)
Number of patients without events		65 (97.0%)	59 (100.0%)	124 (98.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.542 [0.214, 96.539]			
Stratified OR, 95% CI	4.730 [0.212, 105.61]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.412 [0.216, 90.083]			
Stratified RR, 95% CI	4.286 [0.220, 83.569]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.030 [-0.011, 0.071]			
Stratified ARR, 95% CI (CMH method)	0.029 [-0.011, 0.070]			
Test on Differences [c]				
Unstratified p-value	0.4980			
Stratified p-value	0.1861			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by BMI - Hepatic Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	WARNING: Negative of Hessian not positive definite				-
25 - < 30 vs. < 25		-	1.0000	1.0000	
>= 30 vs. < 25		-	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Hypoglycemia (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		1 (0.9%)	0	1 (0.5%)
Number of patients without events		106 (99.1%)	109 (100.0%)	215 (99.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.085 [0.124, 76.562]			
Stratified OR, 95% CI	3.118 [0.121, 80.121]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.056 [0.126, 74.183]			
Stratified RR, 95% CI	3.000 [0.128, 70.418]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.009 [-0.009, 0.028]			
Stratified ARR, 95% CI (CMH method)	0.009 [-0.009, 0.027]			
Test on Differences [c]				
Unstratified p-value	0.4954			
Stratified p-value	0.3173			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE - Hypoglycemia (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE - Hypoglycemia (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE - Hypoglycemia (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		1 (0.9%)	0	1 (0.5%)
Number of patients without events		106 (99.1%)	109 (100.0%)	215 (99.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.085 [0.124, 76.562]			
Stratified OR, 95% CI	3.118 [0.121, 80.121]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.056 [0.126, 74.183]			
Stratified RR, 95% CI	3.000 [0.128, 70.418]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.009 [-0.009, 0.028]			
Stratified ARR, 95% CI (CMH method)	0.009 [-0.009, 0.027]			
Test on Differences [c]				
Unstratified p-value	0.4954			
Stratified p-value	0.3173			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Metabolic Acidosis (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE - Metabolic Acidosis (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE - Metabolic Acidosis (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE - Metabolic Acidosis (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Muscular Disorders (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		6 (5.6%)	7 (6.4%)	13 (6.0%)
Number of patients without events		101 (94.4%)	102 (93.6%)	203 (94.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.866 [0.281, 2.665]			
Stratified OR, 95% CI	0.869 [0.279, 2.711]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.873 [0.303, 2.513]			
Stratified RR, 95% CI	0.868 [0.307, 2.455]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.008 [-0.072, 0.055]			
Stratified ARR, 95% CI (CMH method)	-0.007 [-0.069, 0.056]			
Test on Differences [c]				
Unstratified p-value	0.8013			
Stratified p-value	0.8361			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Muscular Disorders (AESI)
Safety Population

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		3 (6.0%)	3 (5.8%)	6 (5.9%)
Number of patients without events		47 (94.0%)	49 (94.2%)	96 (94.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.043 [0.200, 5.426]			
Stratified OR, 95% CI	1.109 [0.235, 5.224]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.040 [0.220, 4.912]			
Stratified RR, 95% CI	1.100 [0.267, 4.533]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.002 [-0.089, 0.094]			
Stratified ARR, 95% CI (CMH method)	0.007 [-0.087, 0.101]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8777			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Muscular Disorders (AESI)
Safety Population

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 57)	Total (N= 114)
Number of patients at risk		57 (100.0%)	57 (100.0%)	114 (100.0%)
Number of patients with events		3 (5.3%)	4 (7.0%)	7 (6.1%)
Number of patients without events		54 (94.7%)	53 (93.0%)	107 (93.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.736 [0.157, 3.448]			
Stratified OR, 95% CI	0.782 [0.140, 4.368]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.750 [0.176, 3.201]			
Stratified RR, 95% CI	0.797 [0.164, 3.865]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.018 [-0.106, 0.071]			
Stratified ARR, 95% CI (CMH method)	-0.016 [-0.104, 0.073]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7258			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Gender - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.7628
Female vs. Male		0.9605	0.7911	0.7630	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Muscular Disorders (AESI)
Safety Population

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 48)	Total (N= 105)
Number of patients at risk		57 (100.0%)	48 (100.0%)	105 (100.0%)
Number of patients with events		4 (7.0%)	2 (4.2%)	6 (5.7%)
Number of patients without events		53 (93.0%)	46 (95.8%)	99 (94.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.736 [0.304, 9.917]			
Stratified OR, 95% CI	1.265 [0.183, 8.732]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.684 [0.322, 8.799]			
Stratified RR, 95% CI	1.202 [0.198, 7.283]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.029 [-0.059, 0.116]			
Stratified ARR, 95% CI (CMH method)	0.027 [-0.058, 0.112]			
Test on Differences [c]				
Unstratified p-value	0.6855			
Stratified p-value	0.5516			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Muscular Disorders (AESI)
Safety Population

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		2 (4.0%)	5 (8.2%)	7 (6.3%)
Number of patients without events		48 (96.0%)	56 (91.8%)	104 (93.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.467 [0.087, 2.515]			
Stratified OR, 95% CI	0.949 [0.152, 5.921]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.488 [0.099, 2.409]			
Stratified RR, 95% CI	0.980 [0.172, 5.573]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.042 [-0.130, 0.046]			
Stratified ARR, 95% CI (CMH method)	-0.028 [-0.113, 0.056]			
Test on Differences [c]				
Unstratified p-value	0.4548			
Stratified p-value	0.5317			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Age - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.2737
>= 65 vs. < 65		0.5366	0.4059	0.2908	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Muscular Disorders (AESI)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 62)	Total (N= 121)
Number of patients at risk		59 (100.0%)	62 (100.0%)	121 (100.0%)
Number of patients with events		4 (6.8%)	5 (8.1%)	9 (7.4%)
Number of patients without events		55 (93.2%)	57 (91.9%)	112 (92.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.829 [0.212, 3.250]			
Stratified OR, 95% CI	0.859 [0.218, 3.388]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.841 [0.237, 2.980]			
Stratified RR, 95% CI	0.858 [0.247, 2.975]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.013 [-0.106, 0.080]			
Stratified ARR, 95% CI (CMH method)	-0.008 [-0.100, 0.084]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8675			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Muscular Disorders (AESI)
Safety Population

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		2 (4.2%)	2 (4.3%)	4 (4.2%)
Number of patients without events		46 (95.8%)	45 (95.7%)	91 (95.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.978 [0.132, 7.247]			
Stratified OR, 95% CI	1.000 [0.132, 7.570]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.979 [0.144, 6.667]			
Stratified RR, 95% CI	1.000 [0.150, 6.671]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.001 [-0.082, 0.080]			
Stratified ARR, 95% CI (CMH method)	0.000 [-0.080, 0.080]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	1.0000			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by CVD Risk Category - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.8965
Multiple CV risk factors vs. ASCVD and/or HeFH		0.7881	0.4322	0.8965	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Muscular Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 65)	Ezetimibe (N= 70)	Total (N= 135)
Number of patients at risk		65 (100.0%)	70 (100.0%)	135 (100.0%)
Number of patients with events		5 (7.7%)	7 (10.0%)	12 (8.9%)
Number of patients without events		60 (92.3%)	63 (90.0%)	123 (91.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.750 [0.226, 2.492]			
Stratified OR, 95% CI	0.766 [0.228, 2.576]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.769 [0.257, 2.304]			
Stratified RR, 95% CI	0.783 [0.260, 2.355]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.023 [-0.119, 0.073]			
Stratified ARR, 95% CI (CMH method)	-0.021 [-0.117, 0.074]			
Test on Differences [c]				
Unstratified p-value	0.6378			
Stratified p-value	0.6645			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Muscular Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		1 (2.4%)	0	1 (1.2%)
Number of patients without events		41 (97.6%)	39 (100.0%)	80 (98.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.855 [0.113, 72.193]			
Stratified OR, 95% CI	2.882 [0.112, 74.209]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.791 [0.117, 66.540]			
Stratified RR, 95% CI	2.778 [0.119, 65.085]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.024 [-0.022, 0.070]			
Stratified ARR, 95% CI (CMH method)	0.024 [-0.022, 0.070]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3367			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity I - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.2191
High Intensity Statin vs. Other		0.6392	<.0001	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Muscular Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 32)	Ezetimibe (N= 38)	Total (N= 70)
Number of patients at risk		32 (100.0%)	38 (100.0%)	70 (100.0%)
Number of patients with events		3 (9.4%)	3 (7.9%)	6 (8.6%)
Number of patients without events		29 (90.6%)	35 (92.1%)	64 (91.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.207 [0.226, 6.439]			
Stratified OR, 95% CI	1.176 [0.225, 6.144]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.187 [0.257, 5.482]			
Stratified RR, 95% CI	1.126 [0.258, 4.918]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.015 [-0.118, 0.147]			
Stratified ARR, 95% CI (CMH method)	0.017 [-0.114, 0.148]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8001			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Muscular Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		1 (2.4%)	0	1 (1.2%)
Number of patients without events		41 (97.6%)	39 (100.0%)	80 (98.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.855 [0.113, 72.193]			
Stratified OR, 95% CI	2.882 [0.112, 74.209]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.791 [0.117, 66.540]			
Stratified RR, 95% CI	2.778 [0.119, 65.085]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.024 [-0.022, 0.070]			
Stratified ARR, 95% CI (CMH method)	0.024 [-0.022, 0.070]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3367			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Muscular Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		2 (6.1%)	4 (12.5%)	6 (9.2%)
Number of patients without events		31 (93.9%)	28 (87.5%)	59 (90.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.452 [0.077, 2.658]			
Stratified OR, 95% CI	0.451 [0.077, 2.654]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.485 [0.095, 2.465]			
Stratified RR, 95% CI	0.484 [0.095, 2.461]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.064 [-0.205, 0.076]			
Stratified ARR, 95% CI (CMH method)	-0.065 [-0.206, 0.076]			
Test on Differences [c]				
Unstratified p-value	0.4266			
Stratified p-value	0.3759			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity II - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.3415
High Intensity Statin vs. Other Intensity Statin		0.8257	<.0001	-	
None vs. Other Intensity Statin		0.8257	0.5262	0.4316	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Muscular Disorders (AESI)
Safety Population

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 84)	Ezetimibe (N= 91)	Total (N= 175)
Number of patients at risk		84 (100.0%)	91 (100.0%)	175 (100.0%)
Number of patients with events		3 (3.6%)	7 (7.7%)	10 (5.7%)
Number of patients without events		81 (96.4%)	84 (92.3%)	165 (94.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.444 [0.111, 1.778]			
Stratified OR, 95% CI	0.496 [0.114, 2.160]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.464 [0.124, 1.737]			
Stratified RR, 95% CI	0.520 [0.129, 2.096]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.041 [-0.109, 0.026]			
Stratified ARR, 95% CI (CMH method)	-0.042 [-0.110, 0.027]			
Test on Differences [c]				
Unstratified p-value	0.3334			
Stratified p-value	0.2336			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Muscular Disorders (AESI)
Safety Population

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		3 (13.0%)	0	3 (7.3%)
Number of patients without events		20 (87.0%)	18 (100.0%)	38 (92.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.317 [0.305, 130.63]			
Stratified OR, 95% CI	4.867 [0.455, 52.115]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.542 [0.304, 100.86]			
Stratified RR, 95% CI	3.655 [0.464, 28.805]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.130 [-0.007, 0.268]			
Stratified ARR, 95% CI (CMH method)	0.171 [0.006, 0.336]			
Test on Differences [c]				
Unstratified p-value	0.2427			
Stratified p-value	0.0622			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Race - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.0253
non-White vs. White		0.2545	<.0001	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Muscular Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 38)	Total (N= 76)
Number of patients at risk		38 (100.0%)	38 (100.0%)	76 (100.0%)
Number of patients with events		5 (13.2%)	3 (7.9%)	8 (10.5%)
Number of patients without events		33 (86.8%)	35 (92.1%)	68 (89.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.768 [0.391, 7.988]			
Stratified OR, 95% CI	2.123 [0.504, 8.947]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.667 [0.428, 6.486]			
Stratified RR, 95% CI	1.845 [0.564, 6.040]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.053 [-0.085, 0.190]			
Stratified ARR, 95% CI (CMH method)	0.090 [-0.044, 0.224]			
Test on Differences [c]				
Unstratified p-value	0.7110			
Stratified p-value	0.2061			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Muscular Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		0	2 (4.4%)	2 (2.6%)
Number of patients without events		31 (100.0%)	43 (95.6%)	74 (97.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.276 [0.013, 5.954]			
Stratified OR, 95% CI	0.400 [0.039, 4.148]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.287 [0.014, 5.790]			
Stratified RR, 95% CI	0.429 [0.048, 3.830]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.044 [-0.105, 0.016]			
Stratified ARR, 95% CI (CMH method)	-0.047 [-0.110, 0.015]			
Test on Differences [c]				
Unstratified p-value	0.5105			
Stratified p-value	0.2174			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Muscular Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		1 (2.6%)	2 (7.7%)	3 (4.7%)
Number of patients without events		37 (97.4%)	24 (92.3%)	61 (95.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.324 [0.028, 3.776]			
Stratified OR, 95% CI	0.401 [0.045, 3.595]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.342 [0.033, 3.580]			
Stratified RR, 95% CI	0.444 [0.060, 3.298]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.051 [-0.165, 0.064]			
Stratified ARR, 95% CI (CMH method)	-0.048 [-0.167, 0.070]			
Test on Differences [c]				
Unstratified p-value	0.5613			
Stratified p-value	0.3802			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline LDL-C Category - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.1753
130 - < 160 vs. < 130		0.4613	0.5166	0.9999	
>= 160 vs. < 130		0.4613	0.9764	0.2526	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Muscular Disorders (AESI)
Safety Population

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 61)	Total (N= 109)
Number of patients at risk		48 (100.0%)	61 (100.0%)	109 (100.0%)
Number of patients with events		4 (8.3%)	3 (4.9%)	7 (6.4%)
Number of patients without events		44 (91.7%)	58 (95.1%)	102 (93.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.758 [0.374, 8.259]			
Stratified OR, 95% CI	1.863 [0.388, 8.946]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.694 [0.398, 7.212]			
Stratified RR, 95% CI	1.724 [0.411, 7.230]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.034 [-0.061, 0.129]			
Stratified ARR, 95% CI (CMH method)	0.039 [-0.056, 0.135]			
Test on Differences [c]				
Unstratified p-value	0.6971			
Stratified p-value	0.4088			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Muscular Disorders (AESI)
Safety Population

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		2 (3.4%)	4 (8.3%)	6 (5.6%)
Number of patients without events		57 (96.6%)	44 (91.7%)	101 (94.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.386 [0.068, 2.204]			
Stratified OR, 95% CI	0.456 [0.088, 2.360]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.407 [0.078, 2.127]			
Stratified RR, 95% CI	0.500 [0.113, 2.206]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.049 [-0.140, 0.041]			
Stratified ARR, 95% CI (CMH method)	-0.045 [-0.135, 0.045]			
Test on Differences [c]				
Unstratified p-value	0.4048			
Stratified p-value	0.3124			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by History of Diabetes - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.1932
No vs. Yes		0.4755	0.4755	0.2034	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Muscular Disorders (AESI)
Safety Population

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		1 (7.7%)	1 (7.7%)	2 (7.7%)
Number of patients without events		12 (92.3%)	12 (92.3%)	24 (92.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.000 [0.056, 17.903]			
Stratified OR, 95% CI	1.667 [0.074, 37.728]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.000 [0.070, 14.340]			
Stratified RR, 95% CI	1.500 [0.127, 17.667]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.000 [-0.205, 0.205]			
Stratified ARR, 95% CI (CMH method)	0.036 [-0.189, 0.262]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7595			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Muscular Disorders (AESI)
Safety Population

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		1 (3.7%)	5 (13.5%)	6 (9.4%)
Number of patients without events		26 (96.3%)	32 (86.5%)	58 (90.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.246 [0.027, 2.241]			
Stratified OR, 95% CI	0.318 [0.046, 2.210]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.274 [0.034, 2.214]			
Stratified RR, 95% CI	0.381 [0.070, 2.069]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.098 [-0.229, 0.033]			
Stratified ARR, 95% CI (CMH method)	-0.095 [-0.220, 0.030]			
Test on Differences [c]				
Unstratified p-value	0.3877			
Stratified p-value	0.1826			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Muscular Disorders (AESI)
Safety Population

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 67)	Ezetimibe (N= 59)	Total (N= 126)
Number of patients at risk		67 (100.0%)	59 (100.0%)	126 (100.0%)
Number of patients with events		4 (6.0%)	1 (1.7%)	5 (4.0%)
Number of patients without events		63 (94.0%)	58 (98.3%)	121 (96.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.683 [0.400, 33.911]			
Stratified OR, 95% CI	2.410 [0.442, 13.129]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.522 [0.405, 30.641]			
Stratified RR, 95% CI	2.274 [0.459, 11.263]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.043 [-0.023, 0.108]			
Stratified ARR, 95% CI (CMH method)	0.045 [-0.020, 0.110]			
Test on Differences [c]				
Unstratified p-value	0.3701			
Stratified p-value	0.1966			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by BMI - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.1682
25 - < 30 vs. < 25		1.0000	0.5904	0.4535	
>= 30 vs. < 25		1.0000	0.2733	0.4720	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE - Muscular Disorders (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE - Muscular Disorders (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE - Muscular Disorders (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		6 (5.6%)	7 (6.4%)	13 (6.0%)
Number of patients without events		101 (94.4%)	102 (93.6%)	203 (94.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.866 [0.281, 2.665]			
Stratified OR, 95% CI	0.869 [0.279, 2.711]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.873 [0.303, 2.513]			
Stratified RR, 95% CI	0.868 [0.307, 2.455]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.008 [-0.072, 0.055]			
Stratified ARR, 95% CI (CMH method)	-0.007 [-0.069, 0.056]			
Test on Differences [c]				
Unstratified p-value	0.8013			
Stratified p-value	0.8361			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Gender - Muscular Disorders (AESI)
Safety Population

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		3 (6.0%)	3 (5.8%)	6 (5.9%)
Number of patients without events		47 (94.0%)	49 (94.2%)	96 (94.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.043 [0.200, 5.426]			
Stratified OR, 95% CI	1.109 [0.235, 5.224]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.040 [0.220, 4.912]			
Stratified RR, 95% CI	1.100 [0.267, 4.533]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.002 [-0.089, 0.094]			
Stratified ARR, 95% CI (CMH method)	0.007 [-0.087, 0.101]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8777			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Gender - Muscular Disorders (AESI)
Safety Population

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 57)	Total (N= 114)
Number of patients at risk		57 (100.0%)	57 (100.0%)	114 (100.0%)
Number of patients with events		3 (5.3%)	4 (7.0%)	7 (6.1%)
Number of patients without events		54 (94.7%)	53 (93.0%)	107 (93.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.736 [0.157, 3.448]			
Stratified OR, 95% CI	0.782 [0.140, 4.368]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.750 [0.176, 3.201]			
Stratified RR, 95% CI	0.797 [0.164, 3.865]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.018 [-0.106, 0.071]			
Stratified ARR, 95% CI (CMH method)	-0.016 [-0.104, 0.073]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7258			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Gender - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.7628
Female vs. Male		0.9605	0.7911	0.7630	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Age - Muscular Disorders (AESI)
Safety Population

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 48)	Total (N= 105)
Number of patients at risk		57 (100.0%)	48 (100.0%)	105 (100.0%)
Number of patients with events		4 (7.0%)	2 (4.2%)	6 (5.7%)
Number of patients without events		53 (93.0%)	46 (95.8%)	99 (94.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.736 [0.304, 9.917]			
Stratified OR, 95% CI	1.265 [0.183, 8.732]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.684 [0.322, 8.799]			
Stratified RR, 95% CI	1.202 [0.198, 7.283]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.029 [-0.059, 0.116]			
Stratified ARR, 95% CI (CMH method)	0.027 [-0.058, 0.112]			
Test on Differences [c]				
Unstratified p-value	0.6855			
Stratified p-value	0.5516			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Age - Muscular Disorders (AESI)
Safety Population

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		2 (4.0%)	5 (8.2%)	7 (6.3%)
Number of patients without events		48 (96.0%)	56 (91.8%)	104 (93.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.467 [0.087, 2.515]			
Stratified OR, 95% CI	0.949 [0.152, 5.921]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.488 [0.099, 2.409]			
Stratified RR, 95% CI	0.980 [0.172, 5.573]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.042 [-0.130, 0.046]			
Stratified ARR, 95% CI (CMH method)	-0.028 [-0.113, 0.056]			
Test on Differences [c]				
Unstratified p-value	0.4548			
Stratified p-value	0.5317			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Table 1002FDC.053b.204.20.2.1
Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Age - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.2737
>= 65 vs. < 65		0.5366	0.4059	0.2908	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by CVD Risk Category - Muscular Disorders (AESI)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 62)	Total (N= 121)
Number of patients at risk		59 (100.0%)	62 (100.0%)	121 (100.0%)
Number of patients with events		4 (6.8%)	5 (8.1%)	9 (7.4%)
Number of patients without events		55 (93.2%)	57 (91.9%)	112 (92.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.829 [0.212, 3.250]			
Stratified OR, 95% CI	0.859 [0.218, 3.388]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.841 [0.237, 2.980]			
Stratified RR, 95% CI	0.858 [0.247, 2.975]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.013 [-0.106, 0.080]			
Stratified ARR, 95% CI (CMH method)	-0.008 [-0.100, 0.084]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8675			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by CVD Risk Category - Muscular Disorders (AESI)
Safety Population

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		2 (4.2%)	2 (4.3%)	4 (4.2%)
Number of patients without events		46 (95.8%)	45 (95.7%)	91 (95.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.978 [0.132, 7.247]			
Stratified OR, 95% CI	1.000 [0.132, 7.570]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.979 [0.144, 6.667]			
Stratified RR, 95% CI	1.000 [0.150, 6.671]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.001 [-0.082, 0.080]			
Stratified ARR, 95% CI (CMH method)	0.000 [-0.080, 0.080]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	1.0000			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by CVD Risk Category - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.8965
Multiple CV risk factors vs. ASCVD and/or HeFH		0.7881	0.4322	0.8965	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Muscular Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 65)	Ezetimibe (N= 70)	Total (N= 135)
Number of patients at risk		65 (100.0%)	70 (100.0%)	135 (100.0%)
Number of patients with events		5 (7.7%)	7 (10.0%)	12 (8.9%)
Number of patients without events		60 (92.3%)	63 (90.0%)	123 (91.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.750 [0.226, 2.492]			
Stratified OR, 95% CI	0.766 [0.228, 2.576]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.769 [0.257, 2.304]			
Stratified RR, 95% CI	0.783 [0.260, 2.355]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.023 [-0.119, 0.073]			
Stratified ARR, 95% CI (CMH method)	-0.021 [-0.117, 0.074]			
Test on Differences [c]				
Unstratified p-value	0.6378			
Stratified p-value	0.6645			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Muscular Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		1 (2.4%)	0	1 (1.2%)
Number of patients without events		41 (97.6%)	39 (100.0%)	80 (98.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.855 [0.113, 72.193]			
Stratified OR, 95% CI	2.882 [0.112, 74.209]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.791 [0.117, 66.540]			
Stratified RR, 95% CI	2.778 [0.119, 65.085]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.024 [-0.022, 0.070]			
Stratified ARR, 95% CI (CMH method)	0.024 [-0.022, 0.070]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3367			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.2191
High Intensity Statin vs. Other		0.6392	<.0001	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Muscular Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 32)	Ezetimibe (N= 38)	Total (N= 70)
Number of patients at risk		32 (100.0%)	38 (100.0%)	70 (100.0%)
Number of patients with events		3 (9.4%)	3 (7.9%)	6 (8.6%)
Number of patients without events		29 (90.6%)	35 (92.1%)	64 (91.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.207 [0.226, 6.439]			
Stratified OR, 95% CI	1.176 [0.225, 6.144]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.187 [0.257, 5.482]			
Stratified RR, 95% CI	1.126 [0.258, 4.918]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.015 [-0.118, 0.147]			
Stratified ARR, 95% CI (CMH method)	0.017 [-0.114, 0.148]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8001			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Muscular Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		1 (2.4%)	0	1 (1.2%)
Number of patients without events		41 (97.6%)	39 (100.0%)	80 (98.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.855 [0.113, 72.193]			
Stratified OR, 95% CI	2.882 [0.112, 74.209]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.791 [0.117, 66.540]			
Stratified RR, 95% CI	2.778 [0.119, 65.085]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.024 [-0.022, 0.070]			
Stratified ARR, 95% CI (CMH method)	0.024 [-0.022, 0.070]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3367			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Muscular Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		2 (6.1%)	4 (12.5%)	6 (9.2%)
Number of patients without events		31 (93.9%)	28 (87.5%)	59 (90.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.452 [0.077, 2.658]			
Stratified OR, 95% CI	0.451 [0.077, 2.654]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.485 [0.095, 2.465]			
Stratified RR, 95% CI	0.484 [0.095, 2.461]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.064 [-0.205, 0.076]			
Stratified ARR, 95% CI (CMH method)	-0.065 [-0.206, 0.076]			
Test on Differences [c]				
Unstratified p-value	0.4266			
Stratified p-value	0.3759			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.3415
High Intensity Statin vs. Other Intensity Statin		0.8257	<.0001	-	
None vs. Other Intensity Statin		0.8257	0.5262	0.4316	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Race - Muscular Disorders (AESI)
Safety Population

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 84)	Ezetimibe (N= 91)	Total (N= 175)
Number of patients at risk		84 (100.0%)	91 (100.0%)	175 (100.0%)
Number of patients with events		3 (3.6%)	7 (7.7%)	10 (5.7%)
Number of patients without events		81 (96.4%)	84 (92.3%)	165 (94.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.444 [0.111, 1.778]			
Stratified OR, 95% CI	0.496 [0.114, 2.160]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.464 [0.124, 1.737]			
Stratified RR, 95% CI	0.520 [0.129, 2.096]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.041 [-0.109, 0.026]			
Stratified ARR, 95% CI (CMH method)	-0.042 [-0.110, 0.027]			
Test on Differences [c]				
Unstratified p-value	0.3334			
Stratified p-value	0.2336			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Race - Muscular Disorders (AESI)
Safety Population

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		3 (13.0%)	0	3 (7.3%)
Number of patients without events		20 (87.0%)	18 (100.0%)	38 (92.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.317 [0.305, 130.63]			
Stratified OR, 95% CI	4.867 [0.455, 52.115]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.542 [0.304, 100.86]			
Stratified RR, 95% CI	3.655 [0.464, 28.805]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.130 [-0.007, 0.268]			
Stratified ARR, 95% CI (CMH method)	0.171 [0.006, 0.336]			
Test on Differences [c]				
Unstratified p-value	0.2427			
Stratified p-value	0.0622			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Race - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.0253
non-White vs. White		0.2545	<.0001	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Muscular Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 38)	Total (N= 76)
Number of patients at risk		38 (100.0%)	38 (100.0%)	76 (100.0%)
Number of patients with events		5 (13.2%)	3 (7.9%)	8 (10.5%)
Number of patients without events		33 (86.8%)	35 (92.1%)	68 (89.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.768 [0.391, 7.988]			
Stratified OR, 95% CI	2.123 [0.504, 8.947]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.667 [0.428, 6.486]			
Stratified RR, 95% CI	1.845 [0.564, 6.040]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.053 [-0.085, 0.190]			
Stratified ARR, 95% CI (CMH method)	0.090 [-0.044, 0.224]			
Test on Differences [c]				
Unstratified p-value	0.7110			
Stratified p-value	0.2061			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Muscular Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		0	2 (4.4%)	2 (2.6%)
Number of patients without events		31 (100.0%)	43 (95.6%)	74 (97.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.276 [0.013, 5.954]			
Stratified OR, 95% CI	0.400 [0.039, 4.148]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.287 [0.014, 5.790]			
Stratified RR, 95% CI	0.429 [0.048, 3.830]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.044 [-0.105, 0.016]			
Stratified ARR, 95% CI (CMH method)	-0.047 [-0.110, 0.015]			
Test on Differences [c]				
Unstratified p-value	0.5105			
Stratified p-value	0.2174			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Muscular Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		1 (2.6%)	2 (7.7%)	3 (4.7%)
Number of patients without events		37 (97.4%)	24 (92.3%)	61 (95.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.324 [0.028, 3.776]			
Stratified OR, 95% CI	0.401 [0.045, 3.595]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.342 [0.033, 3.580]			
Stratified RR, 95% CI	0.444 [0.060, 3.298]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.051 [-0.165, 0.064]			
Stratified ARR, 95% CI (CMH method)	-0.048 [-0.167, 0.070]			
Test on Differences [c]				
Unstratified p-value	0.5613			
Stratified p-value	0.3802			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline LDL-C Category - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.1753
130 - < 160 vs. < 130		0.4613	0.5166	0.9999	
>= 160 vs. < 130		0.4613	0.9764	0.2526	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by History of Diabetes - Muscular Disorders (AESI)
Safety Population

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 61)	Total (N= 109)
Number of patients at risk		48 (100.0%)	61 (100.0%)	109 (100.0%)
Number of patients with events		4 (8.3%)	3 (4.9%)	7 (6.4%)
Number of patients without events		44 (91.7%)	58 (95.1%)	102 (93.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.758 [0.374, 8.259]			
Stratified OR, 95% CI	1.863 [0.388, 8.946]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.694 [0.398, 7.212]			
Stratified RR, 95% CI	1.724 [0.411, 7.230]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.034 [-0.061, 0.129]			
Stratified ARR, 95% CI (CMH method)	0.039 [-0.056, 0.135]			
Test on Differences [c]				
Unstratified p-value	0.6971			
Stratified p-value	0.4088			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by History of Diabetes - Muscular Disorders (AESI)
Safety Population

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		2 (3.4%)	4 (8.3%)	6 (5.6%)
Number of patients without events		57 (96.6%)	44 (91.7%)	101 (94.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.386 [0.068, 2.204]			
Stratified OR, 95% CI	0.456 [0.088, 2.360]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.407 [0.078, 2.127]			
Stratified RR, 95% CI	0.500 [0.113, 2.206]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.049 [-0.140, 0.041]			
Stratified ARR, 95% CI (CMH method)	-0.045 [-0.135, 0.045]			
Test on Differences [c]				
Unstratified p-value	0.4048			
Stratified p-value	0.3124			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by History of Diabetes - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				0.1932
No vs. Yes		0.4755	0.4755	0.2034	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Muscular Disorders (AESI)
Safety Population

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		1 (7.7%)	1 (7.7%)	2 (7.7%)
Number of patients without events		12 (92.3%)	12 (92.3%)	24 (92.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.000 [0.056, 17.903]			
Stratified OR, 95% CI	1.667 [0.074, 37.728]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.000 [0.070, 14.340]			
Stratified RR, 95% CI	1.500 [0.127, 17.667]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.000 [-0.205, 0.205]			
Stratified ARR, 95% CI (CMH method)	0.036 [-0.189, 0.262]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7595			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Muscular Disorders (AESI)
Safety Population

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		1 (3.7%)	5 (13.5%)	6 (9.4%)
Number of patients without events		26 (96.3%)	32 (86.5%)	58 (90.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.246 [0.027, 2.241]			
Stratified OR, 95% CI	0.318 [0.046, 2.210]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.274 [0.034, 2.214]			
Stratified RR, 95% CI	0.381 [0.070, 2.069]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.098 [-0.229, 0.033]			
Stratified ARR, 95% CI (CMH method)	-0.095 [-0.220, 0.030]			
Test on Differences [c]				
Unstratified p-value	0.3877			
Stratified p-value	0.1826			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Muscular Disorders (AESI)
Safety Population

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 67)	Ezetimibe (N= 59)	Total (N= 126)
Number of patients at risk		67 (100.0%)	59 (100.0%)	126 (100.0%)
Number of patients with events		4 (6.0%)	1 (1.7%)	5 (4.0%)
Number of patients without events		63 (94.0%)	58 (98.3%)	121 (96.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.683 [0.400, 33.911]			
Stratified OR, 95% CI	2.410 [0.442, 13.129]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.522 [0.405, 30.641]			
Stratified RR, 95% CI	2.274 [0.459, 11.263]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.043 [-0.023, 0.108]			
Stratified ARR, 95% CI (CMH method)	0.045 [-0.020, 0.110]			
Test on Differences [c]				
Unstratified p-value	0.3701			
Stratified p-value	0.1966			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by BMI - Muscular Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	Algorithm converged				0.1682
25 - < 30 vs. < 25		1.0000	0.5904	0.4535	
>= 30 vs. < 25		1.0000	0.2733	0.4720	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Neurocognitive Disorders (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE - Neurocognitive Disorders (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE - Neurocognitive Disorders (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE - Neurocognitive Disorders (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		4 (3.7%)	2 (1.8%)	6 (2.8%)
Number of patients without events		103 (96.3%)	107 (98.2%)	210 (97.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.078 [0.372, 11.589]			
Stratified OR, 95% CI	1.811 [0.353, 9.279]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.037 [0.381, 10.891]			
Stratified RR, 95% CI	1.774 [0.370, 8.508]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.019 [-0.025, 0.063]			
Stratified ARR, 95% CI (CMH method)	0.019 [-0.025, 0.062]			
Test on Differences [c]				
Unstratified p-value	0.4433			
Stratified p-value	0.3983			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		2 (4.0%)	0	2 (2.0%)
Number of patients without events		48 (96.0%)	52 (100.0%)	100 (98.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.412 [0.253, 115.59]			
Stratified OR, 95% CI	6.724 [0.299, 150.99]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.196 [0.256, 105.62]			
Stratified RR, 95% CI	5.882 [0.303, 114.28]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.040 [-0.014, 0.094]			
Stratified ARR, 95% CI (CMH method)	0.043 [-0.014, 0.100]			
Test on Differences [c]				
Unstratified p-value	0.2378			
Stratified p-value	0.1178			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 57)	Total (N= 114)
Number of patients at risk		57 (100.0%)	57 (100.0%)	114 (100.0%)
Number of patients with events		2 (3.5%)	2 (3.5%)	4 (3.5%)
Number of patients without events		55 (96.5%)	55 (96.5%)	110 (96.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.000 [0.136, 7.354]			
Stratified OR, 95% CI	0.883 [0.143, 5.452]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.000 [0.146, 6.857]			
Stratified RR, 95% CI	0.881 [0.163, 4.759]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.000 [-0.068, 0.068]			
Stratified ARR, 95% CI (CMH method)	-0.005 [-0.074, 0.063]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8753			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Gender - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.1397
Female vs. Male		<.0001	<.0001	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 48)	Total (N= 105)
Number of patients at risk		57 (100.0%)	48 (100.0%)	105 (100.0%)
Number of patients with events		3 (5.3%)	1 (2.1%)	4 (3.8%)
Number of patients without events		54 (94.7%)	47 (97.9%)	101 (96.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.611 [0.263, 25.958]			
Stratified OR, 95% CI	2.393 [0.314, 18.249]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.526 [0.272, 23.503]			
Stratified RR, 95% CI	2.136 [0.348, 13.108]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.032 [-0.039, 0.102]			
Stratified ARR, 95% CI (CMH method)	0.036 [-0.033, 0.105]			
Test on Differences [c]				
Unstratified p-value	0.6234			
Stratified p-value	0.3356			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		1 (2.0%)	1 (1.6%)	2 (1.8%)
Number of patients without events		49 (98.0%)	60 (98.4%)	109 (98.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.224 [0.075, 20.084]			
Stratified OR, 95% CI	1.395 [0.138, 14.124]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.220 [0.078, 19.017]			
Stratified RR, 95% CI	1.367 [0.150, 12.499]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.004 [-0.047, 0.054]			
Stratified ARR, 95% CI (CMH method)	0.006 [-0.042, 0.054]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8145			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Age - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.6849
>= 65 vs. < 65		0.4154	0.8642	0.6868	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 62)	Total (N= 121)
Number of patients at risk		59 (100.0%)	62 (100.0%)	121 (100.0%)
Number of patients with events		3 (5.1%)	2 (3.2%)	5 (4.1%)
Number of patients without events		56 (94.9%)	60 (96.8%)	116 (95.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.607 [0.259, 9.978]			
Stratified OR, 95% CI	1.468 [0.221, 9.755]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.576 [0.273, 9.101]			
Stratified RR, 95% CI	1.457 [0.240, 8.848]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.019 [-0.053, 0.090]			
Stratified ARR, 95% CI (CMH method)	0.015 [-0.055, 0.085]			
Test on Differences [c]				
Unstratified p-value	0.6745			
Stratified p-value	0.6760			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		1 (2.1%)	0	1 (1.1%)
Number of patients without events		47 (97.9%)	47 (100.0%)	94 (98.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.000 [0.119, 75.519]			
Stratified OR, 95% CI	3.095 [0.121, 78.868]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.939 [0.123, 70.369]			
Stratified RR, 95% CI	3.000 [0.127, 70.997]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.021 [-0.020, 0.061]			
Stratified ARR, 95% CI (CMH method)	0.021 [-0.020, 0.062]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3173			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by CVD Risk Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.3510
Multiple CV risk factors vs. ASCVD and/or HeFH		0.6110	<.0001	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 65)	Ezetimibe (N= 70)	Total (N= 135)
Number of patients at risk		65 (100.0%)	70 (100.0%)	135 (100.0%)
Number of patients with events		1 (1.5%)	1 (1.4%)	2 (1.5%)
Number of patients without events		64 (98.5%)	69 (98.6%)	133 (98.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.078 [0.066, 17.599]			
Stratified OR, 95% CI	1.073 [0.109, 10.582]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.077 [0.069, 16.866]			
Stratified RR, 95% CI	1.072 [0.114, 10.056]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.001 [-0.040, 0.042]			
Stratified ARR, 95% CI (CMH method)	0.001 [-0.039, 0.042]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9602			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		3 (7.1%)	1 (2.6%)	4 (4.9%)
Number of patients without events		39 (92.9%)	38 (97.4%)	77 (95.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.923 [0.291, 29.356]			
Stratified OR, 95% CI	3.000 [0.290, 31.013]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.786 [0.302, 25.670]			
Stratified RR, 95% CI	2.769 [0.309, 24.846]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.046 [-0.047, 0.138]			
Stratified ARR, 95% CI (CMH method)	0.045 [-0.046, 0.137]			
Test on Differences [c]				
Unstratified p-value	0.6165			
Stratified p-value	0.3420			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity I - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.5958
High Intensity Statin vs. Other		0.9579	0.6761	0.5983	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 32)	Ezetimibe (N= 38)	Total (N= 70)
Number of patients at risk		32 (100.0%)	38 (100.0%)	70 (100.0%)
Number of patients with events		1 (3.1%)	1 (2.6%)	2 (2.9%)
Number of patients without events		31 (96.9%)	37 (97.4%)	68 (97.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.194 [0.072, 19.876]			
Stratified OR, 95% CI	1.184 [0.117, 11.953]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.188 [0.077, 18.237]			
Stratified RR, 95% CI	1.177 [0.128, 10.793]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.005 [-0.074, 0.084]			
Stratified ARR, 95% CI (CMH method)	0.005 [-0.074, 0.084]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9052			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		3 (7.1%)	1 (2.6%)	4 (4.9%)
Number of patients without events		39 (92.9%)	38 (97.4%)	77 (95.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.923 [0.291, 29.356]			
Stratified OR, 95% CI	3.000 [0.290, 31.013]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.786 [0.302, 25.670]			
Stratified RR, 95% CI	2.769 [0.309, 24.846]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.046 [-0.047, 0.138]			
Stratified ARR, 95% CI (CMH method)	0.045 [-0.046, 0.137]			
Test on Differences [c]				
Unstratified p-value	0.6165			
Stratified p-value	0.3420			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		33 (100.0%)	32 (100.0%)	65 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity II - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.8921
High Intensity Statin vs. Other Intensity Statin		0.9019	0.9852	0.6350	
None vs. Other Intensity Statin		0.9019	0.9999	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 84)	Ezetimibe (N= 91)	Total (N= 175)
Number of patients at risk		84 (100.0%)	91 (100.0%)	175 (100.0%)
Number of patients with events		2 (2.4%)	1 (1.1%)	3 (1.7%)
Number of patients without events		82 (97.6%)	90 (98.9%)	172 (98.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.195 [0.195, 24.662]			
Stratified OR, 95% CI	2.875 [0.240, 34.462]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.167 [0.200, 23.459]			
Stratified RR, 95% CI	2.667 [0.262, 27.172]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.013 [-0.026, 0.052]			
Stratified ARR, 95% CI (CMH method)	0.016 [-0.022, 0.055]			
Test on Differences [c]				
Unstratified p-value	0.6082			
Stratified p-value	0.3929			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		2 (8.7%)	1 (5.6%)	3 (7.3%)
Number of patients without events		21 (91.3%)	17 (94.4%)	38 (92.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.619 [0.135, 19.414]			
Stratified OR, 95% CI	0.931 [0.128, 6.779]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.565 [0.154, 15.925]			
Stratified RR, 95% CI	0.945 [0.169, 5.281]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.031 [-0.125, 0.188]			
Stratified ARR, 95% CI (CMH method)	0.016 [-0.136, 0.169]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8536			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Race - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.8481
non-White vs. White		0.5247	0.2439	0.8480	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 38)	Total (N= 76)
Number of patients at risk		38 (100.0%)	38 (100.0%)	76 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		38 (100.0%)	38 (100.0%)	76 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		1 (3.2%)	1 (2.2%)	2 (2.6%)
Number of patients without events		30 (96.8%)	44 (97.8%)	74 (97.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.467 [0.088, 24.371]			
Stratified OR, 95% CI	1.581 [0.144, 17.389]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.452 [0.094, 22.342]			
Stratified RR, 95% CI	1.523 [0.178, 13.010]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.010 [-0.066, 0.086]			
Stratified ARR, 95% CI (CMH method)	0.012 [-0.067, 0.091]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7442			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		3 (7.9%)	1 (3.8%)	4 (6.3%)
Number of patients without events		35 (92.1%)	25 (96.2%)	60 (93.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.143 [0.210, 21.819]			
Stratified OR, 95% CI	2.802 [0.326, 24.091]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.053 [0.226, 18.665]			
Stratified RR, 95% CI	2.205 [0.398, 12.218]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.040 [-0.073, 0.154]			
Stratified ARR, 95% CI (CMH method)	0.065 [-0.042, 0.171]			
Test on Differences [c]				
Unstratified p-value	0.6404			
Stratified p-value	0.2847			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline LDL-C Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.9814
130 - < 160 vs. < 130		0.9999	<.0001	0.8354	
>= 160 vs. < 130		0.9999	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 61)	Total (N= 109)
Number of patients at risk		48 (100.0%)	61 (100.0%)	109 (100.0%)
Number of patients with events		4 (8.3%)	0	4 (3.7%)
Number of patients without events		44 (91.7%)	61 (100.0%)	105 (96.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	12.438 [0.653, 236.95]			
Stratified OR, 95% CI	7.939 [0.842, 74.890]			
Relative Risk [a]				
Unstratified RR, 95% CI	11.388 [0.628, 206.47]			
Stratified RR, 95% CI	6.498 [0.784, 53.843]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.083 [0.005, 0.162]			
Stratified ARR, 95% CI (CMH method)	0.090 [0.009, 0.171]			
Test on Differences [c]				
Unstratified p-value	0.0350			
Stratified p-value	0.0119			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		0	2 (4.2%)	2 (1.9%)
Number of patients without events		59 (100.0%)	46 (95.8%)	105 (98.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.156 [0.007, 3.335]			
Stratified OR, 95% CI	0.237 [0.023, 2.403]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.163 [0.008, 3.323]			
Stratified RR, 95% CI	0.256 [0.028, 2.340]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.042 [-0.098, 0.015]			
Stratified ARR, 95% CI (CMH method)	-0.043 [-0.101, 0.014]			
Test on Differences [c]				
Unstratified p-value	0.1989			
Stratified p-value	0.1026			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by History of Diabetes - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	WARNING: Negative of Hessian not positive definite				-
No vs. Yes		<.0001	-	0.9999	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		13 (100.0%)	13 (100.0%)	26 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		27 (100.0%)	37 (100.0%)	64 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 67)	Ezetimibe (N= 59)	Total (N= 126)
Number of patients at risk		67 (100.0%)	59 (100.0%)	126 (100.0%)
Number of patients with events		4 (6.0%)	2 (3.4%)	6 (4.8%)
Number of patients without events		63 (94.0%)	57 (96.6%)	120 (95.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.810 [0.319, 10.256]			
Stratified OR, 95% CI	1.587 [0.304, 8.299]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.761 [0.335, 9.271]			
Stratified RR, 95% CI	1.549 [0.329, 7.290]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.026 [-0.047, 0.099]			
Stratified ARR, 95% CI (CMH method)	0.025 [-0.048, 0.098]			
Test on Differences [c]				
Unstratified p-value	0.6838			
Stratified p-value	0.5059			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by BMI - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	WARNING: Negative of Hessian not positive definite				-
25 - < 30 vs. < 25		1.0000	1.0000	1.0000	
>= 30 vs. < 25		1.0000	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		4 (3.7%)	2 (1.8%)	6 (2.8%)
Number of patients without events		103 (96.3%)	107 (98.2%)	210 (97.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.078 [0.372, 11.589]			
Stratified OR, 95% CI	1.811 [0.353, 9.279]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.037 [0.381, 10.891]			
Stratified RR, 95% CI	1.774 [0.370, 8.508]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.019 [-0.025, 0.063]			
Stratified ARR, 95% CI (CMH method)	0.019 [-0.025, 0.062]			
Test on Differences [c]				
Unstratified p-value	0.4433			
Stratified p-value	0.3983			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Gender - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		2 (4.0%)	0	2 (2.0%)
Number of patients without events		48 (96.0%)	52 (100.0%)	100 (98.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.412 [0.253, 115.59]			
Stratified OR, 95% CI	6.724 [0.299, 150.99]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.196 [0.256, 105.62]			
Stratified RR, 95% CI	5.882 [0.303, 114.28]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.040 [-0.014, 0.094]			
Stratified ARR, 95% CI (CMH method)	0.043 [-0.014, 0.100]			
Test on Differences [c]				
Unstratified p-value	0.2378			
Stratified p-value	0.1178			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Gender - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 57)	Total (N= 114)
Number of patients at risk		57 (100.0%)	57 (100.0%)	114 (100.0%)
Number of patients with events		2 (3.5%)	2 (3.5%)	4 (3.5%)
Number of patients without events		55 (96.5%)	55 (96.5%)	110 (96.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.000 [0.136, 7.354]			
Stratified OR, 95% CI	0.883 [0.143, 5.452]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.000 [0.146, 6.857]			
Stratified RR, 95% CI	0.881 [0.163, 4.759]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.000 [-0.068, 0.068]			
Stratified ARR, 95% CI (CMH method)	-0.005 [-0.074, 0.063]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8753			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Gender - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	Algorithm converged				0.1397
Female vs. Male		<.0001	<.0001	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Age - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 48)	Total (N= 105)
Number of patients at risk		57 (100.0%)	48 (100.0%)	105 (100.0%)
Number of patients with events		3 (5.3%)	1 (2.1%)	4 (3.8%)
Number of patients without events		54 (94.7%)	47 (97.9%)	101 (96.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.611 [0.263, 25.958]			
Stratified OR, 95% CI	2.393 [0.314, 18.249]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.526 [0.272, 23.503]			
Stratified RR, 95% CI	2.136 [0.348, 13.108]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.032 [-0.039, 0.102]			
Stratified ARR, 95% CI (CMH method)	0.036 [-0.033, 0.105]			
Test on Differences [c]				
Unstratified p-value	0.6234			
Stratified p-value	0.3356			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Age - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		1 (2.0%)	1 (1.6%)	2 (1.8%)
Number of patients without events		49 (98.0%)	60 (98.4%)	109 (98.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.224 [0.075, 20.084]			
Stratified OR, 95% CI	1.395 [0.138, 14.124]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.220 [0.078, 19.017]			
Stratified RR, 95% CI	1.367 [0.150, 12.499]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.004 [-0.047, 0.054]			
Stratified ARR, 95% CI (CMH method)	0.006 [-0.042, 0.054]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8145			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Age - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				0.6849
>= 65 vs. < 65		0.4154	0.8642	0.6868	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by CVD Risk Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 62)	Total (N= 121)
Number of patients at risk		59 (100.0%)	62 (100.0%)	121 (100.0%)
Number of patients with events		3 (5.1%)	2 (3.2%)	5 (4.1%)
Number of patients without events		56 (94.9%)	60 (96.8%)	116 (95.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.607 [0.259, 9.978]			
Stratified OR, 95% CI	1.468 [0.221, 9.755]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.576 [0.273, 9.101]			
Stratified RR, 95% CI	1.457 [0.240, 8.848]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.019 [-0.053, 0.090]			
Stratified ARR, 95% CI (CMH method)	0.015 [-0.055, 0.085]			
Test on Differences [c]				
Unstratified p-value	0.6745			
Stratified p-value	0.6760			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by CVD Risk Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		1 (2.1%)	0	1 (1.1%)
Number of patients without events		47 (97.9%)	47 (100.0%)	94 (98.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.000 [0.119, 75.519]			
Stratified OR, 95% CI	3.095 [0.121, 78.868]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.939 [0.123, 70.369]			
Stratified RR, 95% CI	3.000 [0.127, 70.997]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.021 [-0.020, 0.061]			
Stratified ARR, 95% CI (CMH method)	0.021 [-0.020, 0.062]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3173			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by CVD Risk Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	Algorithm converged				0.3510
Multiple CV risk factors vs. ASCVD and/or HeFH		0.6110	<.0001	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity I - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 65)	Ezetimibe (N= 70)	Total (N= 135)
Number of patients at risk		65 (100.0%)	70 (100.0%)	135 (100.0%)
Number of patients with events		1 (1.5%)	1 (1.4%)	2 (1.5%)
Number of patients without events		64 (98.5%)	69 (98.6%)	133 (98.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.078 [0.066, 17.599]			
Stratified OR, 95% CI	1.073 [0.109, 10.582]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.077 [0.069, 16.866]			
Stratified RR, 95% CI	1.072 [0.114, 10.056]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.001 [-0.040, 0.042]			
Stratified ARR, 95% CI (CMH method)	0.001 [-0.039, 0.042]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9602			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity I - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		3 (7.1%)	1 (2.6%)	4 (4.9%)
Number of patients without events		39 (92.9%)	38 (97.4%)	77 (95.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.923 [0.291, 29.356]			
Stratified OR, 95% CI	3.000 [0.290, 31.013]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.786 [0.302, 25.670]			
Stratified RR, 95% CI	2.769 [0.309, 24.846]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.046 [-0.047, 0.138]			
Stratified ARR, 95% CI (CMH method)	0.045 [-0.046, 0.137]			
Test on Differences [c]				
Unstratified p-value	0.6165			
Stratified p-value	0.3420			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline Statin Intensity I - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				0.5958
High Intensity Statin vs. Other		0.9579	0.6761	0.5983	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 32)	Ezetimibe (N= 38)	Total (N= 70)
Number of patients at risk		32 (100.0%)	38 (100.0%)	70 (100.0%)
Number of patients with events		1 (3.1%)	1 (2.6%)	2 (2.9%)
Number of patients without events		31 (96.9%)	37 (97.4%)	68 (97.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.194 [0.072, 19.876]			
Stratified OR, 95% CI	1.184 [0.117, 11.953]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.188 [0.077, 18.237]			
Stratified RR, 95% CI	1.177 [0.128, 10.793]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.005 [-0.074, 0.084]			
Stratified ARR, 95% CI (CMH method)	0.005 [-0.074, 0.084]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.9052			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		3 (7.1%)	1 (2.6%)	4 (4.9%)
Number of patients without events		39 (92.9%)	38 (97.4%)	77 (95.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.923 [0.291, 29.356]			
Stratified OR, 95% CI	3.000 [0.290, 31.013]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.786 [0.302, 25.670]			
Stratified RR, 95% CI	2.769 [0.309, 24.846]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.046 [-0.047, 0.138]			
Stratified ARR, 95% CI (CMH method)	0.045 [-0.046, 0.137]			
Test on Differences [c]				
Unstratified p-value	0.6165			
Stratified p-value	0.3420			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		33 (100.0%)	32 (100.0%)	65 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline Statin Intensity II - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	Algorithm converged				0.8921
High Intensity Statin vs. Other Intensity Statin		0.9019	0.9852	0.6350	
None vs. Other Intensity Statin		0.9019	0.9999	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Race - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 84)	Ezetimibe (N= 91)	Total (N= 175)
Number of patients at risk		84 (100.0%)	91 (100.0%)	175 (100.0%)
Number of patients with events		2 (2.4%)	1 (1.1%)	3 (1.7%)
Number of patients without events		82 (97.6%)	90 (98.9%)	172 (98.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.195 [0.195, 24.662]			
Stratified OR, 95% CI	2.875 [0.240, 34.462]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.167 [0.200, 23.459]			
Stratified RR, 95% CI	2.667 [0.262, 27.172]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.013 [-0.026, 0.052]			
Stratified ARR, 95% CI (CMH method)	0.016 [-0.022, 0.055]			
Test on Differences [c]				
Unstratified p-value	0.6082			
Stratified p-value	0.3929			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Race - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		2 (8.7%)	1 (5.6%)	3 (7.3%)
Number of patients without events		21 (91.3%)	17 (94.4%)	38 (92.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.619 [0.135, 19.414]			
Stratified OR, 95% CI	0.931 [0.128, 6.779]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.565 [0.154, 15.925]			
Stratified RR, 95% CI	0.945 [0.169, 5.281]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.031 [-0.125, 0.188]			
Stratified ARR, 95% CI (CMH method)	0.016 [-0.136, 0.169]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.8536			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Race - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	Algorithm converged				0.8481
non-White vs. White		0.5247	0.2439	0.8480	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 38)	Total (N= 76)
Number of patients at risk		38 (100.0%)	38 (100.0%)	76 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		38 (100.0%)	38 (100.0%)	76 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		1 (3.2%)	1 (2.2%)	2 (2.6%)
Number of patients without events		30 (96.8%)	44 (97.8%)	74 (97.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.467 [0.088, 24.371]			
Stratified OR, 95% CI	1.581 [0.144, 17.389]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.452 [0.094, 22.342]			
Stratified RR, 95% CI	1.523 [0.178, 13.010]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.010 [-0.066, 0.086]			
Stratified ARR, 95% CI (CMH method)	0.012 [-0.067, 0.091]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.7442			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		3 (7.9%)	1 (3.8%)	4 (6.3%)
Number of patients without events		35 (92.1%)	25 (96.2%)	60 (93.8%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.143 [0.210, 21.819]			
Stratified OR, 95% CI	2.802 [0.326, 24.091]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.053 [0.226, 18.665]			
Stratified RR, 95% CI	2.205 [0.398, 12.218]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.040 [-0.073, 0.154]			
Stratified ARR, 95% CI (CMH method)	0.065 [-0.042, 0.171]			
Test on Differences [c]				
Unstratified p-value	0.6404			
Stratified p-value	0.2847			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline LDL-C Category - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	Algorithm converged				0.9814
130 - < 160 vs. < 130		0.9999	<.0001	0.8354	
>= 160 vs. < 130		0.9999	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by History of Diabetes - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 61)	Total (N= 109)
Number of patients at risk		48 (100.0%)	61 (100.0%)	109 (100.0%)
Number of patients with events		4 (8.3%)	0	4 (3.7%)
Number of patients without events		44 (91.7%)	61 (100.0%)	105 (96.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	12.438 [0.653, 236.95]			
Stratified OR, 95% CI	7.939 [0.842, 74.890]			
Relative Risk [a]				
Unstratified RR, 95% CI	11.388 [0.628, 206.47]			
Stratified RR, 95% CI	6.498 [0.784, 53.843]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.083 [0.005, 0.162]			
Stratified ARR, 95% CI (CMH method)	0.090 [0.009, 0.171]			
Test on Differences [c]				
Unstratified p-value	0.0350			
Stratified p-value	0.0119			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by History of Diabetes - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		0	2 (4.2%)	2 (1.9%)
Number of patients without events		59 (100.0%)	46 (95.8%)	105 (98.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	0.156 [0.007, 3.335]			
Stratified OR, 95% CI	0.237 [0.023, 2.403]			
Relative Risk [a]				
Unstratified RR, 95% CI	0.163 [0.008, 3.323]			
Stratified RR, 95% CI	0.256 [0.028, 2.340]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	-0.042 [-0.098, 0.015]			
Stratified ARR, 95% CI (CMH method)	-0.043 [-0.101, 0.014]			
Test on Differences [c]				
Unstratified p-value	0.1989			
Stratified p-value	0.1026			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by History of Diabetes - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	WARNING: Negative of Hessian not positive definite				-
No vs. Yes		<.0001	-	0.9999	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		13 (100.0%)	13 (100.0%)	26 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		27 (100.0%)	37 (100.0%)	64 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 67)	Ezetimibe (N= 59)	Total (N= 126)
Number of patients at risk		67 (100.0%)	59 (100.0%)	126 (100.0%)
Number of patients with events		4 (6.0%)	2 (3.4%)	6 (4.8%)
Number of patients without events		63 (94.0%)	57 (96.6%)	120 (95.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	1.810 [0.319, 10.256]			
Stratified OR, 95% CI	1.587 [0.304, 8.299]			
Relative Risk [a]				
Unstratified RR, 95% CI	1.761 [0.335, 9.271]			
Stratified RR, 95% CI	1.549 [0.329, 7.290]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.026 [-0.047, 0.099]			
Stratified ARR, 95% CI (CMH method)	0.025 [-0.048, 0.098]			
Test on Differences [c]				
Unstratified p-value	0.6838			
Stratified p-value	0.5059			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by BMI - New Onset or Worsening Diabetes Mellitus (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	WARNING: Negative of Hessian not positive definite				-
25 - < 30 vs. < 25		1.0000	1.0000	1.0000	
>= 30 vs. < 25		1.0000	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Renal Disorders (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		4 (3.7%)	0	4 (1.9%)
Number of patients without events		103 (96.3%)	109 (100.0%)	212 (98.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	9.522 [0.506, 179.05]			
Stratified OR, 95% CI	5.598 [0.634, 49.406]			
Relative Risk [a]				
Unstratified RR, 95% CI	9.167 [0.500, 168.21]			
Stratified RR, 95% CI	5.215 [0.627, 43.345]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.037 [0.001, 0.073]			
Stratified ARR, 95% CI (CMH method)	0.038 [0.002, 0.074]			
Test on Differences [c]				
Unstratified p-value	0.0585			
Stratified p-value	0.0392			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Renal Disorders (AESI)
Safety Population

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		4 (8.0%)	0	4 (3.9%)
Number of patients without events		46 (92.0%)	52 (100.0%)	98 (96.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	10.161 [0.533, 193.81]			
Stratified OR, 95% CI	6.894 [0.764, 62.199]			
Relative Risk [a]				
Unstratified RR, 95% CI	9.353 [0.517, 169.36]			
Stratified RR, 95% CI	6.028 [0.739, 49.140]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.080 [0.005, 0.155]			
Stratified ARR, 95% CI (CMH method)	0.087 [0.009, 0.166]			
Test on Differences [c]				
Unstratified p-value	0.0542			
Stratified p-value	0.0251			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Gender - Renal Disorders (AESI)
Safety Population

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 57)	Total (N= 114)
Number of patients at risk		57 (100.0%)	57 (100.0%)	114 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		57 (100.0%)	57 (100.0%)	114 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Gender - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	WARNING: Negative of Hessian not positive definite				-
Female vs. Male		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Renal Disorders (AESI)
Safety Population

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 48)	Total (N= 105)
Number of patients at risk		57 (100.0%)	48 (100.0%)	105 (100.0%)
Number of patients with events		1 (1.8%)	0	1 (1.0%)
Number of patients without events		56 (98.2%)	48 (100.0%)	104 (99.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.575 [0.103, 64.680]			
Stratified OR, 95% CI	2.122 [0.081, 55.860]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.534 [0.106, 60.820]			
Stratified RR, 95% CI	2.045 [0.089, 46.909]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.018 [-0.017, 0.052]			
Stratified ARR, 95% CI (CMH method)	0.015 [-0.017, 0.048]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4142			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Age - Renal Disorders (AESI)
Safety Population

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		3 (6.0%)	0	3 (2.7%)
Number of patients without events		47 (94.0%)	61 (100.0%)	108 (97.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	9.063 [0.457, 179.74]			
Stratified OR, 95% CI	5.956 [0.623, 56.975]			
Relative Risk [a]				
Unstratified RR, 95% CI	8.510 [0.450, 160.96]			
Stratified RR, 95% CI	5.301 [0.617, 45.551]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.060 [-0.006, 0.126]			
Stratified ARR, 95% CI (CMH method)	0.062 [-0.005, 0.129]			
Test on Differences [c]				
Unstratified p-value	0.0884			
Stratified p-value	0.0469			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Age - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				1.0000
>= 65 vs. < 65		-	0.9986	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Renal Disorders (AESI)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 62)	Total (N= 121)
Number of patients at risk		59 (100.0%)	62 (100.0%)	121 (100.0%)
Number of patients with events		4 (6.8%)	0	4 (3.3%)
Number of patients without events		55 (93.2%)	62 (100.0%)	117 (96.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	10.135 [0.534, 192.49]			
Stratified OR, 95% CI	5.222 [0.575, 47.416]			
Relative Risk [a]				
Unstratified RR, 95% CI	9.450 [0.520, 171.79]			
Stratified RR, 95% CI	4.849 [0.568, 41.383]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.068 [0.004, 0.132]			
Stratified ARR, 95% CI (CMH method)	0.066 [0.002, 0.129]			
Test on Differences [c]				
Unstratified p-value	0.0536			
Stratified p-value	0.0446			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by CVD Risk Category - Renal Disorders (AESI)
Safety Population

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		48 (100.0%)	47 (100.0%)	95 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by CVD Risk Category - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	WARNING: Negative of Hessian not positive definite				-
Multiple CV risk factors vs. ASCVD and/or HeFH		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Renal Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 65)	Ezetimibe (N= 70)	Total (N= 135)
Number of patients at risk		65 (100.0%)	70 (100.0%)	135 (100.0%)
Number of patients with events		1 (1.5%)	0	1 (0.7%)
Number of patients without events		64 (98.5%)	70 (100.0%)	134 (99.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.279 [0.131, 81.936]			
Stratified OR, 95% CI	3.554 [0.140, 90.243]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.227 [0.134, 77.840]			
Stratified RR, 95% CI	3.441 [0.145, 81.713]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.015 [-0.015, 0.045]			
Stratified ARR, 95% CI (CMH method)	0.016 [-0.015, 0.046]			
Test on Differences [c]				
Unstratified p-value	0.4815			
Stratified p-value	0.2832			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity I - Renal Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		3 (7.1%)	0	3 (3.7%)
Number of patients without events		39 (92.9%)	39 (100.0%)	78 (96.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	7.000 [0.350, 140.01]			
Stratified OR, 95% CI	7.298 [0.357, 149.06]			
Relative Risk [a]				
Unstratified RR, 95% CI	6.512 [0.347, 122.16]			
Stratified RR, 95% CI	6.481 [0.352, 119.32]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.071 [-0.006, 0.149]			
Stratified ARR, 95% CI (CMH method)	0.071 [-0.007, 0.149]			
Test on Differences [c]				
Unstratified p-value	0.2417			
Stratified p-value	0.0893			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity I - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				1.0000
High Intensity Statin vs. Other		-	0.9991	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Renal Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 32)	Ezetimibe (N= 38)	Total (N= 70)
Number of patients at risk		32 (100.0%)	38 (100.0%)	70 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		32 (100.0%)	38 (100.0%)	70 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Renal Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		3 (7.1%)	0	3 (3.7%)
Number of patients without events		39 (92.9%)	39 (100.0%)	78 (96.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	7.000 [0.350, 140.01]			
Stratified OR, 95% CI	7.298 [0.357, 149.06]			
Relative Risk [a]				
Unstratified RR, 95% CI	6.512 [0.347, 122.16]			
Stratified RR, 95% CI	6.481 [0.352, 119.32]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.071 [-0.006, 0.149]			
Stratified ARR, 95% CI (CMH method)	0.071 [-0.007, 0.149]			
Test on Differences [c]				
Unstratified p-value	0.2417			
Stratified p-value	0.0893			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline Statin Intensity II - Renal Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		1 (3.0%)	0	1 (1.5%)
Number of patients without events		32 (97.0%)	32 (100.0%)	64 (98.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.000 [0.118, 76.397]			
Stratified OR, 95% CI	3.387 [0.128, 89.369]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.912 [0.123, 68.946]			
Stratified RR, 95% CI	3.176 [0.139, 72.747]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.030 [-0.028, 0.089]			
Stratified ARR, 95% CI (CMH method)	0.032 [-0.028, 0.092]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3026			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline Statin Intensity II - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	WARNING: Negative of Hessian not positive definite				-
High Intensity Statin vs. Other Intensity Statin		-	0.9985	-	
None vs. Other Intensity Statin		-	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Renal Disorders (AESI)
Safety Population

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 84)	Ezetimibe (N= 91)	Total (N= 175)
Number of patients at risk		84 (100.0%)	91 (100.0%)	175 (100.0%)
Number of patients with events		2 (2.4%)	0	2 (1.1%)
Number of patients without events		82 (97.6%)	91 (100.0%)	173 (98.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.545 [0.262, 117.20]			
Stratified OR, 95% CI	5.566 [0.255, 121.27]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.412 [0.264, 111.12]			
Stratified RR, 95% CI	5.172 [0.259, 103.18]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.024 [-0.009, 0.056]			
Stratified ARR, 95% CI (CMH method)	0.023 [-0.009, 0.056]			
Test on Differences [c]				
Unstratified p-value	0.2290			
Stratified p-value	0.1464			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Race - Renal Disorders (AESI)
Safety Population

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		2 (8.7%)	0	2 (4.9%)
Number of patients without events		21 (91.3%)	18 (100.0%)	39 (95.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.302 [0.194, 95.438]			
Stratified OR, 95% CI	1.923 [0.066, 55.839]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.958 [0.202, 77.629]			
Stratified RR, 95% CI	1.667 [0.108, 25.833]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.087 [-0.028, 0.202]			
Stratified ARR, 95% CI (CMH method)	0.045 [-0.048, 0.138]			
Test on Differences [c]				
Unstratified p-value	0.4951			
Stratified p-value	0.4533			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Race - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	WARNING: Negative of Hessian not positive definite				-
non-White vs. White		-	0.9991	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Renal Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 38)	Total (N= 76)
Number of patients at risk		38 (100.0%)	38 (100.0%)	76 (100.0%)
Number of patients with events		1 (2.6%)	0	1 (1.3%)
Number of patients without events		37 (97.4%)	38 (100.0%)	75 (98.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.080 [0.122, 78.021]			
Stratified OR, 95% CI	2.636 [0.099, 69.884]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.000 [0.126, 71.400]			
Stratified RR, 95% CI	2.500 [0.110, 56.979]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.026 [-0.025, 0.077]			
Stratified ARR, 95% CI (CMH method)	0.025 [-0.026, 0.077]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3642			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Renal Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		1 (3.2%)	0	1 (1.3%)
Number of patients without events		30 (96.8%)	45 (100.0%)	75 (98.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.475 [0.176, 113.51]			
Stratified OR, 95% CI	4.846 [0.171, 137.68]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.312 [0.181, 102.53]			
Stratified RR, 95% CI	4.125 [0.192, 88.710]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.032 [-0.030, 0.094]			
Stratified ARR, 95% CI (CMH method)	0.032 [-0.030, 0.095]			
Test on Differences [c]				
Unstratified p-value	0.4079			
Stratified p-value	0.2320			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by Baseline LDL-C Category - Renal Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		2 (5.3%)	0	2 (3.1%)
Number of patients without events		36 (94.7%)	26 (100.0%)	62 (96.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.630 [0.167, 78.772]			
Stratified OR, 95% CI	2.351 [0.216, 25.577]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.462 [0.173, 69.281]			
Stratified RR, 95% CI	2.144 [0.250, 18.382]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.053 [-0.018, 0.124]			
Stratified ARR, 95% CI (CMH method)	0.054 [-0.019, 0.128]			
Test on Differences [c]				
Unstratified p-value	0.5099			
Stratified p-value	0.2312			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by Baseline LDL-C Category - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	WARNING: Negative of Hessian not positive definite				-
130 - < 160 vs. < 130		-	0.9991	-	
>= 160 vs. < 130		-	0.9987	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Renal Disorders (AESI)
Safety Population

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 61)	Total (N= 109)
Number of patients at risk		48 (100.0%)	61 (100.0%)	109 (100.0%)
Number of patients with events		1 (2.1%)	0	1 (0.9%)
Number of patients without events		47 (97.9%)	61 (100.0%)	108 (99.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.884 [0.155, 97.499]			
Stratified OR, 95% CI	4.895 [0.180, 132.83]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.796 [0.158, 91.152]			
Stratified RR, 95% CI	4.364 [0.195, 97.562]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.021 [-0.020, 0.061]			
Stratified ARR, 95% CI (CMH method)	0.023 [-0.020, 0.065]			
Test on Differences [c]				
Unstratified p-value	0.4404			
Stratified p-value	0.2207			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by History of Diabetes - Renal Disorders (AESI)
Safety Population

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		3 (5.1%)	0	3 (2.8%)
Number of patients without events		56 (94.9%)	48 (100.0%)	104 (97.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.009 [0.303, 119.24]			
Stratified OR, 95% CI	3.235 [0.338, 30.981]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.717 [0.303, 108.03]			
Stratified RR, 95% CI	2.999 [0.350, 25.715]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.051 [-0.005, 0.107]			
Stratified ARR, 95% CI (CMH method)	0.048 [-0.007, 0.102]			
Test on Differences [c]				
Unstratified p-value	0.2509			
Stratified p-value	0.1374			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by History of Diabetes - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				1.0000
No vs. Yes		-	0.9989	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Renal Disorders (AESI)
Safety Population

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		13 (100.0%)	13 (100.0%)	26 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Renal Disorders (AESI)
Safety Population

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		1 (3.7%)	0	1 (1.6%)
Number of patients without events		26 (96.3%)	37 (100.0%)	63 (98.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.245 [0.166, 108.29]			
Stratified OR, 95% CI	4.765 [0.173, 130.96]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.071 [0.172, 96.270]			
Stratified RR, 95% CI	4.200 [0.190, 92.861]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.037 [-0.034, 0.108]			
Stratified ARR, 95% CI (CMH method)	0.038 [-0.034, 0.110]			
Test on Differences [c]				
Unstratified p-value	0.4219			
Stratified p-value	0.2294			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE by BMI - Renal Disorders (AESI)
Safety Population

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 67)	Ezetimibe (N= 59)	Total (N= 126)
Number of patients at risk		67 (100.0%)	59 (100.0%)	126 (100.0%)
Number of patients with events		3 (4.5%)	0	3 (2.4%)
Number of patients without events		64 (95.5%)	59 (100.0%)	123 (97.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.457 [0.327, 127.65]			
Stratified OR, 95% CI	3.611 [0.380, 34.330]			
Relative Risk [a]				
Unstratified RR, 95% CI	6.176 [0.326, 117.16]			
Stratified RR, 95% CI	3.353 [0.388, 28.951]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.045 [-0.005, 0.094]			
Stratified ARR, 95% CI (CMH method)	0.044 [-0.005, 0.093]			
Test on Differences [c]				
Unstratified p-value	0.2470			
Stratified p-value	0.1079			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with TEAE by BMI - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	WARNING: Negative of Hessian not positive definite				-
25 - < 30 vs. < 25		-	0.9990	-	
>= 30 vs. < 25		-	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE - Renal Disorders (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE - Renal Disorders (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE - Renal Disorders (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		4 (3.7%)	0	4 (1.9%)
Number of patients without events		103 (96.3%)	109 (100.0%)	212 (98.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	9.522 [0.506, 179.05]			
Stratified OR, 95% CI	5.598 [0.634, 49.406]			
Relative Risk [a]				
Unstratified RR, 95% CI	9.167 [0.500, 168.21]			
Stratified RR, 95% CI	5.215 [0.627, 43.345]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.037 [0.001, 0.073]			
Stratified ARR, 95% CI (CMH method)	0.038 [0.002, 0.074]			
Test on Differences [c]				
Unstratified p-value	0.0585			
Stratified p-value	0.0392			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Gender - Renal Disorders (AESI)
Safety Population

Gender: Male

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 52)	Total (N= 102)
Number of patients at risk		50 (100.0%)	52 (100.0%)	102 (100.0%)
Number of patients with events		4 (8.0%)	0	4 (3.9%)
Number of patients without events		46 (92.0%)	52 (100.0%)	98 (96.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	10.161 [0.533, 193.81]			
Stratified OR, 95% CI	6.894 [0.764, 62.199]			
Relative Risk [a]				
Unstratified RR, 95% CI	9.353 [0.517, 169.36]			
Stratified RR, 95% CI	6.028 [0.739, 49.140]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.080 [0.005, 0.155]			
Stratified ARR, 95% CI (CMH method)	0.087 [0.009, 0.166]			
Test on Differences [c]				
Unstratified p-value	0.0542			
Stratified p-value	0.0251			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Gender - Renal Disorders (AESI)
Safety Population

Gender: Female

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 57)	Total (N= 114)
Number of patients at risk		57 (100.0%)	57 (100.0%)	114 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		57 (100.0%)	57 (100.0%)	114 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Gender - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Gender	WARNING: Negative of Hessian not positive definite				-
Female vs. Male		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Age - Renal Disorders (AESI)
Safety Population

Age (years): < 65

Statistic	FDC vs. Ezetimibe	FDC (N= 57)	Ezetimibe (N= 48)	Total (N= 105)
Number of patients at risk		57 (100.0%)	48 (100.0%)	105 (100.0%)
Number of patients with events		1 (1.8%)	0	1 (1.0%)
Number of patients without events		56 (98.2%)	48 (100.0%)	104 (99.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	2.575 [0.103, 64.680]			
Stratified OR, 95% CI	2.122 [0.081, 55.860]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.534 [0.106, 60.820]			
Stratified RR, 95% CI	2.045 [0.089, 46.909]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.018 [-0.017, 0.052]			
Stratified ARR, 95% CI (CMH method)	0.015 [-0.017, 0.048]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.4142			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Age - Renal Disorders (AESI)
Safety Population

Age (years): >= 65

Statistic	FDC vs. Ezetimibe	FDC (N= 50)	Ezetimibe (N= 61)	Total (N= 111)
Number of patients at risk		50 (100.0%)	61 (100.0%)	111 (100.0%)
Number of patients with events		3 (6.0%)	0	3 (2.7%)
Number of patients without events		47 (94.0%)	61 (100.0%)	108 (97.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	9.063 [0.457, 179.74]			
Stratified OR, 95% CI	5.956 [0.623, 56.975]			
Relative Risk [a]				
Unstratified RR, 95% CI	8.510 [0.450, 160.96]			
Stratified RR, 95% CI	5.301 [0.617, 45.551]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.060 [-0.006, 0.126]			
Stratified ARR, 95% CI (CMH method)	0.062 [-0.005, 0.129]			
Test on Differences [c]				
Unstratified p-value	0.0884			
Stratified p-value	0.0469			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Age - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Age (years)	Algorithm converged				1.0000
>= 65 vs. < 65		-	0.9986	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by CVD Risk Category - Renal Disorders (AESI)
Safety Population

CVD Risk Category: ASCVD and/or HeFH

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 62)	Total (N= 121)
Number of patients at risk		59 (100.0%)	62 (100.0%)	121 (100.0%)
Number of patients with events		4 (6.8%)	0	4 (3.3%)
Number of patients without events		55 (93.2%)	62 (100.0%)	117 (96.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	10.135 [0.534, 192.49]			
Stratified OR, 95% CI	5.222 [0.575, 47.416]			
Relative Risk [a]				
Unstratified RR, 95% CI	9.450 [0.520, 171.79]			
Stratified RR, 95% CI	4.849 [0.568, 41.383]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.068 [0.004, 0.132]			
Stratified ARR, 95% CI (CMH method)	0.066 [0.002, 0.129]			
Test on Differences [c]				
Unstratified p-value	0.0536			
Stratified p-value	0.0446			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by CVD Risk Category - Renal Disorders (AESI)
Safety Population

CVD Risk Category: Multiple CV risk factors

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 47)	Total (N= 95)
Number of patients at risk		48 (100.0%)	47 (100.0%)	95 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		48 (100.0%)	47 (100.0%)	95 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline statin dose intensity (high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by CVD Risk Category - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
CVD Risk Category	WARNING: Negative of Hessian not positive definite				-
Multiple CV risk factors vs. ASCVD and/or HeFH		-	1.0000	1.0000	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Renal Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: Other

Statistic	FDC vs. Ezetimibe	FDC (N= 65)	Ezetimibe (N= 70)	Total (N= 135)
Number of patients at risk		65 (100.0%)	70 (100.0%)	135 (100.0%)
Number of patients with events		1 (1.5%)	0	1 (0.7%)
Number of patients without events		64 (98.5%)	70 (100.0%)	134 (99.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.279 [0.131, 81.936]			
Stratified OR, 95% CI	3.554 [0.140, 90.243]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.227 [0.134, 77.840]			
Stratified RR, 95% CI	3.441 [0.145, 81.713]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.015 [-0.015, 0.045]			
Stratified ARR, 95% CI (CMH method)	0.016 [-0.015, 0.046]			
Test on Differences [c]				
Unstratified p-value	0.4815			
Stratified p-value	0.2832			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Renal Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity I: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		3 (7.1%)	0	3 (3.7%)
Number of patients without events		39 (92.9%)	39 (100.0%)	78 (96.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	7.000 [0.350, 140.01]			
Stratified OR, 95% CI	7.298 [0.357, 149.06]			
Relative Risk [a]				
Unstratified RR, 95% CI	6.512 [0.347, 122.16]			
Stratified RR, 95% CI	6.481 [0.352, 119.32]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.071 [-0.006, 0.149]			
Stratified ARR, 95% CI (CMH method)	0.071 [-0.007, 0.149]			
Test on Differences [c]				
Unstratified p-value	0.2417			
Stratified p-value	0.0893			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline Statin Intensity I - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity I	Algorithm converged				1.0000
High Intensity Statin vs. Other		-	0.9991	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Renal Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: Other Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 32)	Ezetimibe (N= 38)	Total (N= 70)
Number of patients at risk		32 (100.0%)	38 (100.0%)	70 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		32 (100.0%)	38 (100.0%)	70 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Renal Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: High Intensity Statin

Statistic	FDC vs. Ezetimibe	FDC (N= 42)	Ezetimibe (N= 39)	Total (N= 81)
Number of patients at risk		42 (100.0%)	39 (100.0%)	81 (100.0%)
Number of patients with events		3 (7.1%)	0	3 (3.7%)
Number of patients without events		39 (92.9%)	39 (100.0%)	78 (96.3%)
Odds Ratio [a]				
Unstratified OR, 95% CI	7.000 [0.350, 140.01]			
Stratified OR, 95% CI	7.298 [0.357, 149.06]			
Relative Risk [a]				
Unstratified RR, 95% CI	6.512 [0.347, 122.16]			
Stratified RR, 95% CI	6.481 [0.352, 119.32]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.071 [-0.006, 0.149]			
Stratified ARR, 95% CI (CMH method)	0.071 [-0.007, 0.149]			
Test on Differences [c]				
Unstratified p-value	0.2417			
Stratified p-value	0.0893			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Renal Disorders (AESI)
Safety Population

Baseline Statin Dose Intensity II: None

Statistic	FDC vs. Ezetimibe	FDC (N= 33)	Ezetimibe (N= 32)	Total (N= 65)
Number of patients at risk		33 (100.0%)	32 (100.0%)	65 (100.0%)
Number of patients with events		1 (3.0%)	0	1 (1.5%)
Number of patients without events		32 (97.0%)	32 (100.0%)	64 (98.5%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.000 [0.118, 76.397]			
Stratified OR, 95% CI	3.387 [0.128, 89.369]			
Relative Risk [a]				
Unstratified RR, 95% CI	2.912 [0.123, 68.946]			
Stratified RR, 95% CI	3.176 [0.139, 72.747]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.030 [-0.028, 0.089]			
Stratified ARR, 95% CI (CMH method)	0.032 [-0.028, 0.092]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3026			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: Stratification factor is the baseline CVD risk category (ASCVD and/or HeFH vs multiple cardiovascular risk factors).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline Statin Intensity II - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline Statin Dose Intensity II	WARNING: Negative of Hessian not positive definite				-
High Intensity Statin vs. Other Intensity Statin		-	0.9985	-	
None vs. Other Intensity Statin		-	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Race - Renal Disorders (AESI)
Safety Population

Race: White

Statistic	FDC vs. Ezetimibe	FDC (N= 84)	Ezetimibe (N= 91)	Total (N= 175)
Number of patients at risk		84 (100.0%)	91 (100.0%)	175 (100.0%)
Number of patients with events		2 (2.4%)	0	2 (1.1%)
Number of patients without events		82 (97.6%)	91 (100.0%)	173 (98.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	5.545 [0.262, 117.20]			
Stratified OR, 95% CI	5.566 [0.255, 121.27]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.412 [0.264, 111.12]			
Stratified RR, 95% CI	5.172 [0.259, 103.18]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.024 [-0.009, 0.056]			
Stratified ARR, 95% CI (CMH method)	0.023 [-0.009, 0.056]			
Test on Differences [c]				
Unstratified p-value	0.2290			
Stratified p-value	0.1464			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Race - Renal Disorders (AESI)
Safety Population

Race: non-White

Statistic	FDC vs. Ezetimibe	FDC (N= 23)	Ezetimibe (N= 18)	Total (N= 41)
Number of patients at risk		23 (100.0%)	18 (100.0%)	41 (100.0%)
Number of patients with events		2 (8.7%)	0	2 (4.9%)
Number of patients without events		21 (91.3%)	18 (100.0%)	39 (95.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.302 [0.194, 95.438]			
Stratified OR, 95% CI	1.923 [0.066, 55.839]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.958 [0.202, 77.629]			
Stratified RR, 95% CI	1.667 [0.108, 25.833]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.087 [-0.028, 0.202]			
Stratified ARR, 95% CI (CMH method)	0.045 [-0.048, 0.138]			
Test on Differences [c]				
Unstratified p-value	0.4951			
Stratified p-value	0.4533			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Race - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Race	WARNING: Negative of Hessian not positive definite				-
non-White vs. White		-	0.9991	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Renal Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): < 130

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 38)	Total (N= 76)
Number of patients at risk		38 (100.0%)	38 (100.0%)	76 (100.0%)
Number of patients with events		1 (2.6%)	0	1 (1.3%)
Number of patients without events		37 (97.4%)	38 (100.0%)	75 (98.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.080 [0.122, 78.021]			
Stratified OR, 95% CI	2.636 [0.099, 69.884]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.000 [0.126, 71.400]			
Stratified RR, 95% CI	2.500 [0.110, 56.979]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.026 [-0.025, 0.077]			
Stratified ARR, 95% CI (CMH method)	0.025 [-0.026, 0.077]			
Test on Differences [c]				
Unstratified p-value	1.0000			
Stratified p-value	0.3642			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Renal Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): 130 - < 160

Statistic	FDC vs. Ezetimibe	FDC (N= 31)	Ezetimibe (N= 45)	Total (N= 76)
Number of patients at risk		31 (100.0%)	45 (100.0%)	76 (100.0%)
Number of patients with events		1 (3.2%)	0	1 (1.3%)
Number of patients without events		30 (96.8%)	45 (100.0%)	75 (98.7%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.475 [0.176, 113.51]			
Stratified OR, 95% CI	4.846 [0.171, 137.68]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.312 [0.181, 102.53]			
Stratified RR, 95% CI	4.125 [0.192, 88.710]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.032 [-0.030, 0.094]			
Stratified ARR, 95% CI (CMH method)	0.032 [-0.030, 0.095]			
Test on Differences [c]				
Unstratified p-value	0.4079			
Stratified p-value	0.2320			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by Baseline LDL-C Category - Renal Disorders (AESI)
Safety Population

Baseline LDL-C (mg/dL): >= 160

Statistic	FDC vs. Ezetimibe	FDC (N= 38)	Ezetimibe (N= 26)	Total (N= 64)
Number of patients at risk		38 (100.0%)	26 (100.0%)	64 (100.0%)
Number of patients with events		2 (5.3%)	0	2 (3.1%)
Number of patients without events		36 (94.7%)	26 (100.0%)	62 (96.9%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.630 [0.167, 78.772]			
Stratified OR, 95% CI	2.351 [0.216, 25.577]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.462 [0.173, 69.281]			
Stratified RR, 95% CI	2.144 [0.250, 18.382]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.053 [-0.018, 0.124]			
Stratified ARR, 95% CI (CMH method)	0.054 [-0.019, 0.128]			
Test on Differences [c]				
Unstratified p-value	0.5099			
Stratified p-value	0.2312			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by Baseline LDL-C Category - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
Baseline LDL-C (mg/dL)	WARNING: Negative of Hessian not positive definite				-
130 - < 160 vs. < 130		-	0.9991	-	
>= 160 vs. < 130		-	0.9987	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by History of Diabetes - Renal Disorders (AESI)
Safety Population

History of Diabetes: Yes

Statistic	FDC vs. Ezetimibe	FDC (N= 48)	Ezetimibe (N= 61)	Total (N= 109)
Number of patients at risk		48 (100.0%)	61 (100.0%)	109 (100.0%)
Number of patients with events		1 (2.1%)	0	1 (0.9%)
Number of patients without events		47 (97.9%)	61 (100.0%)	108 (99.1%)
Odds Ratio [a]				
Unstratified OR, 95% CI	3.884 [0.155, 97.499]			
Stratified OR, 95% CI	4.895 [0.180, 132.83]			
Relative Risk [a]				
Unstratified RR, 95% CI	3.796 [0.158, 91.152]			
Stratified RR, 95% CI	4.364 [0.195, 97.562]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.021 [-0.020, 0.061]			
Stratified ARR, 95% CI (CMH method)	0.023 [-0.020, 0.065]			
Test on Differences [c]				
Unstratified p-value	0.4404			
Stratified p-value	0.2207			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by History of Diabetes - Renal Disorders (AESI)
Safety Population

History of Diabetes: No

Statistic	FDC vs. Ezetimibe	FDC (N= 59)	Ezetimibe (N= 48)	Total (N= 107)
Number of patients at risk		59 (100.0%)	48 (100.0%)	107 (100.0%)
Number of patients with events		3 (5.1%)	0	3 (2.8%)
Number of patients without events		56 (94.9%)	48 (100.0%)	104 (97.2%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.009 [0.303, 119.24]			
Stratified OR, 95% CI	3.235 [0.338, 30.981]			
Relative Risk [a]				
Unstratified RR, 95% CI	5.717 [0.303, 108.03]			
Stratified RR, 95% CI	2.999 [0.350, 25.715]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.051 [-0.005, 0.107]			
Stratified ARR, 95% CI (CMH method)	0.048 [-0.007, 0.102]			
Test on Differences [c]				
Unstratified p-value	0.2509			
Stratified p-value	0.1374			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by History of Diabetes - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
History of Diabetes	Algorithm converged				1.0000
No vs. Yes		-	0.9989	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Renal Disorders (AESI)
Safety Population

BMI (kg/m^2): < 25

Statistic	FDC vs. Ezetimibe	FDC (N= 13)	Ezetimibe (N= 13)	Total (N= 26)
Number of patients at risk		13 (100.0%)	13 (100.0%)	26 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		13 (100.0%)	13 (100.0%)	26 (100.0%)
Odds Ratio [a]				
Unstratified OR, 95% CI	- [- , -]			
Stratified OR, 95% CI	- [- , -]			
Relative Risk [a]				
Unstratified RR, 95% CI	- [- , -]			
Stratified RR, 95% CI	- [- , -]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	- [- , -]			
Stratified ARR, 95% CI (CMH method)	- [- , -]			
Test on Differences [c]				
Unstratified p-value	-			
Stratified p-value	-			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Renal Disorders (AESI)
Safety Population

BMI (kg/m^2): 25 - < 30

Statistic	FDC vs. Ezetimibe	FDC (N= 27)	Ezetimibe (N= 37)	Total (N= 64)
Number of patients at risk		27 (100.0%)	37 (100.0%)	64 (100.0%)
Number of patients with events		1 (3.7%)	0	1 (1.6%)
Number of patients without events		26 (96.3%)	37 (100.0%)	63 (98.4%)
Odds Ratio [a]				
Unstratified OR, 95% CI	4.245 [0.166, 108.29]			
Stratified OR, 95% CI	4.765 [0.173, 130.96]			
Relative Risk [a]				
Unstratified RR, 95% CI	4.071 [0.172, 96.270]			
Stratified RR, 95% CI	4.200 [0.190, 92.861]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.037 [-0.034, 0.108]			
Stratified ARR, 95% CI (CMH method)	0.038 [-0.034, 0.110]			
Test on Differences [c]				
Unstratified p-value	0.4219			
Stratified p-value	0.2294			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE by BMI - Renal Disorders (AESI)
Safety Population

BMI (kg/m^2): >= 30

Statistic	FDC vs. Ezetimibe	FDC (N= 67)	Ezetimibe (N= 59)	Total (N= 126)
Number of patients at risk		67 (100.0%)	59 (100.0%)	126 (100.0%)
Number of patients with events		3 (4.5%)	0	3 (2.4%)
Number of patients without events		64 (95.5%)	59 (100.0%)	123 (97.6%)
Odds Ratio [a]				
Unstratified OR, 95% CI	6.457 [0.327, 127.65]			
Stratified OR, 95% CI	3.611 [0.380, 34.330]			
Relative Risk [a]				
Unstratified RR, 95% CI	6.176 [0.326, 117.16]			
Stratified RR, 95% CI	3.353 [0.388, 28.951]			
Absolute Risk Reduction [b]				
Unstratified ARR, 95% CI	0.045 [-0.005, 0.094]			
Stratified ARR, 95% CI (CMH method)	0.044 [-0.005, 0.093]			
Test on Differences [c]				
Unstratified p-value	0.2470			
Stratified p-value	0.1079			

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Note: The stratification factors are according to the randomization strata (ASCVD and/or HeFH vs. multiple cardiovascular risk factors, and high statin intensity vs other).
[a] Estimated by logit method with zero cell correction. [b] ARR = absolute risk of FDC - absolute risk of Ezetimibe.
[c] For unstratified procedure two-sided p-value based on Chi-square test or Fisher's exact test (if any cell count is <5) is presented.
For stratified procedure two-sided p-value based on CMH test is presented.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Results of Log-Binomial Regression Model of Patients with Non-Severe TEAE by BMI - Renal Disorders (AESI)
Safety Population

	Convergence status of model	Treatment p-value [a]	Subgroup p-value [a]	Treatment and Subgroup interaction p-value [a]	Treatment and Subgroup interaction LR test p-value [b]
BMI (kg/m^2)	WARNING: Negative of Hessian not positive definite				-
25 - < 30 vs. < 25		-	0.9990	-	
>= 30 vs. < 25		-	-	-	

Abbreviations: AESI=adverse event of special interest, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, LR=likelihood ratio, TE(S)AE=treatment-emergent (serious) adverse event.
[a] Wald chi-square p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
[b] Type 3 likelihood ratio test p-value from log-binominal regression model including treatment, subgroup, and treatment x subgroup interaction.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TEAE - Gout (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with TESAE - Gout (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Severe TEAE - Gout (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.

Bempedoic Acid (ETC-1002), Study 1002FDC-053
Effect Measures of Proportion of Patients with Non-Severe TEAE - Gout (AESI)
Safety Population

Statistic	FDC vs. Ezetimibe	FDC (N= 107)	Ezetimibe (N= 109)	Total (N= 216)
Number of patients at risk		107 (100.0%)	109 (100.0%)	216 (100.0%)
Number of patients with events		0	0	0
Number of patients without events		107 (100.0%)	109 (100.0%)	216 (100.0%)

Abbreviations: AESI=adverse event of special interest, ARR=absolute risk reduction, ASCVD=atherosclerotic cardiovascular diseases, BMI=body mass index, CI=confidence interval, CMH=Cochran-Mantel-Haenszel, CVD=cardio-vascular disease, FDC=fixed dose combination, HeFH=heterozygous familial hypercholesterolemia, LDL-C=low-density lipoprotein cholesterol, N=number of patients, OR=odds ratio, RR=relative risk, TE(S)AE=treatment-emergent (serious) adverse event.
Patients were counted as having an event if the maximum severity of their TEAEs is moderate or mild.