Protocol C0251005

A PHASE 1, RANDOMIZED, DOUBLE-BLIND, SPONSOR-OPEN, PLACEBO-CONTROLLED STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY AND PHARMACOKINETICS FOLLOWING SINGLE INTRAVENOUS DOSE OF PF-06823859 IN JAPANESE HEALTHY PARTICIPANTS

Statistical Analysis Plan
(SAP)

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[redacted]

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1. VERSION HISTORY

Table 1. Summary of Changes

Version/ Date	Associated Protocol Amendment	Rationale	Specific Changes
1 21JUL2021	Original 26MAY2021 Amendment 1 09JUL2021	N/A	N/A
2 14APR2022	N/A	Some clarifications were added.	Section 6.1.1: Added clarification on the definition of IRR and viral infections. Sections 6.1.3 and 6.1.4: The categorical classes for vital signs and ECGs were specified in Appendix 1. Overall: Minor edits for the description maintenance.

2. INTRODUCTION

This statistical analysis plan (SAP) provides the detailed methodology for summary and statistical analyses of the data collected in Study C0251005. This document may modify the plans outlined in the protocol; however, any major modifications of the primary endpoint definition or its analysis will also be reflected in a protocol amendment.

2.1. Study Objectives, Endpoints, and Estimands

The following are objectives and endpoints in this study. Estimand framework is not applied to this phase 1 study.

Objectives	Endpoints
Primary:	**Primary:**
• To evaluate the safety and tolerability of single IV dose of 300 and 900 mg PF-06823859 in Japanese healthy participants.	• Assessments of AEs/SAEs including IRR, infusion sites and viral infections, vital signs, ECGs and laboratory tests.
Secondary:	**Secondary:**
• To evaluate the PK profile of single IV dose of 300 and 900 mg PF-06823859 in Japanese healthy participants. • To evaluate the immunogenicity of PF-06823859.	• Serum PF-06823859 PK parameters, as permitted by data: C_{max}, C_{max} (dn), T_{max}, AUC_{inf}, AUC_{inf} (dn), AUC_{last}, AUC_{last} (dn), AUC_{14day}, AUC_{28day}, $t_{1/2}$, CL, V_{ss} and MRT • Incidence of the development of ADA and NAb.

(dn: dose normalized)

2.2. Study Design

This is a Phase 1, randomized, double-blind, sponsor-open, placebo-controlled study to evaluate the safety, tolerability, immunogenicity and PK of PF-06823859 in Japanese healthy adult participants.

Approximately 12 participants are planned to be enrolled into the study. The study consists of 2 cohorts, and approximately 5 participants will be randomized to PF-06823859 and approximately 1 participant will be randomized to placebo in each cohort. Participants who discontinue prior to completion of the study for non-safety related reasons may be replaced at the discretion of the investigator upon consultation with the sponsor. Each participant will receive PF-06823859 or placebo per the scheme summarized in Table 2.

Table 2. Randomization Scheme

Cohort	Treatment	Number of participants
1	PF-06823859 300 mg	5
	Placebo	1
2	PF-06823859 900 mg	5
	Placebo	1

Within 28 days of successful completion of the screening process, eligible participants will be enrolled and randomized to receive a single IV infusion of PF-06823859 or placebo. The participants in Cohort 2 should be dosed following at least 96 hours safety pause after the participants in Cohort 1 have been dosed. Participants will be admitted into the clinical research unit (CRU) approximately 1 day prior to dosing and are required to stay overnight in the CRU through completion of Day 5 evaluations. Participants will return to the CRU for outpatient follow up visits per Schedule of Activities given in the protocol through Day 157. Participants may be asked to return for additional follow up visits beyond the anticipated end of study visit for safety reasons and/or at the discretion of the investigator.

3. ENDPOINTS AND BASELINE VARIABLES: DEFINITIONS AND CONVENTIONS

3.1. Primary Endpoint(s)

Primary endpoints are assessments of AEs/SAEs including IRR, infusion sites and viral infections, vital signs, ECGs and laboratory tests.

3.2. Secondary Endpoint(s)

Secondary endpoints are:

- Serum PF-06823859 PK parameters, as permitted by data: C_{max}, C_{max} (dn), T_{max}, AUC_{inf}, AUC_{inf} (dn), AUC_{last}, AUC_{last} (dn), AUC_{14day}, AUC_{28day}, $t_{1/2}$, CL, V_{ss} and MRT. Definition and method of determination of PK parameters are shown in Table 3. PK parameters which will be calculated as permitted by data are also specified in Table 3.

- Incidence of the development of ADA and NAb.

Table 3. Serum PF-06823859 PK Parameters

Parameter	Definition	Method of Determination
AUC_{14day}	Area under the serum concentration-time profile from time 0 to 14 days post-dose (336 hours)	Linear/Log trapezoidal method
AUC_{28day}	Area under the serum concentration-time profile from time 0 to 28 days post-dose (672 hours)	Linear/Log trapezoidal method
AUC_{last}	Area under the serum concentration-time profile from time 0 to the time of the last quantifiable concentration (C_{last})	Linear/Log trapezoidal method
AUC_{last} (dn)	Dose normalized AUC_{last}	AUC_{last}/Dose
AUC_{inf} [a]	Area under the serum concentration-time profile from time 0 extrapolated to infinite time	$AUC_{last} + (C_{last}*/k_{el})$, where $C_{last}*$ is the predicted serum concentration at the last quantifiable time point estimated from the log-linear regression analysis
AUC_{inf} (dn)	Dose normalized AUC_{inf}	AUC_{inf}/Dose
C_{max}	Maximum serum concentration	Observed directly from data
C_{max} (dn)	Dose normalized C_{max}	C_{max}/Dose

Table 3. Serum PF-06823859 PK Parameters

Parameter	Definition	Method of Determination
T_{max}	Time at which C_{max} occurs	Observed directly from data as time of first occurrence
$t_{1/2}$ [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
CL [a]	Clearance	$Dose/AUC_{inf}$
V_{ss} [a]	Volume of distribution at steady state	CL*MRT
MRT	Mean residence time	$AUMC_{inf}/AUC_{inf}$ – DOF/2, where $AUMC_{inf}$ is the area under the moment curve from time 0 extrapolated to infinity and DOF is the duration of the IV infusion.

a. If data permitted.

3.3. Other Endpoint(s)

N/A

3.4. Baseline Variables

There are no baseline variables used as covariates or stratification factors in this study.

The demographic data will include age, sex, ethnicity, race, weight, body mass index and height. If not specified, baseline variables are those collected on Day 1 prior to dosing or last measurement during screening visits and Day -1.

3.5. Safety Endpoints

3.5.1. Adverse Events

An adverse event is considered a treatment-emergent adverse event (TEAE) to a given treatment if the event starts on or after the first dosing day and time/start time, if collected, but before the last dose plus the lag time. The algorithm will not consider any events that started prior to the first dose date. If an AE starts on the same day as the first dose date, it will be considered treatment emergent unless the CRF data indicates otherwise via explicitly recording time for AE onset and treatment dosing. The default lag time of CDISC and Pfizer Standards (CaPS) will be used for this study.

3.5.2. Laboratory Data

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

To determine if there are any abnormalities of potential clinical concern, the hematology, chemistry and urinalysis safety tests will be assessed against the criteria specified in the CaPS. The assessment will take into account whether each participant's baseline test result is within or outside the laboratory reference range for the particular laboratory parameter.

Baseline will be the last pre-dose measurement collected on Day -1.

3.5.3. Vital Signs

Supine systolic and diastolic blood pressure and pulse rate (PR) will be taken at all time points listed in the Schedule of Activities given in the protocol. The last pre-dose measurement at Day 1 will be used as the baseline.

The maximum decrease and increase from baseline over all measurements taken postdose for supine systolic and diastolic blood pressures will be determined. The maximum increasefrom baseline will be calculated by first subtracting the baseline value from each postdose measurement to give the change from baseline. The maximum of these values over the entire study will then be selected, except in the case where a participant does not show an increase. In such an instance, the minimum decrease should be taken. Similarly, the maximum decrease from baseline will be determined by selecting the minimum value of the change from baseline. In cases where a subject does not show a decrease, the minimum increase should be taken.

3.5.4. Electrocardiograms

Standard 12-lead ECGs will be taken at all time points listed in the Schedule of Activities given in the protocol. The last pre-dose measurement at Day 1 will be used as the baseline.

The QT, QTc, PR, QRS and heart rate will be recorded at each assessment time.

If not supplied, QTcF will be derived using Fridericia's heart rate correction formula:

$$QTcF = QT / (RR)^{1/3} \text{ where } RR = 60/HR \text{ (if not provided)}$$

The maximum absolute value (postdose) and the maximum increase from baseline will be determined over all measurements taken postdose for QTcF, PR and QRS.

The maximum increase from baseline will be calculated by first subtracting the baseline value from each postdose measurement to give the change from baseline. The maximum of these values over the respective period will then be selected, except in the case where a participant does not show an increase. In such an instance, the minimum decrease should be taken.

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 unblinding and releasing the database and classifications will be documented per standard operating procedures.

Participant Analysis Set	Description
Enrolled/Randomly assigned to study intervention	"Enrolled" means a participant's, or their legally authorized representative's, agreement to participate in a clinical study following completion of the informed consent process. 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. A participant will be considered enrolled if the informed consent is not withdrawn prior to participating in any study activity after screening.
Safety Analysis Set	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 concentration	All participants randomly assigned to study intervention who received at least 1 dose of study intervention and in whom at least 1 serum sample concentration value of PF-06823859 is reported.
PK parameter	All participants randomly assigned to study intervention who received at least 1 dose of study intervention and who have at least 1 of the PK parameters of PF-06823859 of interest calculated.
Immunogenicity	All participants randomly assigned to study intervention who received at least 1 dose of study intervention with at least one post-treatment anti-drug (PF-06823859) antibody determination.

If a participant receives a treatment that is not consistent with the treatment they are randomly assigned to, then the participant will be reported under the treatment that the participant actually received for all PK, immunogenicity and safety analyses, where applicable.

5. GENERAL METHODOLOGY AND CONVENTIONS

This is a double-blind and sponsor-open study. As this is a sponsor-open 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. Treatment randomization information will be kept confidential by Pfizer unblinded personnel and will not be released to the blinded investigator or blinded investigator site personnel until the study database has been locked or the investigator requests unblinding for safety reasons. Final analysis will follow the official database release.

5.1. Hypotheses and Decision Rules

There are no statistical hypotheses or decision rules.

5.2. General Methods

All data will be descriptively summarized by treatment (PF-06823859 300 mg, PF-06823859 900 mg, and placebo). Data from placebo in Cohort 1 and Cohort 2 will be pooled for all analyses.

5.2.1. Analyses for Binary Endpoints

Number and percentage of participants in each category will be used to summarize the binary endpoints, if not otherwise specified.

5.2.2. Analyses for Continuous Endpoints

The summary statistics n, arithmetic mean, median, standard deviation (SD), minimum and maximum will be used to summarize the continuous endpoints, if not otherwise speficied.

5.2.3. Analyses for Categorical Endpoints

Number and percentage of participants in each category will be used to summarize the categorical endpoints, if not otherwise specified.

5.3. Methods to Manage Missing Data

5.3.1. Safety Data

Missing values in standard summaries of AEs, laboraty data, vital signs, and ECGs will be imputed according to CaPS.

5.3.2. Pharmacokinetic Data

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, plots of mean profiles and plots of median profiles, summary statistics will be calculated setting concentrations to missing if one of the following cases is true:

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

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

Pharmacokinetic 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 (i.e., 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 dose with ≥ 3 evaluable.

If an individual participant has a known biased estimate of a PK parameter (due for example to an unexpected event such as known loss of drug during IV administration), this will be footnoted in summary tables and will not be included in the calculation of summary statistics.

6. ANALYSES AND SUMMARIES

6.1. Primary Endpoint(s)

The primary endpoints will be listed and summarized by treatment (PF-06823859 300 mg, PF-06823859 900 mg, and placebo) in accordance with CaPS, where the resulting data presentations will consist of participants from the safety analysis set. Data from placebo in Cohort 1 and Cohort 2 will be pooled.

6.1.1. Adverse Events

Adverse events will be listed and summarized in accordance with CaPS.

IRR (Infusion Related Reaction) will include adverse events potentially related to infusion related reaction and will be determined by blind medical review prior to the database release. The incidence and severity of IRR will be summarized by treatment group. The incidence and severity of IRR will also be summarized by system organ class (SOC) and preferred term

(PT) by severity. Separate tables will be prepared by all causalities and treatment-related for these summaries.

The incidence and clinical significance of infusion site reaction will be summarized by treatment group. The incidence and severity of infusion symptoms will also be listed and summarized by treatment group. The detail on infusion site reaction collected in CRF will also be listed.

Viral infections will include adverse events which are specified by the latest targeted medical events (TMEs) related to infections for C025 project. The incidence and severity of viral infections will be summarized by treatment group. The incidence and severity of viral infections will also be summarized by SOC and PT by severity. Separate tables will be prepared by all causalities and treatment-related for these summaries.

6.1.2. Laboratory Data

Laboratory data will be listed and summarized by treatment in accordance with CaPS. Baseline is as defined in Section 3.5.2.

6.1.3. Vital Signs

Absolute values and changes from baseline in supine systolic and diastolic blood pressure and pulse rate will be summarized by treatment and visits, according to CaPS. Tables will be paged by parameter. Baseline is as defined in Section 3.5.3.

Maximum and minimum absolute values and changes from baseline for vital signs will also be summarized by treatment using categories as defined in Appendix 1. Numbers and percentages of participants meeting the categorical criteria will be provided. All planned and unplanned postdose timepoints will be counted in these categorical summaries. All values meeting the criteria of potential clinical concern will be listed.

If necessary, maximum increases or decreases in vital signs may be summarized in addition to the above.

6.1.4. Electrocardiograms

Absolute values and changes from baseline for the ECG parameters (QT interval, heart rate, QTcF interval, PR interval, and QRS interval) will be summarized by treatment and visits following the CaPS. Tables will be paged by parameter. Baseline is as defined in Section 3.5.4.

Maximum increase from baseline for QTcF interval, PR and QRS over all measurements will be summarized by treatment group, according to CaPS.

ECG endpoints and changes from baseline (QTcF, PR and QRS) will also be summarized by cohort and treatment using categories as defined in Appendix 1. The number (%) of

participants meeting the categorical criteria will be provided. All planned and unplanned postdose timepoints will be counted in these categorical summaries. All values meeting the criteria of potential clinical concern will be listed.

6.2. Secondary Endpoint(s)

6.2.1. Pharmacokinetic Analyses

PK parameters for PF-06823859 following single-dose administration will be derived from the serum concentration-time profiles using noncompartmental methods, as data permit.

The PK parameters will be summarized descriptively by treatment group in accordance with Pfizer data standards, as data permit. Missing values will be handled as detailed in Section 5.3. Each PK parameter will be summarized by treatment group and will include the set of summary statistics as specified in the table below:

Table 4. PK Parameters to be Summarized Descriptively

Parameter	Summary Statistics
C_{max}, C_{max} (dn), AUC_{inf}, AUC_{inf} (dn), AUC_{last}, AUC_{last} (dn), AUC_{14day}, AUC_{28day}, MRT, V_{ss}, CL	N, arithmetic mean, median, standard deviation (SD), percent coefficient of variation (%CV), minimum, maximum, geometric mean and geometric %CV.
T_{max}	N, median, minimum, maximum
$t_{1/2}$	N, arithmetic mean, median, SD, %CV, minimum, maximum.

dn: dose normalized

There will be summary tables presenting all PK parameters.

To assess the relationship between the PK parameters and dose, dose normalized AUC_{inf}, AUC_{last} and C_{max} will be plotted against dose, and will include individual participant values and the geometric means for each dose. Geometric means will have a different symbol than the individual values. The values will be dose normalized (to a 1 mg dose) by dividing the individual values and raw geometric means by dose. A footnote will be added to the plots to indicate that geometric means are presented and that data from both cohorts are presented on the plot.

Supporting data from the estimation of $t_{1/2}$ and AUC_{inf} will be listed by analyte where applicable: terminal phase rate constant (k_{el}); goodness of fit statistic from the log-linear regression (r^2); the percent of AUC_{inf} based on extrapolation ($AUC_{extrap\%}$); and the first, last, and number of time points used in the estimation of k_{el}. This data may be included in the clinical study report.

Presentations for PF-06823859 concentrations will include:

- a listing of all concentrations sorted by subject ID, cohort, dose 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 dose 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 lower limit of quantification.
- median concentrations time plots (on both linear and semi-log scales) against nominal time postdose by dose (all treatments on the same plot per scale, based on the summary of concentrations by dose and time postdose).
- mean concentrations time plots (on both linear and semi-log scales) against nominal time postdose by dose (all treatments on the same plot per scale, based on the summary of concentrations by dose and time postdose).
- individual concentration time plots by dose (on both linear and semi-log scales) against actual time postdose (there will be separate spaghetti plots for each dose 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 doses) per scale].

The length of time used for the x-axes of these plots will be decided on review of the data, and will depend on how long PF-06823859 concentration is quantifiable in the matrix.

For summary statistics, median and mean plots by sampling time, the nominal PK sampling time will be used, for individual participant plots by time, the actual PK sampling time will be used.

6.2.2. Immunogenecity Endpoints

The incidence of the development of ADA and NAb will be listed and summarized for participants in the immunogenicity analysis set. Presentations for immunogenecity will include:

- Summary of ADA and NAb by sample
- Summary of ADA and NAb incidence over time
- Summary of incidence of ADA and NAb by dose and time postdose
- Summary of cumulative incidence of ADA and NAb by dose and time postdose
- Impact of ADA and NAb status on PF-06823859 concentrations

- Summary of participants with ADA negative and PK > assay tolerance value at last sampling point

Immunogenicity assay titers will be used to determine incidence for ADA and NAb. Titer values will also be listed.

6.3. Other Endpoint(s)

N/A

6.4. Subset Analyses

No subset analysis will be conducted for this study.

6.5. Baseline and Other Summaries and Analyses

6.5.1. Baseline Summaries

Demographic and baseline characteristics (age, sex, ethnicity, race, weight, body mass index and height) collected prior to the first dose of the study drug will be summarized following the CaPS.

6.5.2. Study Conduct and Participant Disposition

The following participant dispositions will be summarized.

- A summary of participant discontinuations up to end of study;
- Summary of participant dispositions analyzed for PK, immunogenicity, as well as for safety;
- Summary of numbers of participant treated by treatment group.

Data will be reported following the CaPS.

6.5.3. Study Treatment Exposure

Study treatment exposure will be listed.

6.5.4. Concomitant Medications and Nondrug Treatments

All concomitant medications as well as nondrug treatments will be summarized following the CaPS.

6.6. Safety Summaries and Analyses

The details of safety analyses are described in the Section 6.1.

7. INTERIM ANALYSES

No formal interim analysis will be conducted for this study. As this is a sponsor-open 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.

8. APPENDICES

Appendix 1. Categorical Classes for Vital Signs and ECG of Potential Clinical Concern

Categories for Vital Signs

Systolic BP (mm Hg)	min. <90	
Diastolic BP (mm Hg)	min. <50	
Pulse rate (bpm)	min. <40	max. >120
Systolic BP (mm Hg) change from baseline	max. increase ≥30	max. decrease ≥30
Diastolic BP (mm Hg) change from baseline	max. increase ≥20	max. decrease ≥20

Categories for PR and QRS

PR (ms)	max. ≥300
QRS (ms)	max. ≥140
PR (ms) increase from baseline	Baseline >200 and max. ≥25% increase or Baseline ≤200 and max. ≥50% increase
QRS (ms) increase from baseline	≥50% increase

Categories for QT

Absolute value	≥500

Categories for QTcF

Degree of Prolongation	Mild (msec)	Moderate (msec)	Severe (msec)
Absolute value	≥450 and <480	≥480 and <500	≥500
Increase from baseline		≥30 and <60	≥60

Measurements that fulfill these criteria are to be listed in report.

Appendix 2. List of Abbreviations

Abbreviation	Term
ADA	antidrug antibodies
AE	adverse event
AUC	area under the curve
AUC_{14day}	AUC from time 0 to 14 days post-dose
AUC_{28day}	AUC from time 0 to 28 days post-dose
$AUC_{extrap\%}$	percent of AUC_{inf} based on extrapolation
AUC_{inf}	AUC from time 0 extrapolated to infinite time
AUC_{last}	AUC from time 0 to the time of the last quantifiable concentration
BLQ	below the limit of quantitation
CaPS	CDISC and Pfizer Standards
CDISC	Clinical Data Interchange Standards Consortium
C_{max}	maximum observed concentration
CL	clearance
CRF	case report form
CRU	clinical research unit
dn	dose normalized
ECG	electrocardiogram
HR	heart rate
IRR	infusion related reaction
IV	intravenous(ly)
k_{el}	terminal phase rate constant
LLQ	lower limit of quantitation
MRT	mean residence time
N/A	not applicable
NAb	neutralizing antibodies
NC	not calculated
ND	not done
NS	no sample
PD	pharmacodynamic(s)
PK	pharmacokinetic(s)
PR	pulse rate
PT	preferred term
QTc	corrected QT
QTcF	corrected QT (Fridericia method)
SAE	serious adverse event
SAP	statistical analysis plan
SD	standard deviation
SOC	system organ class

Abbreviation	Term
$t_{1/2}$	terminal phase half-life
TEAE	treatment-emergent adverse event
TME	targeted medical event
T_{max}	time to reach C_{max}
V_{ss}	volume at steady state