Protocol C5241013

A Phase 1, Randomized, Open-Label, Two-Part Crossover Study to Assess the Relative Bioavailability of Sisunatovir Following Single Oral Dose of Different Formulations Under Fed and Fasted Conditions in Healthy Adult Participants

Statistical Analysis Plan
(SAP)

Version: 2

Date: 30 Nov 2023

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NOTE: *Italicized* text within this document has been taken verbatim from the Protocol.

1. VERSION HISTORY

Table 1. Summary of Changes

Version/ Date	Associated Protocol Amendment	Rationale	Specific Changes
1 / 02 Aug 2023	Original 07 Jun 2023	N/A	N/A
2 / 30 Nov 2023	Amendment 1 09 Nov 2023	Addition of Part 2 for the evaluation of a low-fat meal on sisunatovir exposure with the WGT formulation	Added Part 2 objective and endpoints in Section 2.2. Added Part 2 study design in Section 2.3. Added Part 2 endpoints in Section 3.2.1. Added analysis of Part 2 endpoints in Section 6.2.1. Added sample codes for Part 2 endpoints analysis in Appendix 1.

2. INTRODUCTION

Sisunatovir (PF-07923568, formerly RV521) is an orally administered CCI [redacted] *for the treatment of adult and pediatric patients with RSV.*

The purpose of the study is to assess the PK, safety, and tolerability of a single oral dose of 2 different formulations of sisunatovir when administered under fasting conditions. The oral PK of a new WGT formulation potentially to be used in future clinical studies will be compared with that of PIC formulation used in completed and ongoing clinical studies. Additionally, the high- and low-fat food effects on the oral PK of the new WGT formulation will be evaluated.

This SAP provides the detailed methodology for summary and statistical analyses of the data collected in Study C5241013.

2.1. Modifications to the Analysis Plan Described in the Protocol

None.

2.2. Study Objectives, Endpoints, and Estimands

The following are the objectives and endpoints in this study. Estimand framework will not be applied to this Phase 1 study in healthy participants.

Objectives	Endpoints
Primary:	***Primary:***
• *To determine the relative biovailability of sisunatovir following a single oral dose of* CCI *mg as PIC vs WGT in a fasted state*	• *AUC_{last}, AUC_{inf} (if data permit*), and C_{max} of PIC vs WGT*
Secondary:	***Secondary:***
• *To determine the effect of a high-fat meal on the relative biovailability of sisunatovir following a single oral dose of* CCI *mg as WGT*	• *AUC_{last}, AUC_{inf} (if data permit*), and C_{max} of WGT under fasted vs with a high-fat meal*
• *To determine the effect of a low-fat meal on the relative biovailability of sisunatovir following a single oral dose of* CCI *mg as WGT*	• *AUC_{last}, AUC_{inf} (if data permit*), and C_{max} of WGT under fasted vs with a low-fat meal*
• *To characterize the safety and tolerability following a single oral dose of* CCI *mg of sisunatovir as PIC or WGT in a fasted state, or as WGT in a fed state*	• *Assessment of TEAEs, clinical laboratory abnormalities, vital signs, and 12-lead ECGs*
Tertiary/Exploratory:	***Tertiary/Exploratory:***
• *To determine additional PK parameters of sisunatovir following a single oral dose of* CCI *mg as PIC or WGT in a fasted state, or as WGT in a fed state*	• *Additional plasma PK parameters:* ○ *CL/F and V_z/F as data permit* ○ *T_{max}* ○ *$t_{½}$, as data permit*

**Should it be deemed that too few AUC_{inf} estimates (eg, less than 10 for a single dose) are obtained from the evaluable participants, AUC_{last} may be selected as the primary/secondary endpoint for CSR reporting (otherwise AUC_{last} will be an exploratory endpoint).*

2.3. Study Design

This is a Phase 1, randomized, open-label, 2-part crossover study to evaluate the PK, food effect, safety, and tolerability of sisunatovir CCI *mg single dose administered as PIC or WGT under fasted conditions, or as WGT with food.*

Part 1

Participants will be admitted to the CRU on Day -1 to undergo baseline procedures. Over the first 2 periods, all participants are planned to receive 1 dose of (A) sisunatovir CCI *mg as PIC and 1 dose of (B) sisunatovir* CCI *mg as WGT in a fasted state. All participants in Period 3 will receive 1 dose of (C) sisunatovir* CCI *mg as WGT with a high-fat meal (Table 2). There is an at least 72-hour washout period between the dose of 2 adjacent periods.*

Part 1 consists of an initial screening period of up to 28 days (while allowing for the return and review of all results, including laboratory tests), a 10-day inpatient stay at the CRU which includes 3 periods, and a follow-up contact that will occur 28-35 days after the last

administration of sisunatovir. For individual participants, the total duration of participation from the screening visit to the follow-up visit will range from approximately 6 weeks (minimum) to approximately 10 weeks (maximum).

Approximately 12 participants will be randomized into 2 sequences with 6 participants each. For each sequence, participants will receive study interventions in a pre-specified manner as listed in Table 2.

Table 2. Part 1 Treatment Sequence

	Period 1	***Period 2***	***Period 3***
Sequence 1 (N=6)	*A*	*B*	*C*
Sequence 2 (N=6)	*B*	*A*	*C*

All study interventions will be administered as a single dose of sisunatovir CCI mg as PIC or WGT.
A= PIC under fasted condition; B = WGT under fasted condition; C= WGT with a high-fat meal.

Part 2

Participants will be admitted to the CRU on Day -1 to undergo baseline procedures. All participants are planned to receive 1 dose of (B) sisunatovir CCI mg as WGT in a fasted state and 1 dose of (D) sisunatovir CCI mg as WGT with a low-fat meal. There is an at least 72-hour washout period between the dose of the 2 periods. Participants who have completed Part 1 are eligible to participate in Part 2.

Table 3. Part 2 Treatment Sequence

	Period 1	***Period 2***
Sequence 1 (N=6)	*B*	*D*
Sequence 2 (N=6)	*D*	*B*

All study interventions will be administered as a single dose of CCI -mg sisunatovir as WGT.
B = WGT under fasted condition; D= WGT with a low-fat meal.

Participants who discontinue from the study for non-safety reasons may be replaced at the sponsor's discretion in collaboration with the investigator.

3. ENDPOINTS AND BASELINE VARIABLES: DEFINITIONS AND CONVENTIONS

PK parameters for sisunatovir will be derived from the concentration-time profiles using noncompartmental methods as data permit. The PK parameters to be assessed in this study, their definition, and method of determination are outlined in Table 4. *In all cases, actual PK sampling times will be used in the derivation of PK parameters when available. In the case that actual PK sampling times are not available, nominal PK sampling time will be used in the derivation of PK parameters.*

Table 4. Plasma PK Parameters

Parameter	*Definition*	*Method of Determination*
AUC_{last}	*Area under the plasma concentration-time profile from time 0 to the time of the last quantifiable concentration (C_{last})*	*Linear/Log trapezoidal method.*
AUC_{inf}[a]	*Area under the concentration-time profile from time 0 extrapolated to infinite time*	*AUC_{last} + (C_{last}*/k_{el}), where C_{last}* is the predicted plasma concentration at the last quantifiable time point estimated from the log-linear regression analysis.*
C_{max}	*Maximum observed plasma concentration*	*Observed directly from data.*
T_{max}	*Time to reach C_{max}*	*Observed directly from data as time of first occurrence*
$t_{½}$[a]	*Terminal half-life*	*$Log_e(2)/k_{el}$, where k_{el} is the terminal phase rate constant calculated by a linear regression of the log-linear concentration-time curve. Only those data points judged to describe the terminal log-linear decline will be used in the regression.*
CL/F[a]	*Apparent clearance*	*Dose/AUC_{inf}.*
V_z/F[a]	*Apparent volume of distribution*	*Dose/(AUC_{inf} • k_{el}).*

a. As data permits.

3.1. Primary Endpoints

The primary endpoints are the plasma AUC_{last}, AUC_{inf} (if data permit) and C_{max} of sisunatovir CCI mg as PIC or WGT in a fasted state. Adjusted geometric mean ratios of AUC_{last}, AUC_{inf} and C_{max} will be derived with Treatment B (sisunatovir CCI mg WGT under fasted condition) as the test treatment and Treatment A (sisunatovir CCI mg PIC under fasted condition) as the reference treatment.

3.2. Secondary Endpoints

3.2.1. Food Effect PK Data

Plasma AUC_{last}, AUC_{inf} (if data permit) and C_{max} of sisunatovir CCI mg as WGT with a high-fat meal. Adjusted geometric mean ratios of AUC_{last}, AUC_{inf} and C_{max} with Treatment C (sisunatovir CCI mg WGT with a high-fat meal) as the test treatment and Treatment B (sisunatovir [redacted] mg WGT under fasted condition) as the reference treatment.

Plasma AUC_{last}, AUC_{inf} (if data permit) and C_{max} of sisunatovir CCI mg as WGT with a low-fat meal. Adjusted geometric mean ratios of AUC_{last}, AUC_{inf} and C_{max} with Treatment D (sisunatovir CCI mg WGT with a low-fat meal) as the test treatment and Treatment B (sisunatovir [redacted] mg WGT under fasted condition) as the reference treatment.

3.2.2. Safety Endpoints

The following data are considered in standard safety summaries (see protocol for collection days, baseline assessment, and list of parameters):

- TEAEs

- laboratory data
- vital signs data
- electrocardiogram (ECG) results

3.2.2.1. Adverse Events

Any adverse events occurring following start of treatment will be considered as treatment emergent adverse event (TEAE). Events that occur during follow-up within the lag time of up to 35 days after the last sisunatovir dose will be counted as treatment emergent and attributed to the last treatment taken. Events that occur during the washout period will be counted as treatment emergent and attributed to the previous treatment taken. The time period for collecting AEs ("active collection period") for each participant begins from the time the participant provides informed consent.

3.2.2.2. Laboratory Data

Safety laboratory tests will be performed as described in the protocol.

For Period 1, the baseline measurement is the last predose measurement on Day -1. For Periods 2 and 3, the baseline measurement is the last predose measurement on Day 1 of each period. Changes from baseline will be defined as the change between the postdose and baseline measurements.

3.2.2.3. Vital Signs

Supine blood pressure (BP) and pulse rate will be measured at times specified in the SoA given in the protocol.

For each period, the baseline measurement is the last predose measurement on Day 1. Changes from baseline will be defined as the change between the postdose and baseline measurements.

3.2.2.4. Electrocardiograms

QT interval, QTcF, PR, QRS and heart rate (HR) will be recorded at each assessment time indicated in the SoA given in the protocol. QTcF will be derived using Fridericia's heart rate correction formula:

QTcF = QT / (RR)^(1/3) where RR = 60/HR (if not provided)

For each period, the baseline measurement is the last predose measurement on Day 1. Changes from baseline will be defined as the change between the postdose and baseline measurements.

3.3. Other Safety Endpoints

None.

3.4. Exploratory Endpoints

Exploratory endpoints are additional plasma PK parameters of sisunatovir (CL/F, V_z/F, T_{max}, $t_{1/2}$) as PIC or WGT in a fasted state, or as WGT in a fed state.

3.5. Baseline Variables

Baseline characteristics will be collected according to the SoA as specified in the protocol.

4. ANALYSIS SETS (POPULATIONS FOR ANALYSIS)

Data for all participants will be assessed to determine if participants meet the criteria for inclusion in each analysis population prior to releasing the database and classifications will be documented per standard operating procedures.

For purposes of analysis, the following analysis sets are defined:

Participant Analysis Set	***Description***
Enrolled	*"Enrolled" means a participant's agreement to participate in a clinical study following completion of the informed consent process and randomization/assignment to study intervention. A participant will be considered enrolled if the informed consent is not withdrawn prior to participating in any study activity after screening. Potential participants who are screened for the purpose of determining eligibility for the study, but do not participate in the study, are not considered enrolled, unless otherwise specified by the protocol.*
Evaluable	*All participants randomly assigned to study intervention and who take at least 1 dose of study intervention.*
Safety	*All participants randomly assigned to study intervention and who take at least 1 dose of study intervention. Participants will be analyzed according to the product they actually received.*
PK Parameter Set	*All randomized participants who receive at least one dose of study medication and in whom at least 1 plasma PK parameter is calculated.*
PK Concentration Set	*All randomized participants who receive at least 1 dose of study medication and in whom at least 1 plasma concentration value is reported.*

5. GENERAL METHODOLOGY AND CONVENTIONS

Final analysis will be performed after study participant data set release following last participant last visit.

5.1. Hypotheses and Decision Rules

No statistical hypothesis will be tested in this study.

5.2. General Methods

5.2.1. Analyses for Binary/Categorical Endpoints

For binary or categorical variables, number of participants, numbers and percentages of participants meeting the categorical criteria will be presented in accordance with the Clinical Data Interchange Standards Consortium and Pfizer Standards (CaPS).

5.2.2. Analyses for Continuous Endpoints

For continuous variables, the data will be summarized using the number of participants, mean, median, standard deviation (SD), minimum, and maximum in accordance with the CaPS. For appropriate PK parameters, geometric mean and geometric coefficient of variation (%CV) will also be summarized.

5.3. Methods to Manage Missing Data

5.3.1. Pharmacokinetic Data

Methods to handle missing PK data are described below.

Concentrations Below the Limit of Quantification:

In all data presentations (except listings), concentrations below the limit of quantification (BLQ) will be set to zero. (In listings BLQ values will be reported as "<LLQ", where LLQ will be replaced with the value for the lower limit of quantification.).

Deviations, Missing Concentrations and Anomalous Values:

In summary tables and plots of median profiles, statistics will be calculated having set concentrations to missing if one of the following cases is true:

1. A concentration has been collected as ND (ie, not done) or NS (ie, no sample).
2. A deviation in sampling time is of sufficient concern or a concentration has been flagged as anomalous by the pharmacokineticist.

Note that summary statistics will not be presented at a particular time point if more than 50% of the data are missing.

An anomalous concentration value is one that, after verification of bioanalytical validity, is grossly inconsistent with other concentration data from the same individual or from other participants. For example, a BLQ concentration that is between quantifiable values from the same dose is considered as anomalous. Anomalous concentration values may be excluded from PK analysis at the discretion of the PK analyst or pharmacokineticist.

PK Parameters:

Actual PK sampling times will be used in the derivation of PK parameters. If a PK parameter cannot be derived from a participant's concentration data, the parameter will be coded as NC (ie, not calculated). (Note that NC values will not be generated beyond the day that a participant discontinues). In summary tables, statistics will be calculated by setting NC values to missing; and statistics will be presented for a particular treatment with ≥3 evaluable measurements. PK parameter analyses will not be performed for a particular parameter if more than 50% of the data are NC.

If an individual participant has a known biased estimate of a PK parameter (due for example to an unexpected event such as vomiting before all the compound is adequately absorbed from the gastrointestinal tract), this will be footnoted in summary tables and will not be included in the calculation of summary statistics or statistical analyses.

5.3.2. Safety Data

Missing values in standard summaries of safety data will be imputed according to CaPS.

6. ANALYSES AND SUMMARIES

The plasma concentrations of sisunatovir will be listed and descriptively summarized by nominal PK sampling time and treatment on the PK Concentration Set. Individual participant and summary profiles (mean and median plots) of the plasma concentration-time data will be plotted by treatment using actual and nominal times, respectively. Mean and median profiles will be presented on both linear and semi-log scales.

Presentations for sisunatovir concentrations will include:

- A listing of all concentrations sorted by participant ID, treatment and nominal time postdose. The concentration listing will also include the actual times. Deviations from the nominal time will be given in a separate listing.

- A summary of concentrations by treatment and nominal time postdose, where the set of statistics will include n, mean, median, SD, %CV, minimum, maximum and the number of concentrations above the LLQ.

- Median concentrations time plots (on both linear and semi-log scales) against nominal time postdose by treatment (all treatments on the same plot per scale, based on the summary of concentrations by treatment and time postdose).

- Mean concentrations time plots (on both linear and semi-log scales) against nominal time postdose by treatment (all treatments on the same plot per scale, based on the summary of concentrations by treatment and time postdose).

- Individual concentration time plots by treatment (on both linear and semi-log scales) against actual time postdose (there will be separate spaghetti plots for each treatment per scale).

- Individual concentration time plots by participant (on both linear and semi-log scales) against actual time postdose [there will be separate plots for each participant (containing all treatments) per scale].

The PK parameters will be summarized descriptively by treatment group in accordance with Pfizer data standards on the PK Parameter Set, as data permit. Missing values will be handled as detailed in Section 5.3.1. Each PK parameter will be summarized by treatment group and will include the set of summary statistics as specified in Table 5.

Table 5. PK Parameters to be Summarized Descriptively by Treatment

Parameter	Summary Statistics
AUC_{inf}, AUC_{last}, C_{max}, CL/F, V_z/F	N, arithmetic mean, median, SD, %CV, minimum, maximum, geometric mean and geometric %CV
T_{max}	N, median, minimum, maximum
$t_{½}$	N, arithmetic mean, median, SD, %CV, minimum, maximum

The following supporting data from the estimation of $t_{½}$ will be listed by treatment group: the terminal phase rate constant (k_{el}); goodness-of-fit statistic from the regression (r^2); the percentage of AUC_{inf} obtained by forward extrapolation (AUC_{extrap}%); and the first, last, and number of time points used in the estimation of k_{el} ($k_{el,t(lo)}$, $k_{el,t(hi)}$, and $k_{el,t(n)}$).

6.1. Primary Endpoints

Plasma AUC_{last}, AUC_{inf} (if data permit) and C_{max} will be summarized descriptively by treatment. Box and whisker plots for AUC_{last}, AUC_{inf} (if data permit) and C_{max} will be plotted by treatment.

For the estimation of rBA of sisunatovir CCI mg as WGT compared to sisunatovir CCI mg as PIC in a fasted state, *natural log transformed AUC_{last}, AUC_{inf} (if data permit) and C_{max} will be analyzed separately using a mixed effect model with sequence (AB or BA), period and treatment included as fixed effects and participant nested within sequence as a random effect. Only data from the first 2 study periods will be used in the analysis. Estimates of the adjusted mean differences (Test-Reference) and corresponding 90% CIs will be obtained from the model. The adjusted mean differences and 90% CIs for the differences will be exponentiated to provide estimates of the ratio of adjusted geometric means (Test/Reference) and 90% CIs for the ratios. Treatment A is the Reference treatment and Treatment B is the Test treatment.*

Residuals from the model will be examined for normality and the presence of outliers via visual inspection of plots of residuals vs predicted values and normal probability plots of residuals but these will not be included in the CSR. If there are major deviations from normality or outliers then the effect of these on the conclusions will be investigated through alternative transformations and/or analyses excluding outliers. Justification for any alternative to the planned analysis will be given in the report of the study.

6.2. Secondary Endpoints

6.2.1. Food Effect PK Data

For the secondary endpoints on the assessment of high-fat food effect, *natural log transformed AUC_{last}, AUC_{inf} (if data permit) and C_{max} of sisunatovir will be analyzed using a mixed effect model with sequence and treatment as fixed effects and participant within sequence as a random effect. Estimates of the adjusted mean differences (Test-Reference) and corresponding 90% CIs will be obtained from the model. The adjusted mean differences and 90% CIs for the differences will be exponentiated to provide estimates of the ratio of adjusted geometric means (Test/Reference) and 90% CI for the ratios. Treatment B (WGT under fasted condition) is the Reference treatment and Treatment C (WGT with a high-fat*

meal) is the Test treatment. Only the data from Treatments B and C will be included in the model.

For the secondary endpoints on the assessment of the low-fat food effect, *natural log transformed AUC_{last}, AUC_{inf} (if data permit) and C_{max} of sisunatovir will be analyzed using a mixed effect model with sequence and treatment as fixed effects and participant within sequence as a random effect. Estimates of the adjusted mean differences (Test-Reference) and corresponding 90% CIs will be obtained from the model. The adjusted mean differences and 90% CIs for the differences will be exponentiated to provide estimates of the ratio of adjusted geometric means (Test/Reference) and 90% CI for the ratios. Treatment B (WGT under fasted condition) is the Reference treatment and Treatment D (WGT with a low-fat meal) is the Test treatment. Only the data from Treatments B and D will be included in the model.*

Residuals from the model will be examined for normality and the presence of outliers via visual inspection of plots of residuals vs predicted values and normal probability plots of residuals but these will not be included in the CSR. If there are major deviations from normality or outliers then the effect of these on the conclusions will be investigated through alternative transformations and/or analyses excluding outliers. Justification for any alternative to the planned analysis will be given in the report of the study.

Exploratory analyses may be performed to assess rBA of sisunatovir for participants who participated in both part 1 and part 2 of the study. These data will be used for internal exploratory purposes and will not be included in the clinical report.

6.2.2. Safety Endpoints

All safety analyses will be performed on the Safety Analysis Set.

Safety data will be presented in tabular and/or graphical format and summarized descriptively, where appropriate.

6.2.2.1. Adverse Events

TEAEs will be reported in accordance with the CaPS.

Participant discontinuations due to adverse events will be detailed by treatment. Data will be reported in accordance with the CaPS.

6.2.2.2. Laboratory Data

Laboratory data will be listed and summarized by treatment in accordance with the CaPS.

6.2.2.3. Vital Signs

Vital sign data will be databased and available upon request.

6.2.2.4. Electrocardiograms

ECG data will be databased and available upon request.

6.3. Other Safety Summaries and Analyses Endpoint(s)

None.

6.4. Exploratory Endpoints

Other plasma PK parameters including CL/F, V_z/F, T_{max} and $t_{1/2}$ will be summarized by treatment group and will include the set of summary statistics as specified in Table 5.

6.5. Subset Analyses

There are no planned subset analyses.

6.6. Baseline and Other Summaries and Analyses

6.6.1. Demographic Summaries

Demographic characteristics will be listed and summarized for Safety Analysis Set in accordance with the CaPS.

6.6.2. Study Conduct and Participant Disposition

Participants evaluation groups will show end of study participant disposition. Frequency counts will be supplied for participant discontinuation(s) by treatment. Data will be reported in accordance with the CaPS.

6.6.3. Study Treatment Exposure

Study treatment exposure will be listed.

6.6.4. Concomitant Medications and Nondrug Treatments

All concomitant medication(s) as well as non-drug treatment(s) will be reported in the listings.

7. INTERIM ANALYSES

No formal 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 modeling, and/or supporting clinical development.

Final analysis will follow the official database release. As this will be an open-label study, there is no formal unblinding of the randomization code.

APPENDICES

Appendix 1. SAS Code for Analyses

An example of the PROC MIXED code is provided below:

For primary objective rBA (Periods 1 and 2):

```
proc mixed data=tab.pk;
        class seq period trt participant;
        model log&var=seq period trt/ ddfm=KR;
        random participant(seq) /subject=participant(seq);
        lsmeans trt;
        estimate 'B vs A' trt -1 1  /cl alpha=0.1;

        ods 'Estimates' out=est&var;
        ods 'lsmeans' out=ls&var;
        ods 'covparms' out=cov&var;
        ods 'tests3' out=tst&var;
run;
```

For secondary objectives high-fat and low-fat FE:

```
proc mixed data=tab.pk;
        class seq trt participant;
        model log&var= seq trt / ddfm=KR;
        random participant(seq) / subject=participant(seq);
        lsmeans trt;
        estimate 'C vs B' trt -1 1  /cl alpha=0.1;

        ods 'Estimates' out=est&var;
        ods 'lsmeans' out=ls&var;
        ods 'covparms' out=cov&var;
        ods 'tests3' out=tst&var;
run;

proc mixed data=tab.pk;
        class seq trt participant;
        model log&var= seq trt / ddfm=KR;
        random participant(seq) / subject=participant(seq);
        lsmeans trt;
        estimate 'D vs B' trt -1 1  /cl alpha=0.1;

        ods 'Estimates' out=est&var;
        ods 'lsmeans' out=ls&var;
        ods 'covparms' out=cov&var;
        ods 'tests3' out=tst&var;
run;
```

/* Letter assignments for treatments (trt) within the estimate statement above are as follows
A: Single dose of sisunatovir CCI mg as PIC under fasted condition;
B: Single dose of sisunatovir [redacted] mg as WGT under fasted condition;
C: Single dose of sisunatovir [redacted] mg as WGT with a high-fat meal.
D: Single dose of sisunatovir [redacted] mg as WGT with a low-fat meal. */

Appendix 2. List of Abbreviations

Abbreviation	Term
%CV	coefficient of variation
AE	adverse event
AUC_{extrap}%	the percent of AUC_{inf} based on extrapolation
AUC_{inf}	area under the concentration-time curve from time 0 to infinity
AUC_{last}	area under the concentration-time curve from 0 to time of last measurable concentration
BLQ	below the limit of quantification
BP	blood pressure
CaPS	Clinical Data Interchange Standards Consortium and Pfizer Standards
CI	confidence interval
C_{last}	estimated plasma concentration at the last quantifiable time point estimated form the log-linear regression analysis
CL/F	apparent clearance
C_{max}	maximum observed plasma concentration
CRU	clinical research unit
CSR	clinical study report
ECG	electrocardiogram
HR	heart rate
k_{el}	the terminal phase rate constant calculated by a linear regression of the loglinear concentration-time curve
LLQ	lower limit of quantification
mg	milligram
ms	millisecond
N/A	not applicable
NC	not calculated
ND	not done
NS	no sample
PIC	Powder in Capsule
PK	pharmacokinetic(s)
PR	time from the beginning of the P wave to the beginning of the QRS complex
QRS	Combination of Q-, R- and S- wave on an electrocardiogram representing ventricular depolarization
QT	time from the start of the Q- wave to the end of T- wave, which represents time taken for ventricular depolarization and repolarization
QTc	corrected QT
QTcF	corrected QT (Fridericia method)
r^2	goodness of fit statistic from the log-linear regression
rBA	relative bioavailability
RR	respiratory rate
RSV	respiratory syncytial virus

Abbreviation	Term
SAP	statistical analysis plan
SD	standard deviation
SoA	schedule of activities
$t_{1/2}$	terminal elimination half-life
TEAE	treatment emergent adverse event
T_{max}	time to reach C_{max}
V_z/F	apparent volume of distribution for extravascular dosing
WGT	Wet Granulation Tablet