Protocol B3461077

A STUDY TO CHARACTERIZE THE SAFETY AND EFFICACY OF TAFAMIDIS ONCE DAILY IN THE TREATMENT OF TRANSTHYRETIN AMYLOID CARDIOMYOPATHY IN CHINESE PARTICIPANTS

Statistical Analysis Plan (SAP)

Version: **2**

Date: 07 Nov 2023

090177e19f1c5412\Approved\Approved On: 08-Nov-2023 04:51 (GMT)

TABLE OF CONTENTS

090177e19f1c5412\Approved\Approved On: 08-Nov-2023 04:51 (GMT)

LIST OF TABLES

APPENDICES

090177e19f1c5412\Approved\Approved On: 08-Nov-2023 04:51 (GMT)

1. VERSION HISTORY

Table 1. Summary of Changes

Version/ Date	Associated Protocol Amendment	Rationale	Specific Changes
2 03 Nov 2023	1 26 Mar 2021	Per protocol amendment 1	• Update whole document per protocol amendment 1 changes • Update use the latest SAP template • Add in details about the endpoints definitions in section 3 • Add in analyses details in Section 6, including COVID-19 analysis • Add in the analysis window for endpoints assessed less frequently in Appendix 1.1 • Add in the Abbreviations in Appendix 2
1 23 Aug 2019	Original 28 Jun 2019	N/A	N/A

2. INTRODUCTION

This statistical analysis plan (SAP) provides the detailed methodology for summary and statistical analyses of the data collected in Study B3461077.

2.1. Modifications to the Analysis Plan Described in the Protocol

Protocol section 9.4.1.2 Electrocardiogram Analyses states categories for QTcF as change from baseline are: ≥30 msec increase, ≥60 msec increase. A ≥75 msec increase category is added in Section 6.2.3.2 as deemed clinical important.

Protocol section 9.4.1.4 Other Safety Assessments states all clinical laboratory data will be summarized by frequency of events and mean changes from baseline. This change from baseline summary will not be done as considered clinical meaningless.

Protocol section 9.4.1.4 Other Safety Assessments states all vital sign measurements will be displayed in listings by participant with changes from baseline values included. This change from baseline values will not be listed as considered clinical meaningless.

Protocol section 9.4.2 states PD endpoints will also be analyzed by TTR genotype. This subset analysis will only be done if sample sizes for both TTR wild-type and variant genotype subsets allowed.

2.2. Study Objectives, Endpoints, and Estimands

Type	Objective	Endpoint	Estimand
Safety	To characterize the safety profile of tafamidis once daily for the treatment of Chinese ATTR-CM patients in clinical practice	Incidence of treatment-emergent adverse events.	Not applicable

090177e19f1c5412\Approved\Approved On: 08-Nov-2023 04:51 (GMT)

		Assessment of laboratory, ECG, Echocardiography, PE, Vital signs, BMI and mBMI at scheduled visits	
Efficacy	To characterize the descriptive efficacy of tafamidis once daily in Chinese ATTR-CM patients	Assessment of 6-MWT, NT-pro BNP, cardiac troponin I, and NYHA at scheduled visits	Not applicable
Pharmacodynamics	To characterize tafamidis pharmacodynamics (PD) in Chinese ATTR-CM patients	TTR stabilization and TTR concentration at baseline (pre dosing) on Day 1, at Months 1, 6, and 12 (or End of Treatment (EOT))	Not applicable
Quality of Life	To characterize the impact on quality of life of tafamidis once daily for the treatment of Chinese ATTR-CM patients	Kansas City Cardiomyopathy Questionnaire overall summary scores, EQ-5D-5L index scores and EQ-5D VAS scores, 12-Item Short Form Survey (SF-12) scores, at Day 1, Months 6, 12 (or EOT)	Not applicable
Pharmacokinetics	To characterize tafamidis pharmacokinetic (PK) in Chinese ATTR-CM patients	Plasma concentrations of tafamidis at Months 1, 6, and 12 (or EOT)	Not applicable

2.3. Study Design

This is a post approval commitment study conducted in China. It is a single-arm, open-label, multicenter study designed to obtain safety, efficacy, PK and PD data in ATTR-CM patients in China. Patients will be evaluated for study eligibility during the screening period between Days -45 and Day -1. At least 53 patients will be treated. All enrolled patients will receive tafamidis free acid (called as tafamidis in the texts hereafter) 61 mg soft capsules orally, once daily for 12 months, starting on Day 1, with scheduled visits at Baseline/Day 1, Month 1, 3, 6, 9 and 12. For the purpose of this study, 1 month is defined as 30 days.

090177e19f1c5412\Approved\Approved On: 08-Nov-2023 04:51 (GMT)

3. ENDPOINTS AND BASELINE VARIABLES: DEFINITIONS AND CONVENTIONS

3.1. Primary Endpoint(s)

- Incidence of treatment-emergent adverse events

An adverse event is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. All adverse events that start after the first dosing but before or on the last dose plus the lag time (28 days) will be flagged as treatment emergent adverse events. Adverse events will be coded according to the Medical Dictionary for Regulatory Activities (MedDRA).

3.2. Secondary Endpoint(s)

Baseline for below endpoints is defined as the last measurement prior to dosing on Day 1 of the study. Change from baseline value is calculated by subtracting the baseline value from follow up visit value.

3.2.1. Efficacy Endpoint(s)

- Change from Baseline in the distance walked during 6 Minute Walk Test (6MWT)

  6MWT is a kind of exercise test for patients with moderate to severe cardiopulmonary disease. It measures the longest distance a patient can walk on a straight course in 6 minutes.

  6MWT will be conducted at baseline, Month 6 and 12.

- Change from Baseline in NT-proBNP concentration

  Plasma amino-terminal pro-B-type natriuretic peptide (NT-proBNP) is a guideline-mandated biomarker in heart failure. Used as an inclusion criterion for therapeutic trials, NT-proBNP enriches trial populations and is a valid surrogate endpoint. NT-proBNP offers prognostic information independent of standard clinical predictors and refines risk stratification.

  Blood sample collection will be performed at baseline, Month 6 and 12 for evaluation of NT-proBNP.

3.2.2. Safety Endpoint(s)

Not applicable.

3.2.3. Pharmacodynamics (PD) Endpoints

- TTR stabilization at Months 1, 6 and 12 (or EOT)

  A responder in TTR stabilization is the participant who achieved TTR stabilization (ie, a participant who is TTR stabilized), defined as the patient whose percent stabilization ≥32%. The stabilization cut-off threshold was based on statistical modeling results: percent stabilization falling above 95% CI in placebo-treated participants with ATTR-CM in Phase 3 Study B3461028 (32%) were determined to be “stabilized”.

090177e19f1c5412\Approved\Approved On: 08-Nov-2023 04:51 (GMT)

- TTR concentration at baseline (pre dosing) on Day 1, at Months 1, 6 and 12 (or EOT)

Refer to the separate Bioanalytical Plan as Appendix of Bioanalytical Report for calculation of TTR concentration and percent stabilization.

3.2.4. Quality of Life Endpoints

All quality of life endpoints will be assessed at baseline, Month 6 and 12 (or EOT)

- Change from baseline in the Kansas City Cardiomyopathy Questionnaire Overall Summary scores (KCCQ-OS)

  Changes from baseline in the KCCQ domain scores (Physical Limitation, Symptom Stability, Symptom Frequency, Symptom Burden, Total Symptom, Self-efficacy, Social Limitation, and Quality of Life) and Clinical Summary Score are also included as endpoints.

  Total Symptom Score is calculated as the mean of Symptom Frequency and Symptom Burden Scores. Clinical Summary Score is calculated as the mean of Physical Limitation Symptom Frequency and Symptom Burden Scores. Overall Summary Score is calculated as the mean of Physical Limitation, Symptom Frequency, Symptom Burden, Quality of Life, and Social Limitation Scores.

- Change from baseline in Short-Form Survey 12 (SF-12, version 2, Acute) score

  The 12-item Short Form Scale scores are summed into 2 scales: physical component summary score (PCS) and mental component summary score (MCS). In addition, 8 sub-scale scores are also included as endpoints: physical function (PF), role physical (RP), role emotional (RE), mental health (MH), bodily pain (BP), general health (GH), vitality (VT), and social function (SF). Higher scores indicate better quality of life.

- Change from baseline in EuroQol 5 Dimensions 5 Levels (EQ-5D-5L) index score and visual analog scale (VAS) scores

3.2.5. Pharmacokinetic (PK) Endpoints

- Plasma concentrations of tafamidis at Month 1, 6 and 12

3.3. Other Safety Endpoints

3.3.1. Laboratory Data

- Incidence of laboratory abnormalities

Laboratory assessments include hematology, serum chemistry, urinalysis, coagulation and RBP tests performed at screening or baseline, Month 1, 6 and 12.

3.3.2. Electrocardiogram Data

- Change from baseline in ECG measurements and incidence of electrocardiogram (ECG) abnormalities

12 lead ECG will be measured during screening, baseline, Month 1, 6 and 12. ECG parameters include heart rate, PR interval, QT interval, QTcF interval and QRS interval.

090177e19f1c5412\Approved\Approved On: 08-Nov-2023 04:51 (GMT)

3.3.3. Echocardiograph Data

- Change from baseline in Echocardiography measurements and incidence of clinically significant changes in Echocardiography from baseline

Echocardiography parameters include end-diastolic interventricular septal wall thickness (mm), left ventricle posterior wall thickness (mm), left ventricular ejection fraction (%), left ventricular stroke volume (mL), fractional shortening (%), left atrial diameter, anterior-posterior (mm), left ventricular end systolic diameter (mm), left ventricular end systolic volume (mL), left ventricular end-diastolic diameter (mm), left ventricular end-diastolic volume (mL), left ventricular mass (g), and the ratio of peak velocity blood flow from gravity in early diastole (the E wave) to peak velocity flow in late diastole caused by atrial contraction (the A wave) (E/A).

Echocardiography will be measured at screening, Month 6 and 12.

3.3.4. Vital Signs

- Incidence of vital sign abnormalities

Vital sign measures include systolic blood pressure, diastolic blood pressure, pulse rate, respiratory rate, and body temperature. Vital signs will be measured at screening, baseline, Month 1, 6 and 12.

3.3.5. Physical Examination

- Incidence of clinical abnormality in physical examination

Full physical examination includes general appearance, head and neck, eyes, ears, skin, nose, throat, genitourinary, neurological, cardiovascular, abdomen, musculoskeletal, and respiratory and assessed at screening. Brief physical examination includes skin, lungs, cardiovascular, and abdomen. It will be assessed at baseline, Month 1, 6 and 12.

3.3.6. Body Mass Index (BMI) and modified Body Mass Index (mBMI)

- Change from baseline in BMI and mBMI

BMI is calculated as Weight (kg) / Height (m) ^2. mBMI is calculated by multiplying BMI (kg/m^2) by serum albumin level (g/L).

Height will be measured at screening. Weight will be measured at screening, baseline, Month 1, 6 and 12.

3.4. Other Endpoints (Efficacy Endpoints)

- Change from Baseline in cardiac troponin I

  Cardiac troponin T (cTnT) and cardiac troponin I (cTnI) were recognized as markers of myocardial damage, Troponin T or troponin I or both may be chronically elevated in cardiac amyloidosis. Cardiac troponin I is thought to be more accurate in assessment of myocardial damage. In the appropriate clinical context of a thickened ventricle and heart failure, an elevated troponin value (outside of an acute coronary syndrome) should trigger suspicion for cardiac amyloidosis.

090177e19f1c5412\Approved\Approved On: 08-Nov-2023 04:51 (GMT)

Blood sample collection will be performed at baseline, Month 6 and 12 for evaluation of cardiac troponin I.

- Change from Baseline in New York Heart Association (NYHA) classification

  The NYHA functional classification is used to describe the functional capacity of adults with congenital heart disease to describe the severity of symptoms and exercise intolerance.

  NYHA functional classification will be assessed at screening, baseline, Month 6 and 12.

3.5. Baseline Variables

- Demographic characteristics
- Basic disease diagnosis
- Medical history
- Serology

4. ANALYSIS SETS (POPULATIONS FOR ANALYSIS)

Participant Analysis Set	Description
Enrolled	All participants who sign the ICD
Safety	All enrolled participants who take at least 1 dose of tafamidis free acid 61 mg soft capsule
Efficacy	The same as the above safety analysis set
Pharmacokinetic (PK)	All safety population who have at least 1 quantifiable plasma tafamidis concentration
Pharmacodynamic (PD)	All safety population who have at least 1 TTR concentration/stabilization value

5. GENERAL METHODOLOGY AND CONVENTIONS

5.1. Hypotheses and Decision Rules

This is an estimation study with no statistical hypothesis nor decision rules.

5.2. General Methods

5.2.1. Analyses for Continuous Endpoints

The data for all continuous endpoints will be summarized by time point in tables containing descriptive statistics (N, mean, standard deviation, standard error of the mean, minimum, 1st, 2nd (median) and 3rd quartiles and maximum) for baseline and change from baseline for those endpoints measured at baseline.

090177e19f1c5412\Approved\Approved On: 08-Nov-2023 04:51 (GMT)

For analyses of PK continuous endpoint of tafamidis concentration, PD continuous endpoints of TTR concentration and percent stabilization (as well as TTR tetramer concentration and FOI used to calculate percent stabilization), percent coefficient of variation (CV%) was used in descriptive statistics instead of standard error of the mean.

5.2.2. Analyses for Categorical Endpoints

The data for categorical endpoints (including binary) will be summarized by contingency tables that show the counts/frequency and percentage in the various categories at each time point. For some categorical endpoints, such as the presence or severity of adverse events, contingency or frequency tables will consider the data over the entire duration of the study and will not be constructed at each time point.

The 2-sided 90% confidence interval for the proportion estimate will be calculated with Clopper-Pearson exact method.

5.3. Methods to Manage Missing Data

For safety data, missing dates and severity of adverse events will be imputed following Pfizer Reporting Standards. No imputation will be done for missing vital signs, ECG, Echocardiography, laboratory and physical examination measurements.

For the KCCQ-OS, SF-12 and EQ-5D-5L instruments, rules suggested by the developers of these will be followed in calculating scores when individual question/items may be missing. If these rules are not enough for calculating a score, then the endpoint will be considered to have a missing value. Missing values in any of the endpoints will not be imputed when summarizing these endpoints using descriptive statistics.

No imputation will be done for 6-MWT, NT-proBNP, tafamidis concentration, TTR stabilization and TTR concentration. Values <LLOQ will be imputed as ½ LLOQ.

6. ANALYSES AND SUMMARIES

All efficacy and safety analyses will base on safety population. The analysis for PD endpoints (TTR stabilization and TTR concentration) will base on PD population. PK analysis will base on PK population. Refer to Section 4 for population definition.

6.1. Primary Endpoint(s)

6.1.1. Incidence of Treatment Emergent Adverse Events

TEAEs will be summarized according to Pfizer Reporting Standards. The summary tables of TEAE and TEAE by System Organ Class (SOC) will be provided. The incidence and severity of TEAE will be presented by SOC and MeDRA Preferred Term (PT). Incidence of serious adverse events and TEAEs that cause withdrawal will be summarized. All adverse events will be listed.

6.2. Secondary Endpoint(s)

For the efficacy endpoints in Section 3.2.1, PD endpoints in Section 3.2.3 and quality of life endpoints in Section 3.2.4, the analysis method described in Section 5.2.1 and Section 5.2.2 will be followed, i.e. the basic summary statistics will be calculated by analysis visit. The estimates over time will be plotted graphically. The individual values will be listed.

090177e19f1c5412\Approved\Approved On: 08-Nov-2023 04:51 (GMT)

6.2.1. Safety Summaries and Analyses Endpoint(s)

Not applicable.

6.2.2. PK Endpoint(s)

Plasma concentrations of tafamidis will be summarized graphically and with descriptive statistics (N, number of participants with observations above lower limit of quantification [NALQ], arithmetic mean, standard deviation, CV%, median, and minimum and maximum) by visit and nominal time. Due to the sparse nature of the pharmacokinetic sampling scheme, a population approach may be used for pharmacokinetic data analysis. Nonlinear mixed-effect modeling may be performed to characterize the pharmacokinetics of tafamidis. If appropriate, these pharmacokinetic data may be used for exposure-response analyses. These analyses results, if conducted, will not be included in CSR but will bereportedly separately.

6.3. Other Safety Summaries and Analyses Endpoints

6.3.1. Laboratory Data

The incidence of laboratory abnormalities observed at any time during the study will be tabulated following Pfizer Reporting Standards. Summary statistics for changes from baseline in RBP will be provided by visit.

6.3.2. Electrocardiograms

Centrally over-read ECG variables will be summarized by mean change from baseline to each measurement time for heart rate, PR interval, QRS interval, QT interval and QTcF (Fridericia correction) intervals. Additionally, the incidence of categorical increases in QTc intervals will be provided. Categories for QTcF are ≥450 msec, ≥480 msec, and ≥500 msec. Categories for QTcF as change from baseline are ≥30 msec increase, ≥60 msec increase and ≥75 msec increase. QTcF is considered the primary QTc value as this correction is more appropriate. In addition, the number (%) of subjects with normal, abnormal not clinically significant, abnormal clinically significant and unevaluable will also be summarized at each visit.

6.3.3. Echocardiograph

The number (%) of subjects with normal, abnormal not clinically significant, abnormal clinically significant and unevaluable will be summarized at each visit. The number (%) of subjects with no baseline/screening, no significant change and significant change compared with baseline will be summarized at each visit. Summary statistics for change from baseline values will also be provided by visit.

6.3.4. Vital Signs

Participants with abnormalities will be summarized by each vital sign parameter. Individual values for actual value will be listed.

6.3.5. Physical Examination

The number and percent of patients with clinical findings at each visit will be summarized following Pfizer Reporting Standards.

090177e19f1c5412\Approved\Approved On: 08-Nov-2023 04:51 (GMT)

6.3.6. BMI and mBMI

BMI and mBMI values at each visit and change from baseline will be presented in summary tables and data listings. Descriptive statistics will be provided by visit.

6.4. Other Endpoints (Efficacy Endpoints)

- Change from Baseline in cardiac troponin I

The analysis method described in Section 5.2.1 will be followed, i.e. the basic summary statistics will be calculated by analysis visit. The estimates over time will be plotted graphically.

- Change from Baseline in New York Heart Association (NYHA) classification

An increase or decrease in NYHA classification relative to baseline will be summarized using a shift table at each time point post-baseline.

6.5. Subset Analyses

All efficacy, safety, quality of life, and PD endpoints (including TTR concentration, percent stabilization [as PD continuous measures], the proportion of participants who achieve TTR stabilization [ie, who has been stabilized, also called responder in TTR stabilization] and its 95% confidence interval [as PD categorical measure]) analyses will be repeated by NYHA baseline classification (I/II or III+). PD endpoints analyses will be repeated by TTR genotype (wild-type or variant), if the sample sizes for both subsets allowed.

6.6. Baseline and Other Summaries and Analyses

6.6.1. Baseline Summaries

Baseline variables will be summarized descriptively. Continuous variables will follow methods in Section 5.2.1. Categorical variables will follow methods in Section 5.2.2. Medical history will be listed by participant.

6.6.2. Study Conduct and Participant Disposition

The end of treatment subject disposition will be shown. Frequency/counts will be provided for subject discontinuation(s) and completion.

6.6.3. Study Treatment Exposure

The duration of treatment will be calculated as: data of the last dose – date of the first dose + 1. Any missed doses/off drug period will be ignored in the duration calculation. The treatment exposure will be defined as the number of days that participant took the study drug (gaps not counted). Both will be summarized in following categories (days): 1, 2-30 (≤1 month), 31-90 (1-3 months), 91-180 (3-6 months), 181-270 (6-9 months), ≥271 (9-12 months).

Since study treatment should be taken once daily, study drug compliance will be calculated for each patient as: treatment exposure / treatment duration × 100. Compliance will be listed as both a continuous and categorical (<80%, ≥80%) endpoint.

090177e19f1c5412\Approved\Approved On: 08-Nov-2023 04:51 (GMT)

6.6.4. Concomitant Medications and Nondrug Treatments

Concomitant medication usage by medication type will be tabulated using the WHO-Drug dictionary and listed following Pfizer Data Standard. Nondrug treatment will be listed as well.

6.7. Additional Analyses Depicting COVID-19 Pandemic Impact

In order to report the impact of COVID-19 on clinical trial populations and study data, the following listings and summaries will be produced:

- Listing of subjects with alternative facility or telehealth visits due to COVID-19 pandemic
- A separate summary table solely for subject discontinuations from investigational product and withdrawal from study related to COVID-19 pandemic, if any, will be provided
- Protocol deviations related to COVID-19 pandemic will be summarized and listed separately. Both important and non-important PDs related to COVID-19 pandemic will be reported
- COVID-19 related AEs, if any, will be reported separately

7. INTERIM ANALYSES

No interim analysis will be conducted for this study. As this is an open-label study, the sponsor may conduct unblinded reviews of the data during the course of the study for the purpose of safety assessment, facilitating PK/PD modeling, and/or supporting clinical development.

7.1. Introduction

Not applicable.

7.2. Interim Analyses and Summaries

Not applicable.

Appendix 1. Data Derivation Details

Appendix 1.1. Definition and Use of Visit Windows in Reporting

To maximize the use of all available data, the analysis visit windows are expanded. For endpoints with post-baseline assessments at Month 1, 6 and 12 (except PK endpoints), the analysis windows are defined in below table. The study day will be calculated as: date of assessment/collection – date of the first dose + 1. If two or more visits/observations fall into the same window, the visit / observation closest to the target day should be used in the analyses. If there is a tie, the later visit should be used. Note: for ECG and Echocardiogram, the central laboratory reading data takes priority. For NT-proBNP, TNI and RBP, only the central laboratory reading data are included in analysis.

Visit Label	Target Day	Definition [Day Window] - Lower	Definition [Day Window] - Upper

090177e19f1c5412\Approved\Approved On: 08-Nov-2023 04:51 (GMT)

Baseline	1	Day 1 = date of first dose of study treatment taken in the study Prior to first dose of study treatment taken in the study	
Month 1	31	16	105
Month 6	181	106	270
Month 12	361	≥271 (Note: Set upper at Day 375 for PD endpoints)	

For endpoints with post-baseline assessments only at Month 6 and 12, the analysis visit windows are defined as below.

Visit Label	**Target Day**	**Definition [Day Window] - Lower**	**Definition [Day Window] - Upper**
Baseline	1	Day 1 = date of first dose of study treatment taken in the study Prior to first dose of study treatment taken in the study	
Month 6	181	91	270
Month 12	361	≥271	

For PK, tafamidis concentrations will be measured at Month 1 pre-dose and 3 hours (±1.5 hours) post-dose; Month 6, 7 hours (± 2.5 hours) post-dose; Month 12, 1 hour (± 30 minutes) post-dose. The PK sampling windows are defined in below table. The sampling time window will be calculated as: time of sample collection – time of dosing of most recent study treatment.

Visit Label	**Planned Time Post Dose (hours)**	**Definition [Time Window] – Lower (hours)**	**Definition [Time Window] – Upper (hours)**
Month 1	0 (Pre-dose)	Prior to dosing of study treatment on the sample collection day	
Month 1	3	1.5	4.5
Month 6	7	4.5	9.5
Month 12	1	0.5	1.5

Appendix 2. List of Abbreviations

Abbreviation	**Term**
6-MWT	6-minutes walk test
AE	Adverse event
ATTR-CM	Transthyretin amyloid cardiomyopathy
ATTR-PN	Transthyretin Amyloid Polyneuropathy
BMI	Body Mass Index
BP	Body pain
CI	Confidence interval
cTNT	Cardiac troponin T
cTNI	Cardiac troponin I
CV	Coefficient of variation
E/A	Ratio of peak velocity blood flow from gravity in early diastole (the E wave) to peak velocity flow in late diastole caused by atrial contraction (the A wave).

090177e19f1c5412\Approved\Approved On: 08-Nov-2023 04:51 (GMT)

Abbreviation	Term
ECG	Electrocardiogram
EOT	End of Treatment
EQ-5D VAS	EuroQoL 5 Dimensions visual analogue scale
EQ-5D-5L	EuroQoL 5 Dimensions 5 Levels
FOI	Fraction of initial tetramer concentration
KCCQ	Kansas City Cardiomyopathy Questionnaire
mBMI	Modified Body Mass Index
MCS	Mental component summary score
MH	Mental health
NT-proBNP	N Terminal prohormone B type Natriuretic Peptide
NYHA	New Year Heart Association
PCS	Physical component summary
PD	Pharmacodynamics(s)
PK	Pharmacokinetic(s)
PR	PR interval
QD	Once daily
QRS	QRS complex
QT	QT interval
QTc	Corrected QT
QTcF	Corrected QT (Fridericia method)
RE	Role emotional
RP	Role physical
SAE	Serious adverse event
SAP	Statistical analysis plan
SF	Social function
SF-12	12-short item survey form
TEAE	Treatment-emergent adverse events
TnI	Troponin I
TTR	Transthyretin

090177e19f1c5412\Approved\Approved On: 08-Nov-2023 04:51 (GMT)