Statistical Analysis Plan

Title:	A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Bempedoic Acid 180 mg + Ezetimibe 10 mg Fixed Dose Combination Compared to Bempedoic Acid, Ezetimibe, and Placebo Alone in Patients Treated with Maximally Tolerated Statin Therapy.
Protocol:	ETC-1002FDC-053
Clinical Phase:	3
Product:	ETC-1002FDC
Version (Date):	Statistical Analysis Plan – Final Version 1.1 (June 08, 2018)
Status:	Final

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On behalf of:

Esperion Therapeutics

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NCT number: NCT03337308
This NCT number has been applied to the document
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1 List of Abbreviations

Abbreviation or Specialist Term	Explanation
AE	Adverse event
AESI	Adverse events of special interest
ALB	Albumin
ALK-P	Alkaline phosphatase
ALT	Alanine aminotransferase
ANCOVA	Analysis of covariance
ApoB	Apolipoprotein B
ASCVD	Atherosclerotic cardiovascular diseases
AST	Aspartate aminotransferase
ATC	Anatomical therapeutic classification
BA	Bempedoic acid
BMI	Body mass index
BP	Blood pressure
BUN	Blood urea nitrogen
Ca	Calcium
CI	Confidence interval
CK	Creatine kinase
CO_2	Carbon dioxide
CRF	Case Report Form
CRO	Contract research organization
CV	Cardiovascular
DBP	Diastolic blood pressure
eCRF	Electronic case report form
ECG	Electrocardiogram
eGFR	Estimated glomerular filtration rate
EOS	End of Study
EZE	Ezetimibe
FAS	Full analysis set
FDA	Food and drug administration
FDC	Fixed-dose combination
FSH	Follicle-stimulating hormone
Hct	Hematocrit
HDL-C	High-density lipoprotein cholesterol
HeFH	Heterozygous familial hypercholesterolemia
hs-CRP	High-sensitivity C-reactive protein
ICH	International Conference on Harmonisation
IMP	Investigational medicinal product
IND	Investigational New Drug Application
INR	International normalized ratio
IWRS	Interactive web response system
LDH	Lactate dehydrogenase

Abbreviation or Specialist Term	Explanation
LDL-C	Low-density lipoprotein cholesterol
LSM	Least square mean
MCH	Mean corpuscular hemoglobin
MCHC	Mean corpuscular hemoglobin concentration
MCV	Mean corpuscular volume
MedDRA	Medical Dictionary for Regulatory Activities
non-HDL-C	Non-high-density lipoprotein cholesterol
PE	Physical examination
PK	Pharmacokinetic(s)
PMM	Pattern mixture model
PT	Preferred term
RBC	Red blood cell
SAS	Statistical analysis system
SAE	Serious adverse event
SAP	Statistical Analysis Plan
SBP	Systolic blood pressure
SD	Standard Deviation
SE	Standard error
SGOT	Serum glutamic oxaloacetic transaminase
SGPT	Serum glutamic pyruvic transaminase
SOC	System organ class
SP	Safety population
TB	Total bilirubin
TC	Total cholesterol
TEAE	Treatment-emergent adverse event
TG	Triglycerides
TSH	Thyroid-stimulating hormone
ULN	Upper limit of normal
WBC	White blood cell
WHO	World Health Organization

2 Introduction

The purpose of this document is to describe the statistical methods, data derivations and data summaries to be employed in ETC-1002FDC-053. The preparation of this statistical analysis plan (SAP) has been based on International Conference on Harmonisation (ICH) E3 and E9 Guidelines and in reference to Protocol ETC-1002FDC-053 (Protocol Amendment 1, October 18, 2017).

The SAP will supersede the protocol in the event of any differences between the two documents in the plans for data analysis, and the protocol will be amended if appropriate. The SAP will be included as an appendix in the clinical study report for this protocol.

3 Study Objectives and Endpoints

3.1 Objectives

The co-primary objectives are to assess LDL-C lowering efficacy in patients receiving maximally tolerated statin therapy and treated for 12 weeks with BA 180 mg + EZE 10 mg FDC versus each of the following:

- Placebo
- BA 180 mg
- EZE 10 mg

The secondary objectives are:

- To assess the efficacy of BA 180 mg + EZE 10 mg FDC versus placebo alone, BA alone, and EZE alone on high-sensitivity C-reactive protein (hs-CRP), non-HDL-C, TC, ApoB, HDL-C, and TG after 12 weeks of treatment

- To characterize the safety and tolerability of BA 180 mg + EZE 10 mg FDC versus BA alone, EZE alone and placebo alone through 12 weeks of treatment

The exploratory objectives are:

- To assess the efficacy BA 180 mg + EZE 10 mg FDC versus placebo alone, BA alone, and EZE alone on percentage of patients attaining LDL-C <70 mg/dL after 12 weeks of treatment

- To characterize the plasma trough concentrations of BA and/or EZE when administered as BA 180 mg + EZE 10 mg FDC, BA alone, and EZE alone

3.2 Endpoints

The following endpoints will be used to evaluate the objectives of the study.

3.2.1 Primary Endpoint

• Percent change from baseline to Week 12 in LDL-C

3.2.2 Secondary Endpoint

• Percent change from baseline to Week 12 in hs-CRP, non-HDLC, TC, ApoB, HDL-C, and TG.

3.2.3 Exploratory Endpoints

• Percentage of patients attaining LDL-C <70 mg/dL after 12 weeks of treatment.

• Plasma trough concentrations at Weeks 4, 8, and 12 of BA (ETC 1002 and its active metabolite ESP15228) and EZE (glucuronidated EZE and unconjugated EZE) in BA 180 mg + EZE 10 mg FDC-treated arm, BA-treated arm, and/or EZE alone treated arm.

3.2.4 Safety Endpoints

• Patient incidence of adverse events (AEs)

• Clinical safety laboratory (including hematology, blood chemistry, and urinalysis) results

• Vital signs, electrocardiograms (ECGs) and physical examination (PE) findings

4 Study Design

4.1 Study Design

This is a Phase 3, randomized, double-blind, parallel group, multicenter study of BA + EZE versus its individual components and placebo. Screening (S1) will occur approximately within 2 weeks prior to randomization. Patients who are deemed not eligible for randomization at any point during screening will be notified by clinical site personnel regarding their eligibility status and considered screen failures. Approximately 350 eligible patients will be randomized 2:2:2:1 on Day 1/Week 0 (T1) to receive either BA 180 mg + EZE 10 mg FDC (N = 100), BA 180 mg (n = 100), EZE 10 mg (n = 100), or placebo (n = 50) for 12 weeks. Randomized patients will return for clinic visits at Week 4 (T2), Week 8 (T3) and Week 12 (T4). Patients who withdraw from investigational medicinal product (IMP) treatment will be asked to continue to be followed for safety and efficacy using the protocol-specified visit schedule and procedures.

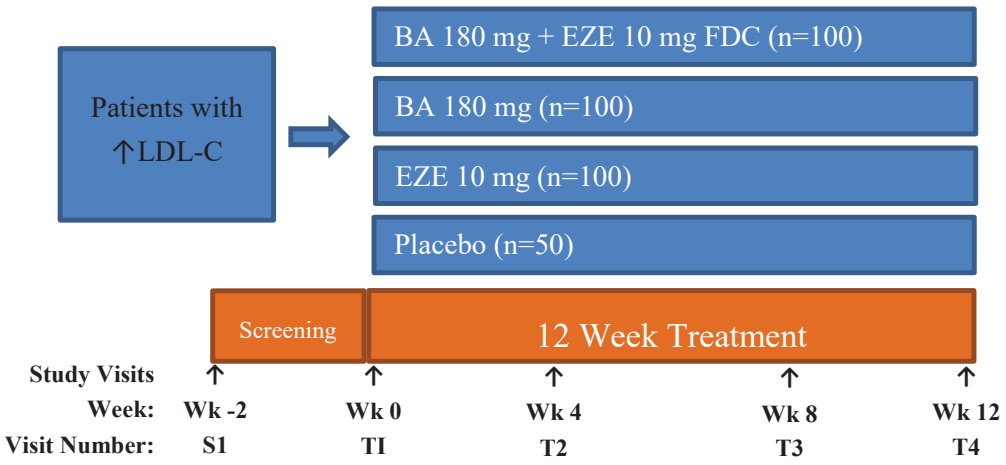
Eligible patients will have documented atherosclerotic cardiovascular diseases (ASCVD), heterozygous familial hypercholesterolemia (HeFH), and/or multiple cardiovascular risk factors and require additional LDL-C-lowering therapy despite receiving maximally tolerated statin background therapy. Maximally tolerated statin therapy may include

statin regimens other than daily dosing or no statin at all (if not tolerated); however, doses of simvastatin ≥40 mg/day are prohibited. A patient's currently used and maximally tolerated statin therapy will be determined by the investigator based on their medical judgment and local standard of care. Available sources, including the patient's self-reported history of lipid-modifying therapy will also be considered.

Patients will be stratified based on baseline/current statin intensity (high intensity statin versus other) and disease characteristics (ASCVD and/or HeFH versus multiple CV risk factors). High intensity statin includes atorvastatin 40-80 mg/day and rosuvastatin 20-40 mg/day, all others will be categorized as 'other' for randomization and stratification purposes. Definition of ASCVD and/or HeFH or multiple CV risk factors are provided in inclusion criteria. Enrollment will be monitored and a cap may be placed, if necessary, to ensure appropriate distribution into either of the statin intensity categories.

The Study Flow Chart is presented in Figure 1.

Figure 1: Study Flow Chart



For details of study assessments, see the Schedule of Events in Appendix 1.

4.2 Randomization

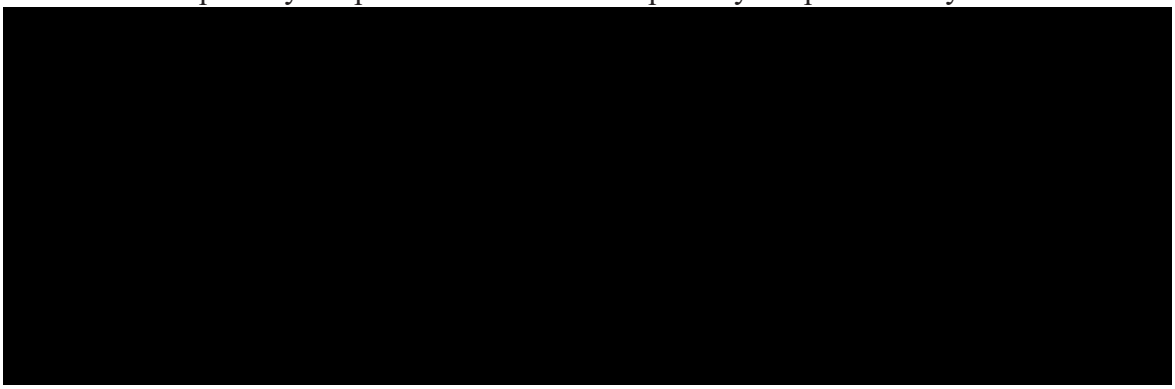
During the Treatment Period, patients will receive double-blind IMP. At Day 1 (Visit T1), patients will be randomized to receive either BA 180 mg + EZE 10 mg FDC, BA 180 mg, EZE 10 mg or placebo with 2:2:2:1 ratio.

The randomization will be stratified by baseline statin intensity (high intensity vs. other) and disease characteristics (ASCVD and/or HeFH vs. multiple CV risk factors). Only atorvastatin 40-80 mg/day and rosuvastatin 20-40 mg/day are considered high intensity statin and all others will be considered as 'other' for randomization purpose.

The criteria for determining these 2 stratification factors are further detailed in criteria for selection of patients in protocol. The investigator or designee will utilize IWRS during the visit to randomize the patient and obtain the appropriate IMP container via medication identification numbers. A patient is considered to be randomized when the corresponding randomization box is checked within the eCRF.

4.3 Sample Size Justification

The sample size of 100 patients per active treatment group and 50 patients in the placebo arm (2:2:2:1) of this study (350 patients total) was selected to provide adequate power for each of the co-primary endpoint as well as the co-primary endpoint family as a whole.



5 Statistical and Analytical Plans

5.1 General Statistical Considerations

In general, summary statistics for continuous variables will include the number of patients, mean, median, SD or standard error (SE), first and third quartiles, minimum, and maximum. Minimum and maximum will be presented same number of decimal places as reported/collected, one additional decimal place for mean and median, and two additional decimal places for SD.

For categorical variables, the frequency and percentage will be given. Percentage will be presented with one decimal place. All categories will be presented (even if no patients are counted in the category). Counts of zero in any category will be presented without percentage.

Data will be presented on listings in order of patient, assessment date and assessment (in order collected on CRF, unless specified otherwise). Dates will be presented in format DDMMMYYYY.

The visit schedules and window are shown below.

Visit	S1	T1	T2	T3	T4
Slotted Study Week	-2	0	4	8	12/EOS
Target Study Day	Day -13	Day 1	Day 29	Day 57	Day 85
Analysis Visit Windows	[-∞, -1]	[1]	[2,34]	[35, 62]	[63, +∞]
Protocol defined visit window	Day -16 to -5	Day 1	Day 29 ± 5	Day 57 ± 5	Day 85 ± 5

5.2 Statistical Analysis Plans

5.2.1 Analysis Population

5.2.1.1 Full Analysis Set (FAS)

The full analysis set (FAS), used for all of the efficacy analyses, is defined as all randomized patients. Patients in FAS will be analyzed in the treatment group they are randomized to regardless of the treatment received.

5.2.1.2 Safety Population (SP)

The Safety Population (SP), used for all of the safety summaries, is defined as all randomized patients who received at least 1 dose of blinded IMP. Patients in the SP will be included in the treatment group that they actually received, regardless of their randomized treatment.

5.2.1.3 Treatment Completer Analysis Set

Treatment completer analysis set a subset of full analysis set and will include subjects who complete 12-week treatment as indicated on the end of treatment CRF and have non-missing LDL-C value at Week 12.

5.2.1.4 PK Analysis Set (PKS)

The PK analysis set (PKS), used for all of the PK-related summaries, is defined as all patients in the SP who have at least 1 PK assessment unless major protocol deviations are identified to have affected the PK data or if key dosing or sampling information is missing. All PK samples with data available will be included in the summary unless the sample time is outside of 18 to 30 hours window since last dose of study drug or dosing and/or sampling time are missing. PK result listing will list all results regardless of sampling window.

5.2.2 Baseline Definition

Baseline LDL-C is defined as the mean of the values from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1) (i.e., the last two non-missing values on or prior to Day 1). If only one value is available then that single value will be used as baseline.

Baseline for non-HDL-C, HDL-C, TC, and TG is defined as the mean of the values

from Week -2 (Visit S1) and pre-dose Day 1/Week 0 (Visit T1) (i.e., the last two non-missing values on or prior to Day 1). If only one value is available then that single value will be used as baseline.

Baseline for ApoB and hs-CRP is defined as the pre-dose Day 1/Week 0 (Visit T1) value (i.e. the last non-missing value on or prior to Day 1). If this is not available, then the last non-missing value prior to the first dose of double-blind study medication (including unscheduled assessments) will be used as baseline.

Baseline of other laboratory parameters, vital signs and physical examination is defined as the last non-missing value prior to the first dose of study drug.

5.2.3 Protocol Violations and Deviations

A full list of protocol violations and deviations will be compiled and reviewed by the clinical team to identify major versus minor violations/deviations before final database lock. For violations at study entry, patients will be assessed against the inclusion and exclusion criteria of the protocol. For on-study deviations, compliance with the protocol will be examined using blinded review of the source data with regard to prohibited therapies, and timing and availability of planned assessments. The determination of major versus minor protocol deviations will be conducted prior to the database lock. Any protocol deviation related to inclusion/exclusion criteria will be summarized in table as well as listing. Any major on-study protocol deviation will also be summarized by treatment group, and all protocol deviations will be listed.

5.2.4 Patient Disposition

Disposition, including reason for withdrawal from IMP and the study, will be summarized by treatment group. In addition, the number of patients who withdraw from the study and withdraw from study drug will be summarized by discontinuation reason.

5.2.5 Demographic and Baseline Characteristics

Demographic information and patient baseline characteristics including, but not limited to, gender, race, age, and baseline vital signs will be summarized by treatment group.

The following demographic and baseline characteristics will be summarized by treatment group, as well as overall, for safety population and for FAS population: age (years), age will be summarized as a continues variable and by age group (18-40, 41-64, 65-74, and >=75), gender, race, ethnicity, height (cm), weight (kg), body mass index (BMI) (kg/m^2), BMI group (<25, 25-<30, >=30 kg/m^2), eGFR, systolic and diastolic blood pressure (mmHg), heart rate, history of diabetics and hypertension, background statin therapy, disease characteristics, tobacco history, alcohol history, fasting lipid parameters (TC [mg/dL], calculated LDL-C [mg/dL], HDL-C [mg/dL], non-HDL-C [mg/dL] and TG [mg/dL]), ApoB(mg/dL), and hs-CRP (mg/dL).

Data will be summarized using descriptive statistics for continuous variables and using counts and percentages for categorical variables by treatment group and overall.

5.2.6 Subgroups Variables

1) Gender (male vs. female)
2) Age (< 65 yrs. vs. ≥65 yrs.)
3) Baseline CVD risk category (ASCVD and/or HeFH vs. multiple CV risk factors)
4) Baseline statin intensity (high intensity vs. other)
5) Race (white vs. other)
6) Baseline LDL category (< 130 mg/dL vs. ≥130 - <160 mg/dL vs. ≥160 mg/dL) (efficacy only)
7) History of diabetes (yes vs. no)
8) Body Mass Index (BMI) (< 25, 25 - < 30, ≥ 30 kg/m2)

In case the number of patients within a subgroup is too small for a meaningful analysis, the analyses may not be performed or the subgroup levels may be combined.

5.2.7 Medical History

General medical history will be summarized by treatment group by system organ class (SOC) and preferred term (PT) using Medical Dictionary for Regulatory Activities (MedDRA), as well as overall, for safety population and presented in a by-patient listing. Where appropriate, terms will be coded using the latest version of MedDRA.

5.2.8 Prior Medications and Concomitant Medications/Procedures

Prior medications are defined as medications that ended prior to the initiation of double-blind study drug. Concomitant medications are defined as medications that were ongoing at the time of double-blind study drug initiation or new medications that started post double-blind study drug initiation and within 30 days following the date of the last dose of study drug.

Medications, including prior statin medications, will be coded using WHO Drug (Sept 2016, or later). The frequency of use of prior medications and use of concomitant medications will be summarized by treatment group, as well as overall, for the safety population according to Anatomical Therapeutic Chemical (ATC) class and preferred term. Prior medications, concomitant medications, and concomitant procedures will be listed for each patient.

5.2.9 Study Drug Exposure and Compliance

The length of exposure to study drug (FDC, BA, EZE or placebo) will be calculated as the number of days from the first dose of double-blind study drug to the last dose of double-blind study drug, regardless if the patient missed one or more doses of study drug. Length of exposure will be summarized by treatment group using descriptive statistics for the safety population.

The overall compliance to study drug calculated based on tablet count will be summarized by treatment group using summary statistics. The number and percentage of patients who were compliant with taking study drug will be summarized by treatment group for the safety population for the following categories <80%; >= 80%. Overall compliance will be calculated as: 100* (Total Dispensed Tablets - Total Returned Tablets) / Treatment Duration in day. Overall compliance during the study will be calculated by using study drug dispensation data.

The study drug administration and compliance data, including reasons for poor compliance, will be listed for each patient.

5.3 Efficacy Endpoints and Analyses

All the efficacy endpoints and analyses will be done by using FAS (Full analysis set), and Treatment Completer Analysis Set.

5.3.1 Co-Primary Endpoint Analysis

The co-primary efficacy endpoints consist of three comparisons of the percent change from baseline to Week 12 in LDL-C: FDC vs. placebo, FDC vs. EZE; and FDC vs. BA.

In cases where triglycerides (TG) is >400 mg/dL or LDL-C is ≤50 mg/dL, a measured LDL (LDL-M) will be used instead of LDL-C for the analysis of that time point. If both values are available, the LDL-M will be used.

An ANCOVA with treatment group and randomization stratification as factors and baseline LDL-C as a covariate will be performed to compare treatment groups (LDL-C: FDC vs. placebo, FDC vs. EZE; and FDC vs. BA) for the primary endpoint using the FAS. In case of number of subjects within a stratum is too small for a meaningful analysis, the strata may be combined to obtain larger cell size. The least squares mean (LSM) and SE, 95% confidence interval (CI) and associated p-values for each treatment groups, as well as for each treatment group comparison of interests. To account for possibility of unequal variances between the groups, the ANCOVA model will be implemented within mixed model framework where <repeated/group=> option will be used to allow separate estimation of residual variances for different groups.
Each of the comparisons within the co-primary endpoint family will be conducted at a significance level of 0.05. If and only if all three testing achieve statistical significance, the study is claimed to meet its primary objective and the hypothesis testing will continue to secondary endpoints, otherwise all statistical comparisons for secondary endpoints are considered descriptive only.

An example Statistical Analysis System (SAS) code for ANCOVA analysis is shown as below:

```
PROC MIXED DATA=adxx ;
    class armcd stratum;
    model pchg = blres armcd stratum / solution ddfm=kenwardroger;
     repeated/ group=armcd;
    lsmeans armcd / diff;
```

Missing values for primary endpoint will be imputed using multiple imputation method, taking account for the adherence to the treatment. For patients with missing data and no longer receiving treatment at Week 12 (defined as lab date is > 7 days post last dose of IMP), their LDL-C will be imputed as their baseline value, for those with missing data but still receiving treatment, their LDL-C value will be imputed using a regression model based imputation model including treatment, stratification factor, baseline LDL-C as auxiliary variables. The imputation will be performed for 200 times and imputed datasets will be analyzed using an ANCOVA model with treatment, stratification as factors and baseline LDL-C as a covariate. Approximately 200 imputed datasets will be created; results from the analysis of each imputed dataset will be combined using Rubin's method. The final combined least squares mean (LSM) and standard error (SE) will be provided for both treatment groups, along with the LSM for each treatment comparison, its 95% confidence interval (CI) and associated p-value. More details will be provided in the programming specifications.

5.3.2 Secondary and Exploratory Efficacy Endpoint Analyses

Key secondary efficacy endpoints, which include the percent change from baseline to Week 12 in LDL-C, non-HDL-C, TC, and apoB, will be analyzed in a similar manner as the primary efficacy endpoint.

For hsCRP, a non-parametric (Wilcoxon rank-sum test) analysis with Hodges-Lehmann estimates and confidence interval will be performed because based on historical knowledge, publication precedence (Brendan etc., 2006) and recent data available, hsCRP is known to be skewed by extreme values and have non-normal distribution. HDL and TGs will be summarized using descriptive statistics for the observed value and the change/percent change from baseline at each protocol scheduled visits.

If co-primary endpoint family achieves statistical significance, a list of selected secondary endpoints will be tested in sequential order within each comparison group. The alpha allocation among the three comparison groups is: alpha = 0.01 for FDC vs. Placebo alpha = 0.02 for FDC vs. EZE; alpha = 0.02 for FDC vs. BA.

Missing values for these secondary endpoints will be imputed using multiple imputations method as described for primary endpoint. All other secondary endpoints not included in the step-down procedure (Figure 2) will be tested at significant level of 0.05 without multiplicity adjustment. Only observed data will be used for these analysis.

Other secondary endpoints of HDL-C and TGs will be summarized using descriptive statistics at week 12.

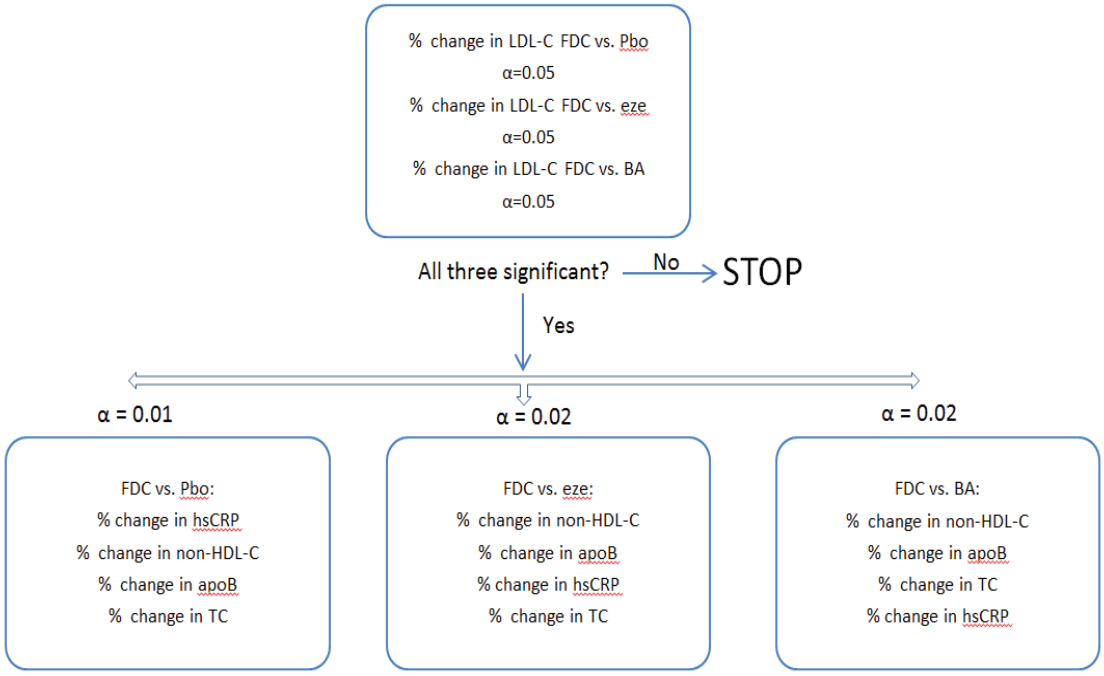
By-visit summary for all efficacy endpoints (LDL-C, non-HDL-C, TC, ApoB, hsCRP, HDL-C and TGs) using FAS and treatment completer set will be provided for both conventional and standard units.

5.3.3 Sensitivity Analyses for Efficacy Endpoints

Sensitivity analyses will be performed for the co-primary endpoints and key secondary endpoints using:

- Treatment completer analysis set using FAS with no imputation for missing data
- Observed data from the FAS with no imputation for missing data

Figure 2: The statistical testing of the treatment comparisons



5.3.4 Subgroup Analysis for Co-primary Endpoints

The co-primary endpoints for LDL-C will be analyzed within subgroups described in section 5.2.6. The treatment and subgroup interaction will be examined by including treatment, subgroup, baseline and treatment by subgroup interaction term in the ANCOVA model for the overall population first. No imputation will be performed on missing data for subgroup analyses. In case the number of subjects within a subgroup/treatment is too small for a meaningful analysis or small cell size is causing convergence issue, the analyses may not be performed or the subgroup levels may be combined.

A forest plot of treatment effect for each of the LDL-C endpoint comparison within each subgroup will be provided.

5.3.5 Exploratory Endpoints

Percent of patients with LDL-C <70 mg/dL after Week 12 will be summarized by treatment group. Comparisons between treatment groups (FDC vs. EZE, FDC vs. BA, and FDC vs. placebo) on the proportion of patients achieving an LDL-C <70 mg/dL after 12 week treatment will be performed using Fisher's exact test or Pearson's chi-square test on observed data, i.e. the denominator will be number of patients who have LDL-C value at week 12.

Descriptive summary for plasma trough concentrations of BA and/or EZE will be provided at Weeks 4, 8, and 12 by treatment group.

5.4 Safety Endpoints and Analyses

For all safety endpoints, the safety population (SP) will be used. Descriptive summary will be provided for safety endpoints.

The summarization of AEs will include only TEAEs (defined as AEs that begin or worsened on or after the date of first dose of double-blind IMP until 30 days after last dose of IMP). All TEAEs, SAEs, related AEs, Adverse events of special interest (AESIs) will be summarized by MedDRA SOC, severity and relationship to study drug for each treatment group. Fatal AE, AEs leading to discontinuation of IMP or study, will each be summarized by treatment group.

Clinical safety laboratories, including hematology, blood chemistry, coagulation (for subjects taking anti-coagulation medication only), glucose (by history of diabetics), and urinalysis; PE findings; vital signs; ECG readings; and weight will be summarized by the value and by change/percent change from baseline (where appropriate) at each protocol scheduled time point.

5.4.1 Adverse Events (AEs)

AEs will be coded using the latest version of MedDRA and preferred term PT. Patients with AEs that are ongoing at study completion or study withdrawal must be followed until resolution, until determined to be stable/chronic, or for 30 days after the last study visit, whichever comes first. Summary tables will focus on TEAEs; however, listings will include all AEs (with non-TEAEs flagged).

In summary tables, TEAEs will be counted as “Not Related” if relationship to study drug was recorded as ‘Not Related’ or “Unlikely”. Events will be counted as “Related” if relationship to study drug was recorded as ‘Possibly’, ‘Probably’, ‘Definitely’ or if relationship to study drug is missing.

Overviews of TEAEs will include total number of TEAEs and patient incidence of TEAE, TE SAE, related TEAE, related TE SAE, AESI, TEAE leading to withdrew of IMP, Fatal TEAE. Individual TEAE summary will be presented by treatment group containing the following counts and percentages for:

- patients with TEAEs by SOC and PT
- patients with TEAEs by descending order of frequency of PT
- patients with treatment-related TEAEs by SOC and PT
- patients with treatment-related TEAEs by PT
- patients with TE SAEs by SOC and PT
- patients with TE SAEs by PT
- patients with treatment-related TE SAEs by SOC and PT

- withdrawal from study drug due to TEAEs by SOC and PT
- Fatal TEAEs by SOC and PT
- Patients with at least one AESI by AESI category and SOC and PT
- Patients with serious AESI by AESI category and SOC and PT

The AE overview summaries will count a patient at most once in each AE category (at the "highest/most extreme" designation of each category regardless of preferred term) and percentages will be based on the total number of patients in the safety population.

In addition to a comprehensive listing of all AEs (with non-TEAEs flagged), separate listings will be generated for AESI, SAEs, AEs resulting in withdrawal of study drug, and AEs with a fatal outcome for safety population.

5.4.2 Adverse Events of Special Interest (AESIs)

AESIs include hepatic disorders (including increase from baseline in hepatic aminotransferases), musculoskeletal events (AE and CK evaluation), new onset diabetes/hyperglycemia, renal events, metabolic acidosis and/or hypoglycemia, and neurocognitive/neurologic events. The list of AESI terms is pre-defined by the Esperion and is included in Appendix 2.

- AESIs of muscle related symptoms will be summarized by treatment group. CK levels will be summarized by the value and change from baseline in the value, by treatment group and visit. In addition, the number and percent of patients with abnormal CK (> 5 × ULN, > 10 × ULN) values will be summarized. These summaries of patients with abnormal CK will be performed overall; by normal baseline CK; and by abnormal baseline CK.
- Cases of new onset of diabetes will be recorded as AEs and will be summarized using the appropriate SOC. These events will be summarized by severity, and relationship to study drug for each treatment group. Fasting glucose will be summarized at scheduled time point by history of diabetics.
- Neurocognitive events will be evaluated by routine safety monitoring of PE findings and AEs. Neurocognitive events will be identified using pre-specified MedDRA terms and will be summarized by SOC, severity, and relationship to IMP for each treatment group

AESI will be presented in a listing and summarized by AESI category, SOC, PT and treatment group.

5.4.3 Subgroup Analysis for Adverse Events

The TEAE, related TEAE, TE SAE, and AESI summaries by SOC and PT will be provided for relevant subgroups described in 5.2.6 with the exception of baseline LDL

category.

5.4.4 Laboratory Evaluations

Continuous laboratory parameters (serum chemistry, hematology, coagulation for those who received anti-coagulation therapy patients), urinalysis, urinalysis [microscopic]) listed in Table 4; and fasting glucose will be summarized using descriptive statistics for the observed value and the change/percent change from baseline at each protocol scheduled visits by history of diabetics. Missing values for any of the laboratory evaluations will not be imputed; that is, only observed case data will be used. Categorical urinalysis data will be provided in the listing.

As part of the AESI evaluation, below safety lab abnormality will be summarized by treatment group. All post-baseline lab values are being considered. Further details are provided in Section 5.4.4.1 through 5.4.4.4.

- ALT or AST (> 3x ULN and >5xULN)
- TB (> 2x ULN)
- Potential Hy's Law case: (ALT and/or AST > 3xULN with concurrent TB > 2xULN)
- CK (> 5x ULN) and (>10x ULN)
- Fasting Glucose (mg/dL) (≤50, and ≥126) by history of diabetics
- Creatinine (change from baseline for >1 mg/dL)
- eGFR (< 15 mL/min/1.73m2, 15 –< 30 mL/min/1.73m2)
- Hgb (g/dL) (decrease from baseline for ≥2 g/dL)
- Hgb (<8 g/dL)

Table 4: Clinical Laboratory Parameters (Safety)

Hematology • Hematocrit (Hct) • Hemoglobin (Hgb) • Mean corpuscular hemoglobin (MCH) • Mean corpuscular hemoglobin concentration (MCHC) • Mean corpuscular volume (MCV) • Platelet count • Red blood (RBC) cell count • White blood (WBC) cell count with differential (absolute values only) Urinalysis (Dipstick) • Clarity • Bilirubin • Color • Glucose • Ketones • Leukocyte esterase • Nitrate • Occult blood • pH • Protein • Specific gravity • Urobilinogen Urinalysis (Microscopic)-only if urine dipstick abnormal • Bacteria • Casts • Crystals • Epithelial cells • Red blood cell (RBC) • WBC	Blood Chemistry (serum, fasting) • Albumin (ALlb) • Alkaline phosphatase (AlLk-P) • Alanine aminotransferase (ALT; SGPT) • Aspartate aminotransferase (AST; SGOT) • Blood urea nitrogen (BUN) • Calcium (Ca) • Carbon dioxide (CO2) • Chloride (Cl) • Creatinine • Creatine kinase (CK) • Glucose • Lactate dehydrogenase (LDH) • Phosphorus • Potassium (K) • Sodium (Na) • Total and direct bilirubin (TB) • Total protein • Uric acid Coagulation (In all patients at screening, then only in patients receiving anticoagulant therapy that in the investigator's judgment require monitoring at Visit T1 and 3 to 5 days post Visit T1) • Prothrombin time • International normalized ration (INR)

The number and percentage of patients with laboratory abnormalities (i.e., laboratory values outside the stated laboratory normal range) will be summarized at each time point (i.e., including baseline and post-baseline time points) for each laboratory parameter by treatment groups. The determination of laboratory abnormalities will take into account any unscheduled laboratory assessments. Additional lab-related summaries will be provided as follows for hepatic safety, musculoskeletal safety, diabetes and hyperglycemia, and renal safety.

5.4.4.1 Hepatic Safety

Liver-associated enzymes and TB will be summarized by the value and change from baseline in the value, by treatment group and visit. In addition, the number and percent of patients with abnormal values for ALT (> 3 × ULN, > 5 × ULN), AST (> 3 × ULN, > 5 × ULN, and TB (> 2×ULN)" will be summarized. These summaries of patients with abnormal values will be performed overall safety population; by normal baseline; and by abnormal baseline for each of ALT, AST and TB. Hy's law criteria (>3 × ULN for either ALT or AST, with accompanying TB >2 × ULN) will also be applied to the data; any potential Hy's law cases will be listed separately. Note: In the case of patients with Gilbert's disease, TB will be fractionated and the determination of 2 × ULN will be based upon direct (conjugated) bilirubin.

5.4.4.2 Musculoskeletal Safety

CK levels will be summarized by the value and change from baseline in the value, by treatment group and visit as well as baseline eGFR category. In addition, the number and percent of patients with abnormal CK values (>5 x ULN, > 10 x ULN) will be summarized for overall safety population. These summaries of patients with abnormal CK will be performed overall, normal baseline CK, and abnormal baseline CK.

5.4.4.3 Diabetes and Glycemia

For fasting serum glucose, a shift table from baseline with the number and percent of patients will be categorized as below:

Fasting glucose: >= 126 mg/dL; 100-125 mg/dL, and < 100 mg/dL. These tables will be summarized by history of Diabetes.

Descriptive summary for fasting serum glucose will be provided by history of diabetics and treatment group at each scheduled visit.

5.4.4.4 Renal Safety

Baseline eGFR will be summarized by treatment group for actual value and for baseline eGFR categories. Shift tables of eGFR category from baseline over the study, will be provided by treatment group. Shift tables of urine protein (negative/positive) from baseline over the study, will be provided by treatment group. Values of CK over the study will be summarized by treatment group and by baseline eGFR category.

5.4.5 Physical Examinations (PEs)

Listings of PE data will include only those records where the body system at the baseline PE was normal, but the body system at a post-baseline PE was marked as 'Change from previous exam, clinically significant.' Only changes from baseline physical examination findings that meet the definition of an AE will be recorded on the AE page of the eCRF and will be summarized with other AEs.

5.4.6 Vital Signs

Actual values and changes from baseline in vital signs (SBP, DBP, heart rate, weight) will be summarized using descriptive statistics by treatment group and post-baseline time point on the observed values.

Vital signs data will be listed for each patient, with increases from baseline of >15 mmHg in systolic or diastolic blood pressure flagged.

For vital signs, observed values and changes from baseline will be summarized for all post-baseline study visits.

5.4.7 Electrocardiogram (ECG)

Shift tables for ECG data from baseline to end-of-study will be provided by treatment group. The data will be categorized as 'Normal'; 'Abnormal, not clinically significant'; and 'Abnormal, clinically significant.' Baseline is defined as the last value prior to the first dose of study medication. Listings of ECG data will include only those records where the baseline ECG was either 'Normal' or 'Abnormal, not clinically significant', but the end-of-study ECG was marked as 'Abnormal, clinically significant'.

6 Reference

1. Sharrett AR, Ballantyne CM, Coady SA, Heiss G, Sorlie PD, Catellier D, et al. Atherosclerosis Risk in Communities Study Group. Coronary Heart Disease Prediction from Lipoprotein Cholesterol Levels, Triglycerides, Lipoprotein(A), Apolipoproteins A-I and B, and HDL Density Subfractions. The Atherosclerosis Risk in Communities (ARIC) Study. Circulation. 2001;104:1108-13.
2. World Health Organization (WHO) Fact Sheet No 317 Updated January 2015.
3. Robinson JG. Management of Familial Hypercholesterolemia: A Review of the recommendations from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. J Managed Care Pharm. 2013;19(2):139-49.
4. Haase A, Goldberg AC. Identification of people with heterozygous familial hypercholesterolemia. Curr Opin Lipidol. 2012;23:282-9.
5. ICH Topic E3: Structure and Content of Clinical Study Reports (CPMP/ICH/137/95- adopted December 1995).
6. ICH Topic E9: Statistical Principles for Clinical Trials (CPMP/ICH/363/96 – adopted March 1998).
7. Brendan M.Everett, Tobias Kurth, Julie E.Buring, Paul M.Ridker. "The Relative Strength of C-Reactive Protein and Lipid Levels as Determinants of Ischemic Stroke Compared With Coronary Heart Disease in Women." Journal of the American College of Cardiology (2006), Volume 48, Issue 11, Pages 2235-2242.

7 Appendices

Appendix 1: Schedule of Events (Patient Visit Schedule)

Visit	**S1[1]**	**T1**	**T2**	**T3**	**T4[2]**
Week	**-2**	**0**	**4**	**8**	**12/EOS**
Procedure	**Day -16 to -5**	**Day 1**	**Day 29 ± 5**	**Day 57 ± 5**	**Day 85 ± 5**
Informed Consent	X				
Enrollment Criteria	X	X			
Demographics	X				
Medical History	X				
Concomitant\Prohibited Medications	X	X	X	X	X
Adverse Event Recording	X	X	X	X	X
Physical Exam		X			X
Weight[3]	X	X[3]	X	X	X
Height/BMI	X				
12-Lead ECG[4]		X			X
Vital Signs[5]	X	X	X	X	X
Serology[6]	X				
Serum Pregnancy/FSH [7]	X				
Urine Pregnancy		X			
TSH	X				
Clinical Safety Labs[8]	X	X	X	X	X
Basic Fasting Lipids[9]	X	X	X	X	X
Special Fasting Lipids and Other Biomarkers[10]		X			X
HbA_{1C}	X				
Plasma Trough Study Drug			X	X	X
Randomization		X			
Double Blind Drug Dispensing		X	X	X	
Drug Return			X	X	X

[1] *An optional visit approximately 10 days later MAY be completed if patient fails to meet specified entry criteria. If this optional visit is completed, the repeat value will be used to determine eligibility.*

[2] *All procedures will be completed at end of study or early termination.*

[3] *Body weight will be measured in the morning while fasting, using consistent scales, after voiding, and without shoes and outerwear (e.g., coats).*

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[4] *Single 12-lead ECG will be collected prior to any blood sample collection.*

[5] *Vital signs will include SBP, DBP, and HR, and will be collected prior to any blood sample collection. Patient will rest for 5 minutes prior to assessments.*

[6] *Serology for Hep B antigen, Hep C antibody.*

[7] *FSH completed in appropriate postmenopausal women only; pregnancy test completed in non-postmenopausal women only.*

[8] *Clinical safety labs include hematology, blood chemistry, and urinalysis. Coagulation panel only if receiving anticoagulants that in the investigator's judgement requires monitoring (then test at T1 and repeat 3-5 days after starting IMP).*

[9] *Basic fasting lipids include total cholesterol, calculated LDL-C, HDL-C, non-HDL-C, and triglycerides.*

[10] *Includes apoB and hs-CRP.*

Appendix 2: AESI (Adverse Event of Special Interest)

AESI Category	Associated MedDRA Preferred Terms
Creatine kinase elevations	Blood creatine phosphokinase abnormal
Creatine kinase elevations	Blood creatine phosphokinase increased
Creatine kinase elevations	Blood creatine phosphokinase MM abnormal
Creatine kinase elevations	Blood creatine phosphokinase MM increased
New onset or worsening diabetes mellitus	Blood glucose abnormal
New onset or worsening diabetes mellitus	Blood glucose increased
New onset or worsening diabetes mellitus	Diabetes mellitus
New onset or worsening diabetes mellitus	Diabetes mellitus inadequate control
New onset or worsening diabetes mellitus	Diabetic ketoacidosis
New onset or worsening diabetes mellitus	Glucose tolerance impaired
New onset or worsening diabetes mellitus	Glucose urine present
New onset or worsening diabetes mellitus	Glycosuria
New onset or worsening diabetes mellitus	Glycosylated haemoglobin increased
New onset or worsening diabetes mellitus	Hyperglycaemia
New onset or worsening diabetes mellitus	Impaired fasting glucose
New onset or worsening diabetes mellitus	Ketoacidosis
New onset or worsening diabetes mellitus	Ketosuria
New onset or worsening diabetes mellitus	Ketosis
New onset or worsening diabetes mellitus	Type 2 diabetes mellitus
New onset or worsening diabetes mellitus	Urine ketone body present
Hepatic enzyme elevations	Alanine aminotransferase abnormal
Hepatic enzyme elevations	Alanine aminotransferase increased
Hepatic enzyme elevations	Aspartate aminotransferase abnormal
Hepatic enzyme elevations	Aspartate aminotransferase increased
Hepatic enzyme elevations	Blood bilirubin abnormal
Hepatic enzyme elevations	Blood bilirubin increased
Hepatic enzyme elevations	Hepatic enzyme abnormal
Hepatic enzyme elevations	Hepatic enzyme increased
Hepatic enzyme elevations	Hypertransaminaseaemia
Hepatic enzyme elevations	Liver function test abnormal
Hepatic enzyme elevations	Liver function test increased
Hepatic enzyme elevations	Transaminases abnormal
Hepatic enzyme elevations	Transaminases increased
Hypoglycemia	Blood glucose abnormal
Hypoglycemia	Blood glucose decreased
Hypoglycemia	Hypoglycaemia
Hypoglycemia	Hypoglycaemic coma
Hypoglycemia	Hypoglycaemic encephalopathy

AESI Category	Associated MedDRA Preferred Terms
Hypoglycemia	Hypoglycaemic seizure
Hypoglycemia	Shock hypoglycaemic
Metabolic acidosis	Metabolic acidosis
Muscular disorders	Muscular weakness
Muscular disorders	Muscle necrosis
Muscular disorders	Muscle spasms
Muscular disorders	Myalgia
Muscular disorders	Myoglobin blood increased
Muscular disorders	Myoglobin blood present
Muscular disorders	Myoglobin urine present
Muscular disorders	Myoglobinaemia
Muscular disorders	Myoglininuria
Muscular disorders	Myopathy
Muscular disorders	Myopathy toxic
Muscular disorders	Necrotizing myositis
Muscular disorders	Pain in extremity
Muscular disorders	Rhabdomyolysis
Neurocognitive disorder	Amnesia
Neurocognitive disorder	Cognitive disorder
Neurocognitive disorder	Confusional state
Neurocognitive disorder	Disorientation
Neurocognitive disorder	Memory impairment
Neurocognitive disorder	Mental status changes
Renal disorders	Acute kidney injury
Renal disorders	Acute prerenal failure
Renal disorders	Blood creatinine abnormal
Renal disorders	Blood creatinine increased
Renal disorders	Blood urea abnormal
Renal disorders	Blood urea increased
Renal disorders	Blood urea nitrogen/Creatinine ratio increased
Renal disorders	Creatinine renal clearance abnormal
Renal disorders	Creatinine renal clearance decreased
Renal disorders	Glomerular filtration rate abnormal
Renal disorders	Glomerular filtration rate decreased
Renal disorders	Oliguria
Renal disorders	Prerenal failure
Renal disorders	Renal failure
Renal disorders	Renal function test abnormal
Renal disorders	Renal impairment
Gout	Gout

Addendum to Statistical Analysis Plan

Title:	A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Bempedoic Acid 180 mg + Ezetimibe 10 mg Fixed Dose Combination Compared to Bempedoic Acid, Ezetimibe, and Placebo Alone in Patients Treated with Maximally Tolerated Statin Therapy.
Protocol:	ETC-1002FDC-053
Clinical Phase:	3
Product:	ETC-1002FDC
Date:	Dec 24, 2018

Addendum to the Statistical Analysis Plan for Study 1002FDC-053

An Ad-hoc Sensitivity Analysis

Esperion completed the planned analysis as described in Study 1002FDC-053 SAP for all data collected in the study. During an in-depth review of the data, after unblinding, a data issue was identified that involved three sites. A formal investigation to assess the root cause of the data issue was launched. After review of the investigative results, the conclusion led us to question the data collected at three sites [redacted]

To answer the question and ensure the integrity of the data and related analysis and quality, we propose to conduct sensitivity analysis. The focus of the sensitivity analysis is to examine if the data issue impacts the efficacy and safety results of the trial. We will repeat selected key analyses after excluding all 81 patients from these 3 sites, [redacted] and [redacted]

After excluding patients from these 3 sites [redacted], we will provide tables for disposition and demographics. We will repeat the statistical analyses for:

1. The co-primary efficacy endpoints, which consist of three comparisons of the percent change from baseline to Week 12 in LDL-C: bempedoic acid-ezetimibe fixed dose combination (FDC) vs. placebo, FDC vs. ezetimibe, and FDC vs. bempedoic acid;
2. Key secondary efficacy endpoints which include the percent change from baseline to Week 12 in non-HDL-C, TC, apoB, and hsCRP;
3. Overview of treatment emergent adverse events; and
4. Laboratory parameter of interested including ALT and AST abnormalities. The clinical relevance and statistical significance for the results will be re-evaluated for the primary and key secondary endpoints.

The safety profile will also be reviewed during the sensitivity analysis. The list of tables for sensitivity analysis is provided in

Table 1.

Table 1. List of Tables for Study 1002FDC-053 Sensitivity Analysis.

T14.1.1.1	Patient Disposition
T14.1.2.1	Demographic and Baseline Characteristics - Safety Population
T14.1.2.2	Demographic and Baseline Characteristics - Full Analysis Set
T14.2.1.1.1	Primary Analysis: Percent Change from Baseline in Low-density Lipoprotein Cholesterol (LDL-C) at Week 12 (Multiple Imputation (MI)) Full Analysis Set
T14.2.1.1.3	Sensitivity Analysis: Percent Change from Baseline in Low-density Lipoprotein Cholesterol (LDL-C) at Week 12 (Observed Data) Treatment Completer Analysis Set
T14.2.1.2.1	Statistical Analysis of Percent Change from Baseline in High-sensitivity C-reactive Protein (hsCRP) at Week 12 via Non-parametric Approach (Observed Data) Full Analysis Set
T14.2.1.3.1	Statistical Analysis of Percent Change from Baseline in Non-High-density Lipoprotein Cholesterol (Non-HDL-C) at Week 12 (Multiple Imputation (MI)) Full Analysis Set
T14.2.1.4.1	Statistical Analysis of Percent Change from Baseline in Apolipoprotein B (apo-B) at Week 12 (Multiple Imputation (MI)) Full Analysis Set
T14.2.1.5.1	Statistical Analysis of Percent Change from Baseline in Total Cholesterol at Week 12 (Multiple Imputation (MI) Full Analysis Set
T14.2.2.1	Low-density Lipoprotein Cholesterol (LDL-C) Values and Changes and Percent Changes from Baseline (Conventional Unit) - Full Analysis Set
T14.2.7.1	Summary for Bempedoic Acid Plasma Concentrations by Visit - PK Analysis Set
T14.2.7.2	Summary for Ezetimibe Plasma Concentrations by Visit - PK Analysis Set
T14.3.1.1.1	Overview of Treatment-emergent Adverse Events - Safety Population

T14.3.1.2.1	Treatment-emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term - Safety Population
T14.3.1.2.2	Treatment-emergent Serious Adverse Events (TE SAEs) by System Organ Class and Preferred Term - Safety Population
T14.3.1.2.3	Treatment-emergent Adverse Events (TEAEs) Resulting in Withdrawal of IMP by System Organ Class and Preferred Term - Safety Population
T14.3.1.2.5	Treatment-emergent Adverse Events of Special Interest (AESIs) by System Organ Class and Preferred Term - Safety Population
T14.3.1.4.1	Study-Drug Related Treatment-emergent Adverse Events (TEAEs) by System Organ Class and Preferred Term - Safety Population
T14.3.5.1a	Laboratory Parameters of Interest: Laboratory Abnormalities - Safety Population
Subset of T14.3.4.1.1	Values, Change from Baseline and Percent Change from Baseline in Serum Chemistry Lab Values for uric acid, hemoglobin and creatinine – Safety Population

Addendum II to Statistical Analysis Plan

Title:	A Randomized, Double-Blind, Parallel Group Study to Evaluate the Efficacy and Safety of Bempedoic Acid 180 mg + Ezetimibe 10 mg Fixed Dose Combination Compared to Bempedoic Acid, Ezetimibe, and Placebo Alone in Patients Treated with Maximally Tolerated Statin Therapy.
Protocol:	ETC-1002FDC-053
Clinical Phase:	3
Product:	ETC-1002FDC
Date:	Dec 17, 2018

Addendum II to the Statistical Analysis Plan for Study 1002FDC-053

Post-hoc Analysis

Esperion completed the planned analyses as described in Study 1002FDC-053 SAP for all data collected in the study. After unblinding, some issues of clinical interest were identified. The following is the listing of the tables to address these issues.

Listing of Tables:

Table 17.2.1.1	Statin at Baseline by Anatomic Therapeutic Chemical Class and Preferred Term Full Analysis Set
Table 17.3.1.1	Post-Randomization Abnormal Liver Function Summary Safety Population
Table 17.4.1.1.1	Laboratory Parameters of Interest: Laboratory Abnormalities Subjects on High Intensity Statin at Baseline Safety Population
Table 17.4.1.1.2	Laboratory Parameters of Interest: Laboratory Abnormalities Subjects on Other Intensity Statin at Baseline Safety Population
Table 17.4.1.1.3	Laboratory Parameters of Interest: Laboratory Abnormalities Subjects on No Statin at Baseline Safety Population
Table 17.5.1.1.1	Percent Change from Baseline in Low-density Lipoprotein Cholesterol (LDL-C) at Week 12 by Calculated Baseline Statin Intensity (Observed Data) Full Analysis Set
Table 17.5.1.1.2	Percent Change from Baseline in Low-density Lipoprotein Cholesterol (LDL-C) at Week 12 by Calculated Baseline Statin Intensity (Observed Data) Treatment Completer Analysis Set