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STATISTICAL ANALYSIS PLAN

A double-blind, single-center, randomized, placebo- and positive-controlled, parallel-group trial with a nested crossover part on the electrocardiographic effects of 100 and 400 mg pritelivir per day in healthy subjects: a through QT/QTc trial

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Contents

LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation or Specialist Term	Explanation
AE	Adverse Event
CTR	Clinical Trial Report
DRM	Data Review Meeting
ECG	Electrocardiogram
H	High
HR	Heart rate
IMP	Investigational Medicinal Product
L	Low
MedDRA	Medical Dictionary for Regulatory Activities
PK	Pharmacokinetic(s)
PKS	Pharmacokinetic Set
PR	ECG PR Interval
PROC	Procedure in SAS
QRS	ECG Ventricular Conductance Time
QT	ECG QT interval uncorrected
QTc	ECG QT interval corrected
QTcF	ECG QT interval corrected using Fridericia's formula
QTcI	ECG QT interval corrected using a subject specific ("individual") correction
QTcS	ECG QT interval corrected using a trial specific correction
RPL	Richmond Pharmacology Ltd
SAP	Statistical Analysis Plan
SAS	Statistical Analysis Software
SD	Standard Deviation
SOC	System Organ Class
TOM	Trial Operation Manual
SS	Safety Set
TEAE	Treatment-Emergent Adverse Event
t_{max}	Time to Maximum Observed Plasma Concentration

1. INTRODUCTION

The purpose of this Statistical Analysis Plan (SAP) is to define the variables and provide details of the planned analysis for addressing the objectives of this trial.

The protocol dated 25 November 2022, version 2.0 was used to prepare this SAP.

Statistical analysis and reporting will be performed by Richmond Pharmacology (RPL) for safety, demographics and ECG analysis as described within this SAP. Pharmacokinetic (PK) parameters calculations and statistical analyses are out of scope of this SAP and details will be provided by Venn Life Sciences.

2. Trial OBJECTIVES AND ENDPOINTS

2.1 Trial objectives

Primary

- To define the effects of pritelivir on the QTcF interval derived from 12-lead ECGs in comparison with placebo in male and female subjects

Secondary

- To assess pharmacokinetic properties of multiple doses of pritelivir and to examine the correlations between pritelivir plasma concentration and its effects, if any, on the QTcF interval
- To evaluate additional electrocardiographic effects of pritelivir
- To show the trial's assay sensitivity by assessing the effects of moxifloxacin (positive control vs. placebo) on the QTcF interval
- To investigate the safety and tolerability of pritelivir

2.2 Endpoints

Primary

- QTc using Fridericia correction method (QTcF). The primary endpoint is defined as the model based QTcF change from baseline (ΔQTcF), where baseline is the average of the 3 pre-dose measurements of Day 1. ECGs from Day 1, Day 6 and Day 16 will be used for comparison against baseline.

Secondary

- Heart rate
- PR interval
- QRS interval
- Uncorrected QT interval
- Change in ECG morphological patterns

Safety and tolerability

- Overall tolerability
- Nature, frequency, duration, intensity, seriousness, and causality of adverse events

- Physical examination, vital signs, and body temperature
- Clinical laboratory parameters: serum chemistry, hematology and coagulation parameters, urinalysis
- Standard 12-lead ECG collected using a 12-lead ECG device

Pharmacokinetics

Plasma concentrations of pritelivir and its metabolites AIC090015 and AIC090105 will be determined for the purpose of the concentration-effect analysis (described in this document) as well as for standard pharmacokinetic evaluation (described in the separate PK SAP).

Moxifloxacin plasma concentrations will be determined for the purpose of the concentration-effect analysis to demonstrate assay sensitivity. The concentrations will be reported, but no pharmacokinetic parameters will be determined.

Pharmacogenomics/ gene expression

- Post-hoc analysis of alleles associated with altered drug metabolism/ disposition may be determined.

3. TRIAL DESIGN

3.1 Overall Trial Design

This Phase 1 clinical trial is a double-blind, single-center, randomized, placebo- and positive-controlled, parallel-group, 'nested crossover' trial with multiple oral dose administration of pritelivir or matching placebo as well as a single oral administration of moxifloxacin (positive-control) and corresponding matching placebo in healthy male and female subjects.

Subjects will be in-house from Day -2 to Day 20 and will be randomized to one of the 2 parallel treatment groups: Group 1 will receive a therapeutic and a supra-therapeutic dose of pritelivir plus moxifloxacin placebo. Group 2 will receive pritelivir placebo as well as moxifloxacin and matching placebo (nested crossover: Group 2a and Group 2b). 12-lead ECG triplicates will be recorded from the bedside 12-lead-ECG on the Days -1, 1, 2, 6, 16, and 17 and will be analysed afterwards in each group for these 6 days of documentation by a blinded reader.

It is of note that Holter ECG data will be collected in parallel at screening to exclude anyone with pre-existing cardiac problems as well as on Days -1, 1, 2, 6, 16, and 17 as a back-up for the bedside 12-lead-ECGs.

In Group 1, 32 male and female subjects (at least 12 subjects per sex) will receive a loading dose of 400 mg pritelivir on Day 1. Afterwards they will receive 100 mg pritelivir qd from Day 2 to 6 and 400 mg pritelivir qd from Day 7 to 16. Furthermore, these subjects will receive matching moxifloxacin placebo on the Days 2 and 17.

In Group 2, 32 male and female subjects (at least 12 subjects per sex) will receive the respective amounts of tablets of matching pritelivir placebo from Day 1 to Day

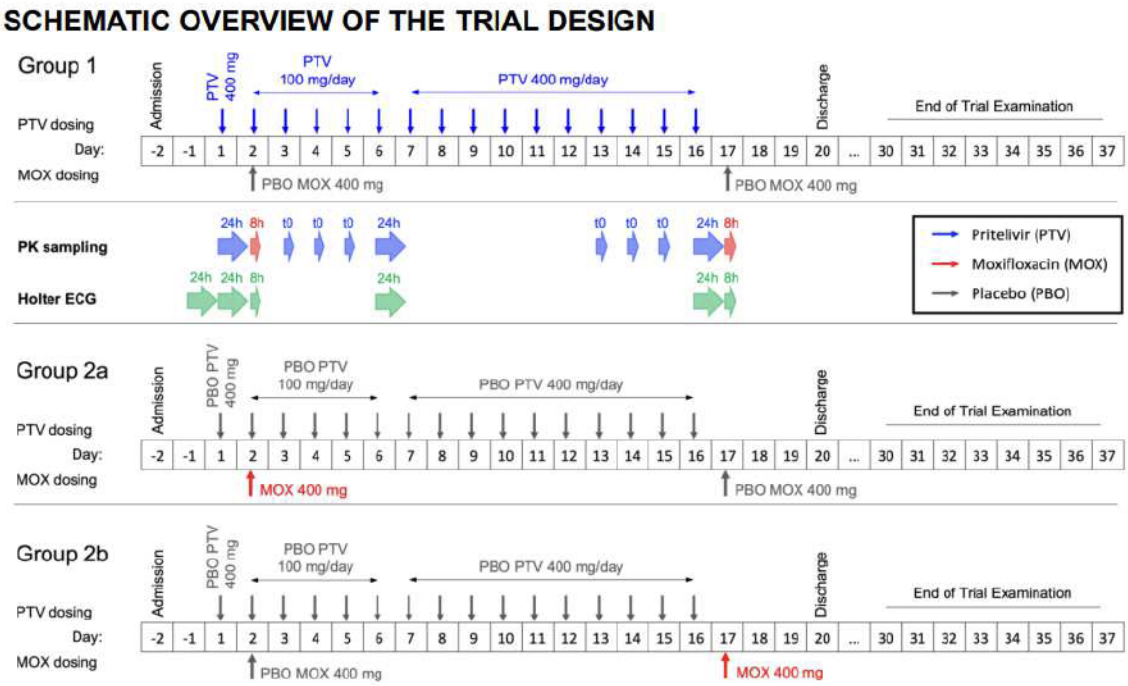
16 in Group 2 as verum tablets in Group 1. Furthermore, subjects in Group 2a (16 male and female subjects) will receive 400 mg moxifloxacin on Day 2 and matching moxifloxacin placebo on Day 17 and subjects in Group 2b (16 male and female subjects) will receive 400 mg moxifloxacin on Day 17 and matching moxifloxacin placebo on Day 2.

Different measures will be needed, and data evaluations generated for Group 1 and Group 2, however, to maintain double blinding between Group 1 and Group 2;

- 12-lead ECG triplicates will be recorded and analysed from the bedside 12-lead-ECG devices in subjects of both groups on the Days -1, 1, 2, 6, 16 and 17.
- PK samples will be collected from subjects of both groups on the Days 1, 6, and 16 for pritelivir and the metabolites AIC090015 and AIC090105 as well as for moxifloxacin on the Days 2 and 17.
- Over-encapsulated moxifloxacin- and matching placebo will be used.

If AEs interfere with adequate ECG recording, a Risk Benefit Committee (participants from AiCuris as well as the Principal Investigator) might decide to lower the (supra-therapeutic) dose in individual subjects.

Figure 1: Trial flow chart



3.2 Sample Size

Simulations by Huang et al suggest that using concentration-response analysis, assay sensitivity can be shown with at least 24 subjects [1]. Since in this trial, the

time between the 2 periods of the nested crossover is 14 days, it seems prudent to allow for a slightly higher variability of ΔQTc and, therefore, a sample size of 32 subjects has been planned. Assuming a true effect of at most 3 ms, i.e., a margin of 7 ms, the power to show absence of an effect of pritelivir is higher than that to show assay sensitivity where the margin may be assumed to be 5 ms. Therefore, 32 subjects in the active group were chosen.

3.3 Randomisation and Blinding

Subject Randomisation

Subjects will be randomly assigned to Group 1, Group 2a, or Group 2b at a 2:1:1 ratio. All subjects in this trial will be assigned to a treatment regimen according to a randomization schedule generated by a statistician using PROC Plan. Details regarding the unique screening and subject number will be included in the TOM.

Maintenance and methods for ensuring blinding

The pharmacy staff preparing the IMP will not be blinded to trial drug assignment. During the trial, the individual randomization codes will be kept in the site's clinical trials pharmacy, accessible to the pharmacy personnel only. Upon completion of the trial, after the database lock and after the blind is revealed, the randomization list will be filed in the Trial Master File. Administrative and operational staff of the trial site, including Principal Investigator and trial manager as well as monitors, AiCuris staff and data managers will remain blinded during the course of the trial until Database Lock and finalization of the Statistical Analysis Plan.

Unblinding Procedure

In the event of an emergency, an envelope for each subject containing his/her trial drug assignment will be available in the pharmacy at the clinical trial site. Unblinding should only be considered for the safety of the subject. If unblinding is deemed necessary by the Investigator, the Investigator or designee can unblind the subject's treatment allocation using the envelope available from the pharmacy. The Investigator or designee must note the date, time, and reason for unblinding and inform the Sponsor of unblinding as soon as practicably possible.

4. STATISTICAL ANALYSES

4.1 General Notes for Statistical Analyses

Statistical analysis and reporting will be performed by RPL for safety, demographics and ECG analysis and by Venn Life Sciences for pharmacokinetics.

In general, descriptive statistics for continuous variables will include number of non-missing values (n), arithmetic mean, standard deviation (SD), median, minimum, and maximum.

Categorical variables will be summarized using frequency counts and percentages.

For all tables, descriptive statistics for minimum and maximum will be presented with the same decimal digits as the original data, and with 1 more decimal place

than the original data for mean and median; SD and SE will be reported with 2 more decimal places than the original data. Degrees of freedom based on the Kenward Roger approximation will be presented with one decimal.

The analyses will be presented overall (where appropriate) and by the treatment groups.

All collected data will be presented in by-subject listings. Listings will be ordered by treatment group and subject number and will include all randomized subjects.

Unless otherwise stated, baseline will be defined as the last non-missing value prior to first administration of trial drug. Changes from baseline values will be calculated as the post-baseline assessment value minus the baseline value. Only observed values from scheduled time points will be used to create summary tables.

If repeated measurements are made at a time point, the first scheduled value will be used for summary analysis, unless otherwise stated in relevant section of this SAP.

Deviations from the planned analyses will be described in the final clinical trial report (CTR).

4.2 Interim Analysis

No interim analysis is planned for this trial.

4.3 Analysis Sets

The analysis of data will be based different analysis sets according to the purpose of analysis. Subject eligibility for each analysis set will be finalised before the database hard lock. A subject who withdraws prior to the last planned observation in a trial period will be included in analyses up to the time of discontinuation.

The following data sets will be used for analysis and presentation of the trial data:

Safety Set

The safety set (SS) will consist of all randomised subjects who received at least one dose of the trial medication.

PK Set

The Pharmacokinetic Set (PKS) will include all subjects in SS who had at least 1 valid plasma concentration-time point to be included in the PK analysis. The PKS will be used for the PK analyses (out of scope for this SAP).

ECG set for concentration-QTc analysis

The ECG set will include all subjects in the SS that have at least one valid pre-dose ECG assessment and one valid post-dose assessment ECGs are considered valid if they are based on at least 2 replicates with measurable QTc and RR.

The analysis set for concentration-QTc analysis will be a subset of the intersection of the PK set and the ECG set. It contains all measurements with a valid plasma

concentration and valid QTc results. Post dose values where the time of blood sampling and that of the ECG measurement (last triplicate) deviate by more than

- 11 min for timepoints 15 min to 1 h post dose
- 16 min for timepoints 2 h to 4 h post dose
- 18 min for timepoint 5 h post dose
- 33 min for timepoints 6 h to 12 h post dose.

will be excluded. If this rule leads to more than 3 exclusions in a subject per ECG day, it will be replaced by the following procedure: plasma concentrations at the time of the ECG (last triplicate) will be interpolated, based on the plasma concentrations preceding and following the time of ECG. More specifically, this will be done by a linear interpolation for ECG times before the individual T_{max} of the respective subject, and by a log-linear interpolation for times thereafter. For the first post-dose ECG on Day 1, a plasma concentration of nought at the time of drug administration will be imputed for this interpolation. With this procedure, no exclusions due to time between ECG and PK are expected.

For concentration QTc analyses, the pre-dose values of Day 1 will only be used for baseline calculation. For later days, values of one pre-dose timepoint only will be included. This will be the – 20 min timepoint if it is valid, otherwise the -40 min timepoint may be used if the time between the respective ECG (last triplicate) and blood draw does not exceed 40 min.

4.4 Subject Disposition

All subjects will be included in the summary of subject disposition. This will present the overall number of subjects, the frequency and percentage of subjects randomized and treated, and who completed or discontinued from the trial, along with reason for discontinuation.

Furthermore, the number and percentage of subjects in each analysis set will be tabulated. Discontinued subjects will be listed. Subject assignment to analysis sets will be listed. For the set of concentration-QTc analysis, measurements excluded and the reason for exclusion will be listed. Screen Failures will not be listed or included in summary tables.

4.5 Demographic Characteristics

Individual participant demographics (age, sex, ethnicity and race) and body measurement data (height, weight, and BMI) at screening will be listed. These demographic characteristics and body measurements will be summarized by treatment group and overall, using the safety analysis set. Other baseline characteristics will be listed only.

4.6 Inclusion and Exclusion Criteria

The inclusion and exclusion criteria text will be listed, as well as failed eligibility criteria for each randomised subject, if any.

4.7 Protocol Deviations

The final review of protocol deviations will be performed at the DRM prior to database lock. The protocol deviations will be listed.

4.8 Medical and Surgical History

Medical and Surgical history data will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) dictionary Version 24.0 (or higher) and listed individually. Surgical history data will be listed separately. Medical and Surgical history data will be summarised using frequency and percentage by SOC and preferred term.

4.9 Trial Drug Administration

Trial drug administration data including treatment received, dose (unit), date and time of administration will be listed by subject.

4.10 Prior and Concomitant Medications

All prior and concomitant medications will be coded using the World Health Organization Drug Dictionary version 2022 (or higher) and will be listed individually. The frequency and percentage of prior and concomitant medications will be summarized by Anatomical Therapeutic Chemical and Preferred Name. Separate tables will be given for prior and concomitant medications. Prior medications are defined as those for which the end date and time is prior to the date, and time of first trial drug administration. Concomitant medications are defined as those with start date and time on or after the date and time of first trial drug administration and those with start date and time prior to the first trial drug administration but with end date and time on or after the date and time of first trial drug administration.

If medication dates are incomplete and it is not clear whether the medication was concomitant, it will be assumed to be concomitant.

4.11 Safety Analysis

Safety analyses will be performed on the safety set, unless otherwise stated.

Safety analyses will include an analysis of all AEs, ECGs, clinical laboratory data, vital sign measurements and physical examination results and will be presented using descriptive statistics. No formal statistical analysis will be performed.

4.11.1 Adverse Events

A Treatment Emergent Adverse Event (TEAE) is defined as any adverse event which commences or any worsening of pre-existing conditions after the start of administration of trial drug. AEs with unknown start date/time will be assumed to be treatment-emergent unless the end date/time is known to be before the first administration of trial drug.

AE data will be listed and TEAEs summarised using descriptive statistics: the number (and percentage) of participants who experienced any AEs and the number of AE episodes will be summarized for each treatment group. All AEs will be summarized and listed by using the System Organ Class (SOC) and Preferred Term (PT) assigned to the event using the MedDRA. Changes in intensity of an AE should be recorded as a separate AE with a new onset. The number of participants who experienced drug-related AEs will also be summarized. Any SAEs and/or AEs that led to trial withdrawal will be summarized and listed.

4.11.2 Laboratory Data

All safety clinical laboratory data will be listed. Laboratory test results will also be compared to laboratory reference ranges. Those values outside of the applicable range will be flagged as high or low, and as clinically significant or not (CS/NCS). The number of participants that present out-of-range, and clinically relevant values, will be summarized. The quantitative laboratory data and changes from baseline will be summarized using descriptive statistics (mean, median, standard deviation, minimum, maximum). Change from baseline values at each assessment will be calculated as the assessment value minus the baseline value. The qualitative urinalysis data will be listed only.

The scheduled lab value will be used for summary analysis if repeated measurements are made at any time point.

For summary statistics, a lab value with "<" will be replaced with a numeric value by removing the "<" sign. In the listings, the values will be displayed as originally reported by the laboratory.

4.11.3 Vital Signs

Vital signs data (SBP, DBP, pulse rate, temperature) will be listed and summarized, along with changes from baseline, using descriptive statistics (mean, median, standard deviation, minimum, maximum). Out-of-reference-range values will be flagged as high or low and as being clinically relevant or not. The number of participants presenting out-of-range and clinically relevant values will be summarized.

Normal ranges for the relevant parameters are presented below:

Parameter	Normal Range
Temperature (tympanic)	35-38°C
Systolic Blood Pressure (Supine)	90–130 mmHg
Diastolic Blood Pressure (Supine)	40–90mmHg
Heart Rate (supine)	40–100 bpm

4.11.4 Holter

Holter data (Start / End Date time and evaluation) will be listed by subject.

4.11.5 Physical Examination

The physical examination performed at screening and at the end of-trial visit will be listed only and include an assessment of the following: general appearance, skin, eyes/ears/nose, neck, lymph nodes, throat, heart, lungs, abdomen, musculoskeletal system and extremities.

4.11.6 Electrocardiograms

All adjudicated and un-adjudicated ECG data (PR, QRS, QT, QTcF and HR) and overall ECG evaluation will be listed, including a H/L flag for out-of-reference-range values. Reference ranges for ECGs are as follows:

Parameter	Normal Range
Heart Rate (Supine)	40-100 bpm
PR Interval	120–210 ms
QRS duration	≤120 ms
QTcF	≤450 ms (Males) ; ≤470 ms (Females)

Below analyses will be performed on the adjudicated ECGs – mean values from selected triplicates from each time-point after adjudication.

ECG data and changes from baseline will be summarised using descriptive statistics.

For summary statistics, the (arithmetic) mean of the last 3 evaluable ECGs at each timepoint will be used for each timepoint.

The change from baseline will be derived using the arithmetic mean value of each timepoint triplicate minus baseline value, where baseline is the arithmetic mean of the pre-dose values of Day 1 (see below for baseline definition).

Furthermore, categorical analysis of QTcF data will be presented as follows:

- Absolute QTcF interval prolongation
  - QTcF interval > 450 ms to ≤ 480 ms
  - QTcF interval > 480 ms to ≤ 500 ms
  - QTcF interval > 500 ms
- Change from baseline in QTcF interval
  - QTcF interval increases from baseline > 30 msec to ≤ 60 msec
  - QTcF interval increases from baseline > 60 ms
- Fulfilling both, absolute QTcF values >500 ms and ΔQTcF >60 ms;

Additional categorical analysis will be presented as follows:

- Absolute PR values >200 ms, >220 ms, with a pre-dose value below the respective threshold
- ΔPR ≥25%, i.e., post-dose PR outside the range of (0.75, 1.25) of the baseline value
- Absolute QRS duration >110 ms and >120 ms
- ΔQRS ≥25%, i.e., post-dose QRS outside the range of (0.75, 1.25) of the baseline value
- Absolute HR of <50 bpm or ≥100 bpm
- Heart rate decrease ≥25% from baseline to a HR of <50 bpm and/or increase ≥25% from baseline to a HR of ≥100 bpm.

The mean change from baseline value of QT_cF will be plotted by treatment group and by time-point. The number of subjects presenting out-of-range and clinically relevant values will be summarised by timepoint and across all timepoints. A subject will be counted once if they have multiple out of range values for a given timepoint.

4.12 ECGs analyses (adjudicated)

Statistical analyses of ECG variables will be performed according to the recommendations provided by the guideline ICH-E14 and its Q&A documents. QTc and HR data will be analysed using a concentration-effect model (see below). The concentration-ECG analyses will be performed on the set for concentration-QTc analysis, all other analyses not requiring PK data will be performed on the ECG-Set.

Baseline for quantitative ECG variables will be the average of the 3 pre-dose values measured on Day 1 (which in turn are the average over the individual triplicates).

4.12.1 Concentration-QTc analysis

The primary endpoint is defined as the concentration-QTc-model based QTcF differences from baseline (ΔQTcF), where baseline is the average of the 3 pre-dose measurements of Day 1. ECGs from Day 1, Day 6 and Day 16 will be used for

comparison against baseline. More specifically, a series of 7 linear mixed effect models relating the change from baseline to the concentrations of pritelivir and the metabolites AIC090015 and AIC090105, together or separately, will be fitted (M1: pritelivir only, M12: Pritelivir and AIC090015, M13: pritelivir and AIC090105, M123: all moieties, M2 AIC090015 only, M23: both metabolites, no parent, M3: AIC090105 only). Apart from these concentrations, the models will include fixed effects for time and treatment ("treatment intercept" with levels active and placebo) and baseline as a covariate. Random effects per subject for the intercept and, if feasible, for the concentrations included in the respective models will be given. More specifically, if a model does not converge even after rescaling of the covariates, the random effects for concentrations will be removed. If convergence is still not given, the covariance structure may be simplified. Selection of the primary model will be based on model fit and the Akaike Information Criterion. More specifically, among the models with no significant (at the two sided 5 % level) treatment intercept, the one with lowest AIC will be selected as primary. If the treatment intercept for all models differs significantly from nought, nonlinear e-max models may be investigated. Predictions of the effect of pritelivir and metabolites at the concentrations seen at t_{max} of each of the moieties involved will be used to exclude an effect of regulatory concern (ie, a one-sided 95% confidence interval for ΔQTcF completely below 10 ms).

Diagnostic plots will be given for all models. These include the presentation of observed vs. predicted values and the plot of the residuals against the variables in the model as well as against day.

If the primary model is based on one moiety only, observed ΔQTc versus concentration will be presented. In addition, a decile plot as described in the White Paper [2] will be presented with the partial residual with respect to concentration as dependent and concentration as independent variable.

The groups 2a and 2b will be pooled for analysis.

The appropriateness of the models used will be investigated. In particular, this includes the absence of a delayed effect (respective to all 3 moieties) and any relevant deviations from linearity. Absence of a delayed effect will be investigated by a simultaneous plot of ΔΔQTcF and the mean concentration of the three moieties, where ΔΔQTcF will be obtained from the contrasts of the linear mixed effects model to describe the time course – see below. Note that a delayed effect will be a problem only if the maximum of ΔΔQTc (U_{max}) is later than the T_{max} of all three moieties.
Deviations from linearity will be judged from the treatment intercept and the diagnostic plots. A significant treatment intercept will be taken as an indicator for inappropriateness of the model.

4.12.2 Assay sensitivity

A comparison between moxifloxacin and matching placebo will be done in groups 2a and 2b to demonstrate assay sensitivity using a similar model to the model M1 described above. Assay sensitivity will be concluded if the lower limit of the one-sided 95% CI for the predicted effect will be >5 ms.

4.12.3 Effect on Heart rate and alternative correction

If there are indications that pritelivir has an effect on HR exceeding 10 bpm, HR will also be submitted to a similar analysis as QTcF. If this confirms an effect exceeding 10 bpm, then an individual correction will be determined based on the ECG data from Day -1, and QT values corrected according to this method (QTcI) will replace QTcF in the primary analyses. More specifically, a linear model relating log QT to log RR (including an intercept) will be fitted to the data of each subject separately and the coefficient for log RR (β say) will be used to define QTcI =QT/RR [sec]$^{\beta}$ for each subject. The appropriateness of the corrections will also be displayed graphically using ΔQTc and ΔRR.

4.12.4 Other analyses

All quantitative ECG variables and their change from baseline will be summarized by timepoint and treatment group. The difference between the 2 treatment groups will also be presented. In addition, they will be analysed with respect to their time course using a mixed effects linear model. This model will have treatment (pritelivir, placebo) and time as well as their interaction as fixed effects and a random intercept per subject. The time course of the drug effect will be estimated from the contrast using treatment and time by treatment interaction.

4.13 Pharmacokinetic Data

PK parameter analysis and report are out of scope for this SAP and details on this analysis will be provided by Venn Life Sciences.

5. REFERENCES

1. Dalong Patrick Huang, Janell Chen, Qianyu Dang & Yi Tsong (2019) Assay sensitivity in "Hybrid thorough QT/QTc (TQT)" study, Journal of Biopharmaceutical Statistics, 29:2, 378-384, DOI: 10.1080/10543406.2018.1535498
2. Garnett C, Bonate P, Dang Q, Ferber G, Huang D, Liu J, Mehortra D, Riley P, Sager P, Tornoe C, Wang Y. Scientific white paper on concentration-QT_c modelling. Journal of Pharmacokinetics and Pharmacodynamics. 2018;45, 383-397. https://link.springer.com/article/10.1007%2Fs10928-017-9558-5. Accessed on 15 October 2021.

RICHMOND Pharmacology

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