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Title:

An Open-Label Extension Trial of UT-15C SR in Subjects with Pulmonary Arterial Hypertension

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ABBREVIATIONS AND DEFINITIONS

Abbreviation	Definition
6MWD	Six minute walk distance
AE	Adverse event
BID	Twice daily
CRF	Case report form
CSR	Clinical study report
ERA	Endothelin receptor antagonist
K-M	Kaplan-Meier
MedDRA	Medical Dictionary for Regulatory Activities
OL	Open-label
PAH	Pulmonary arterial hypertension
PDE-5i	Phosphodiesterase type 5 inhibitor
PT	Preferred term
SAP	Statistical Analysis Plan
SOC	System organ class
SR	Sustained release
TID	Three times daily
WHO	World Health Organization

1 PREFACE

This statistical analysis plan (SAP) provides further details of the planned analyses for the TDE-PH-304 study. The purpose of this SAP is to ensure that the statistical methodologies that will be used, and the data listings, summary tables, and figures which will be produced, are appropriate and complete to support valid conclusions regarding the study objectives and the completion of the Clinical Study Report (CSR). Additional post-hoc or unplanned analyses, which are not defined in this SAP, may be performed to support the clinical development program. Such analyses will be documented in the CSR.

2 STUDY OBJECTIVES AND ENDPOINTS

2.1 OBJECTIVES

The objectives of this study are to:

- Provide, or continue to provide, UT-15C sustained release (SR) for eligible subjects who participated in protocols TDE-PH-202, TDE-PH-203, TDE-PH-205, TDE-PH-301, TDE-PH-302, TDE-PH-308, or additional UT-15C SR clinical protocols.
- Assess the long-term safety of UT-15C SR in these subjects through assessment of adverse events and laboratory parameters.
- Assess the effect of continued therapy with UT-15C SR on exercise capacity after one year of treatment.

2.2 ENDPOINTS

The safety endpoints are as follows:

- Adverse events (AEs)
- Clinical laboratory parameters

Pulmonary arterial hypertension (PAH) concomitant medications also will be documented.

Efficacy will be assessed by a 6-Minute Walk Test and Borg Dyspnea Score to be conducted after each subject has completed one year of therapy with UT-15C SR.

3 STUDY DESIGN

This is an open-label (OL) study. Each subject's visit schedule will allow assessments after defined periods of exposure to UT-15C SR (3, 6, 12, 24, and 36 months total exposure). The study will continue with yearly visits beyond 36 months until either UT-15C SR is approved by the appropriate regulatory authorities or the study is discontinued by the sponsor. Therefore, the actual date of each visit will be determined by the date on which the subject first received UT-15C SR (e.g., the date of study drug initiation in TDE-PH-301, TDE-PH-302, or TDE-PH-308 for subjects who were randomized to active therapy in those studies, and the date of UT-15C SR initiation in this study for subjects who were randomized to placebo in the previous controlled study). Note that the TDE-PH-202, TDE-PH-203, and

TDE-PH-205 studies are OL in design and therefore will follow the regimen for subjects receiving UT-15C SR.

Subjects enrolled from the TDE-PH-202 study who were in Dose Groups 1 or 2 and permanently discontinued treatment may enter the study if they undergo all premature termination assessments prior to discontinuing study drug and complete all remaining scheduled study visits and assessments (with the exception of the hemodynamic measurements) through Week 12. These subjects should follow the same procedures as subjects who received placebo in the previous study and will begin on a dose of 0.25mg twice daily (BID).

Subjects randomized to UT-15C SR in Protocol TDE-PH-301, TDE-PH-302, or TDE-PH-308 will complete visits 2-5 and yearly visits thereafter, while subjects randomized to placebo in Protocol TDE-PH-301, TDE-PH-302, or TDE-PH-308 will complete visits 1-5 and yearly visits thereafter. A 6-Minute Walk Test and Borg Dyspnea Score will be conducted at the visit occurring 12 months after the subject's initial exposure to UT-15C SR.

Monthly telephone calls must be conducted for all subjects actively participating in TDE-PH-304, regardless of study drug allocation in the previous study. In addition to the scheduled study visits, all subjects must be seen in the clinic no less than once every six months for routine standard of care medical evaluation.

4 RANDOMIZATION

This study is not randomized. All subjects will receive UT-15C SR during the OL study.

5 SEQUENCE OF PLANNED ANALYSES

Interim analyses will occur to support regulatory submissions (e.g., NDA, 120-day safety updates, etc.) and as frequently as yearly in order to continuously monitor the long-term safety of oral treprostinil in this ongoing study. For each interim analysis, the data currently in the database will be soft locked by Data Management and provided to Statistics and Programming for creation of output as described in this analysis plan.

6 SAMPLE SIZE CONSIDERATIONS

The sample size for this study was not derived through a power calculation, but rather an assumption about the number of subjects who would enroll in this OL study after completion of their UT-15C SR clinical protocol. The sample size is expected to be approximately 900 subjects from protocols TDE-PH-202, TDE-PH-203, TDE-PH-205, TDE-PH-301, TDE-PH-302, and TDE-PH-308, plus additional subjects from any additional UT-15C SR clinical protocols evaluating subjects with PAH.

7 ANALYSIS POPULATIONS

All available data from all subjects enrolled in the TDE-PH-304 study will be used as detailed in this analysis plan. Additionally, subjects who were treated with active drug during the parent study and who enrolled in the TDE-PH-304 study will have the data from the parent study included in the data analyses and listings for this study, as detailed in this SAP.

Subjects who were treated with placebo during the parent study and who enrolled in the TDE-PH-304 study will have baseline data only from the parent study included in the data analyses and listings for this study, as detailed in this SAP.

8 GENERAL CONSIDERATIONS FOR DATA ANALYSES

All available data for subjects enrolled in TDE-PH-304 (regardless of treatment with active drug) will be included in each soft lock and will be listed. All available data for enrolled subjects who were treated with active drug in study TDE-PH-304 will be summarized, as detailed in this SAP. Subjects from the 200 series studies (TDE-PH-202, TDE-PH-203, and TDE-PH-205) that enrolled into the TDE-PH-304 study will be pooled for summarization purposes with the two de novo subjects previously enrolled in the TDE-PH-301 study. These two de novo subjects were initially enrolled in TDE-PH-301, but were later withdrawn from that study following a temporary drug recall in June 2006 and were subsequently directly enrolled in the TDE-PH-304 OL study. Likewise, subjects from studies TDE-PH-301 and TDE-PH-308 will be pooled for summarization purposes.

In general, listings will be sorted by subject number and scheduled assessment (if applicable). Listings will include assessment date, assessment time (if available), and study day. For data collected on a fixed schedule, the assessment identifier will also be included on the listing.

In general, the data will be summarized by scheduled assessment (if applicable). For continuous variables, the summary statistics will include the mean, standard deviation, standard error, median, lower quartile, upper quartile, minimum, and maximum. Minimums and maximums will be expressed using the level of precision in which the variable was collected. All other statistics will be rounded, using an additional decimal point. For discrete variables, summaries will include the frequency and percent in each category. Percentages will be rounded to a whole number. Whenever practical, categories of discrete variables will be ordered and labeled as they appear in the case report form (CRF), and all categories represented on the CRF will be included in summaries, even when they do not apply to any subjects in the study.

8.1 EXAMINATION OF SUBGROUPS

All summaries will be provided by previous study and overall to allow examination of impact from previous study. Other exploratory subgroup analyses will be performed as data permit.

8.2 PREMATURE DISCONTINUATION AND MISSING DATA

A subject may voluntarily withdraw or be withdrawn from the study by the Investigator at any time for reasons including, but not limited to, the following:

- The subject wishes to withdraw from further participation.
- A serious or life-threatening AE occurs or the Investigator considers that it is necessary to discontinue study drug to protect the safety of the subject.
- The subject deviated from the protocol.
- The subject's behavior is likely to undermine the validity of his/her results.
- The subject becomes pregnant

8.3 MULTIPLE COMPARISONS AND MULTIPLICITY

No multiple comparison adjustments are planned for analysis of this study.

9 STUDY POPULATION

9.1 SUBJECT ACCOUNTABILITY

A listing of subject disposition and study drug exposure will include subject number, previous study number, first and last active drug dose dates, data cutoff date, study drug exposure (weeks), discontinuation status, reason for discontinuation, and any details regarding discontinuation status. Study drug exposure will account for all active drug exposure, including time on active drug during the parent study, where applicable. A comprehensive listing will be generated containing subject number and previous study number. The summary of subject accountability will include the number (percent) of subjects in each double-blind study treatment group, who consented prior to study assessments, who discontinued the study prematurely, who reached each visit as their maximum visit, and each reason for discontinuation. These summaries will be provided by previous study and overall.

9.2 ELIGIBILITY CRITERIA

The listing of admission criteria will include each subject's status regarding meeting all admission criteria for the TDE-PH-304 study as well as any details noted in the CRF. The listing of admission criteria violations will include only those subjects who did not meet all admission criteria and any details regarding their criteria evaluation. The summary of admission criteria violations will include a categorical summary of the CRF question "Did the subject meet all entry criteria," with possible choices of no, yes, and missing, by previous study and overall.

9.3 OTHER DESCRIPTIONS OF STUDY POPULATION

9.3.1 Demographics

The listing of subject demographics will include subject, previous study number, age (years), sex, ethnicity, and race. Age is calculated as the age at the time of the first dose of active drug (active drug dosing occurred either during the parent study or during the OL study, depending on whether subjects were treated with active or placebo in the parent study, respectively). The summary of demographics will include descriptive statistics for age (years) and categorical summaries for age (<18, 18-64, >64 years), sex, ethnicity, and race. Each categorical summary will include a row for missing, as applicable, in order to sum to 100% of subjects. These summaries will be provide by previous study and overall.

9.3.2 PAH History

The listing of PAH history will include the number of years since PAH diagnosis, etiology, WHO functional class at baseline, background PAH therapy (none, endothelin receptor antagonist [ERA], phosphodiesterase type 5 inhibitor [PDE-5i], and ERA+PDE-5i), background ERA, and background PDE-5i. The number of years since PAH diagnosis is calculated as the time from diagnosis to first dose of active drug. The summary of PAH history will include descriptive statistics for years since PAH diagnosis, six minute walk

distance at baseline, and Borg Dyspnea Score at baseline. The summary will also include categorical summaries for etiology, background PAH therapy, background ERA, background PDE-5i, and WHO functional class at baseline.

9.3.3 PAH Therapy

The listing of PAH Concomitant Medications will include subject, previous study, and all concomitant PAH medications that were denoted as either ongoing at the start of the TDE-PH-304 study or added during the TDE-PH-304 study (start date of medication is on or after start date of study enrollment), with appropriate designation. The correspondence of raw concomitant medication names to coded generic terms will be listed. The summaries of PAH concomitant medications will be separated by those ongoing at the start of the TDE-PH-304 study and those added during the TDE-PH-304 study. These summaries will be provided by previous study and overall, and will include the number (percent) of subjects reporting each WHO Drug Dictionary medication name, as well as the number of records for each medication name. The PAH medications that were added during the TDE-PH-304 study will also be categorically summarized by PAH therapy class (ERA, PDE-5i, oral/inhaled prostacyclin, parenteral prostacyclin, and none) within each previous study and overall.

9.3.4 Concomitant Therapy

The listing of Other Concomitant Medications will include subject, previous study, and all concomitant medications that were reported during the study (start date of medication is on or after start date of study enrollment). The summary will be provided by previous study and overall and will include the number (percent) of subjects reporting each medication category (as specified on the CRF), as well as the number of records for each medication category, at each scheduled visit.

10 EFFICACY ANALYSES

10.1 SIX MINUTE WALK TEST

The listing of six minute walk distance (6MWD) will include subject, previous study, and all reported 6MWDs, and their associated Borg Dyspnea Scores. The summaries of 6MWD at Month 12 will be provided by previous study and overall, treatment assignment in previous study (active/placebo), PAH medication use (no new therapy added/new PAH therapy added), PAH etiology (idiopathic/familial, collagen vascular disease, other), baseline WHO functional class, and dosing quartiles and tertiles. The summaries will include a categorical summary of current status, as well as descriptive statistics for baseline 6MWD, 6MWD at Month 12, and the change in 6MWD from baseline to Month 12.

Achievement of a walk distance of at least 380 meters at Month 12 will be summarized by previous study and overall. Achievers and non-achievers will then be summarized based on their baseline walk ($\leq$380 meters vs. >380 meters) by previous study and overall.

Note that all six-minute walk test summaries will exclude subjects from study TDE-PH-205 since the goal of that study was to maintain six-minute walk test performance after transition; thus, no improvements were expected. All associated listings, however, will include the subjects from TDE-PH-205.

The summaries of the Borg Dyspnea Score at Month 12 will be provided by previous study and overall, previous study treatment assignment, and PAH medication use. The summaries will include a categorical summary of current status, as well as descriptive statistics for baseline Borg Dyspnea Score, Borg Dyspnea Score at Month 12, and the change in Borg Dyspnea Score from baseline to Month 12. Note that the Borg Dyspnea Score summaries will exclude subjects from study TDE-PH-205 since the goal of that study was to maintain six-minute walk test performance after transition; thus, no improvements were expected.

10.2 CLINICAL EVENTS

Clinical events, including death, study discontinuation for any reason, addition of PAH therapy, and addition of parenteral PAH therapy, will be listed, including date of each event, if applicable, as well as the subject's previous background therapy status (naïve, single background therapy, or double background therapy). Note that events may have occurred during the parent study for those subjects treated with active drug during the parent study, thus event data from the parent study will be included in these data analyses. The following combinations of clinical events will be utilized for summarization and plotting purposes, separately:

- Study discontinuation for any reason
- Death or discontinuation due to disease progression
- Death, discontinuation due to disease progression or addition of PAH therapy
- Death, discontinuation due to disease progression or addition of parenteral PAH therapy
- Death

Summary tables will be produced by previous study and overall and will display the number (percent) of subjects who experienced each event combination detailed above. Kaplan-Meier (K-M) curves for the above combinations of clinical events will be provided separately. Each K-M plot will include a time to clinical event curve for each of the previous studies overlaid on the same plot.

11 SAFETY ANALYSES

11.1 EXTENT OF EXPOSURE

Study drug exposure will be listed, including subject number, previous study, concomitant medication use, BID to three times daily (TID) transition, exposure (weeks), and categorical exposure (by visit). Exposure is calculated as the time exposed to active study drug. For subjects treated with active drug during the parent study, exposure calculations will include their exposure during the parent study. For subjects treated with placebo during the parent study, exposure calculations will include only the exposure to active drug during the OL study. The summary of disposition and study drug exposure will detail the number (percent) of subjects who died during the study, as well as the study drug exposure both by categorical visits (≥3 months, ≥6 months, etc.) and using descriptive statistics. The total study drug exposure (pt-years) will also be displayed.

Study drug dosing will be summarized at each visit by previous study and overall. The summary will include a categorical summary of current status (in study, death, progression of PAH, AE, consent withdrawn, lost to follow-up, discontinued for other reasons, etc.) and study drug dose (<1 mg, 1-<2.5 mg, 2.5-<5 mg, 5-<10 mg, 10-<20 mg, 20-<30 mg BID/TID), as well as a descriptive statistics summary of study drug dose (mg BID/TID).

Study drug dosing will also be summarized at each visit by PAH background medication use, grouping subjects into monotherapy and combination therapy groups. The summary table will mimic that presented in the summary of study drug dosing by previous study, but will produce a separate summary table for each PAH background medication use group.

The summary of BID to TID transition will detail the number (percent) of subjects who completed this transition and who had to transition back to BID (if applicable), and descriptive statistics on the doses both before and after the transition by previous study and overall. All of these summaries will be provided by previous study and overall.

11.2 ADVERSE EVENTS

Adverse event summaries will include treatment emergent AEs. Treatment emergent AEs include those reported during the parent study for those subjects who were treated with active drug during the parent study. For subjects treated with placebo during the parent study, only those AEs reported during the TDE-PH-304 study are considered treatment emergent.

The AEs will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) and all summaries will utilize the preferred term (PT) and/or System Organ Class (SOC). The correspondence of raw AE terms to PTs and SOCs will be listed. All AEs and serious AEs will be listed by subject, including onset date/day, cessation date/day, verbatim term, PT, SOC, seriousness, severity, relationship to study drug, frequency, and action taken with study drug. The summaries of AEs will be provided by previous study and overall. The summaries of AEs, serious AEs, severe AEs, AEs reasonably or possibly related to study drug, and AEs leading to permanent discontinuation of study drug will include the number of subjects (percent of subjects) and number of events for each reported PT. The summary of AEs by body system will include the same statistics, but will group the PTs by their respective SOCs.

The summary of AEs by exposure will include the number of subjects (percent of subjects) and number of events for each reported PT, as well as the number of events per patient year of exposure. Note that only those subjects with calculated exposure will have AEs contributing to this summary.

11.3 DISEASE RELATED EVENTS

The disease-related events reported during the TDE-PH-304 study will be listed, including subject number, previous study, and symptom. The summary will include the number (percent) of subjects who reported each symptom by previous study and overall.

11.4 DEATHS

All deaths occurring within 30 days of study TDE-PH-304 participation will be listed by subject, including previous study, first dose, last dose, discontinuation date, reason for discontinuation, date of death, day of death, and cause of death. The summary of deaths will be presented by previous study and overall and will include the number (percent) of subjects who died within 30 days of study participation and their causes of death.

11.5 CLINICAL LABORATORY TESTS

All clinical laboratory data from the parent studies and from study TDE-PH-304 will be incorporated in these laboratory listings and summaries. The laboratory data will be listed by subject and previous study, including all hematology and clinical chemistry parameters by scheduled time point. Each parameter will include its respective normal range in the row label. A designation for low (L) and high (H) will be included for those laboratory values that are outside the normal range. The listing of urinalysis will also be presented by subject and previous study and will include each scheduled and unscheduled urinalysis assessment. The date/time, study day, and window will be provided for each assessment as well as the result of the test.

Plots will be generated for both hematology and clinical chemistry shifts from baseline. For each parameter, two plots will be generated displaying baseline values on the x-axis and minimum/maximum values on the y-axis, respectively. The plots will be scatter plots that utilize a different plotting symbol for each previous study denotion. A line of unity will be overlaid on the plot to aid in understanding the shift from baseline for each parameter.

12 APPENDICES

12.1 INCLUSION AND EXCLUSION CRITERIA

A subject is eligible for inclusion in this study if all of the following criteria apply:

1. The subject has remained on study drug and completed all assessments during the Treatment Phase of the previous study (TDE-PH-202, TDE-PH-203, TDE-PH-205,TDE-PH-301, TDE-PH-302, or TDE-PH-308 [or other studies evaluating PAH])

OR

The subject permanently discontinued study drug during the Treatment Phase of the previous study (TDE-PH-301, TDE-PH-302, or TDE-PH-308) due to clinical worsening, completed premature termination assessments prior to discontinuing study drug, completed all remaining scheduled study visits, AND received placebo during the Treatment Phase of the previous study (TDE-PH-301, TDE-PH-302, or TDE-PH-308).

OR

The subject was randomized into Dose Group 1 or Dose Group 2 in the TDE-PH-202, permanently discontinued study drug during the 12-week Treatment Phase due to clinical worsening, completed all premature termination assessments prior to discontinuing study drug, and completed all remaining scheduled study visits and assessments (with the exception of the hemodynamic measurements) through Week 12. Such subjects should start treatment with UT-15C in the open-label study at 0.25 mg BID.

2. The subject voluntarily gives informed consent to participate in the study.
3. Women of child bearing potential include any female who has experienced menarche and who has not undergone successful surgical sterilization (hysterectomy, bilateral tubal ligation or bilateral oophorectomy) or is not postmenopausal (defined as amenorrhea for at least 12 consecutive months). Sexually active women of childbearing potential must use two effective forms of contraception during the length of the study. Medically acceptable forms of effective contraception include: (1) approved hormonal contraceptives (such as birth control pills), (2) barrier methods (such as a condom or diaphragm) used with a spermicide, (3) an intrauterine device (IUD), (4) partner vasectomy, or (5) abstinence. Males participating in the study must use a condom during the length of the study, and for at least 48 hours after discontinuing study medication.

A subject is ineligible for inclusion in this study if any of the following criteria apply:

1. The subject permanently discontinued study drug during the previous study (TDE-PH-202, TDE-PH-203, TDE-PH-205, TDE-PH-301, TDE-PH-302, or TDE-PH-308) due to treatment related adverse events.

2. The subject permanently discontinued study drug during the Treatment Phase of the previous study (TDE-PH-202, TDE-PH-203, TDE-PH-205, TDE-PH-301, TDE-PH-302, or TDE-PH-308) due to clinical worsening (as defined in those study protocols) and did not undergo premature termination assessments prior to discontinuing study drug, and/or did not complete all remaining study visits through the final scheduled visit.

3. The subject permanently discontinued study drug during the Treatment Phase of the previous study (TDE-PH-301, TDE-PH-302, or TDE-PH-308) due to clinical worsening, completed premature termination assessments prior to discontinuing study drug, completed all remaining scheduled study visits AND received UT-15C SR during the Treatment Phase of the previous study (TDE-PH-301, TDE-PH-302, or TDE-PH-308).

   Subjects enrolled in the TDE-PH-202 study who were randomized into the iMTD group who clinically worsen may not participate. Subjects who permanently discontinue study drug during the 12-week Treatment Phase due to treatment related adverse events are not eligible even if they complete all remaining scheduled study visits. Subjects who permanently discontinue study drug during the 12-week Treatment Phase and do not undergo premature termination assessments prior to discontinuing study drug and/or who do not complete all remaining study visits through the Week 12 visit are also not eligible.

4. The subject must not have developed any concurrent illness or condition during the conduct of the previous study, including but not restricted to, sleep apnea, chronic renal insufficiency, anemia, uncontrolled systemic hypertension or left sided heart disease, unless their physician feels that entry into this study would not be detrimental to their overall health.

12.2 LIST OF TABLES

Table titles suggested here may be altered or edited as appropriate by the clinical data programmers while maintaining the original intent of the summary.

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