Pfizer Inc.
Protocol #: C4971002 (TTI-622-02)

A Phase I/II Study of PF-07901801 (TTI-622) in Combination with Pegylated Liposomal Doxorubicin (PLD) in Patients with Platinum-Resistant Ovarian Cancer

Statistical Analysis Plan

Version 1.0

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ABBREVIATIONS

Abbreviation	Definition
ADA	Anti-drug Antibody
AE	Adverse Event
ALT	Alanine Aminotransferase
ANC	Absolute Neutrophil Count
AST	Aspartate Aminotransferase
BSA	Body Surface Area
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CM	Concomitant Medications
CR	Complete Response
CRF	Case Report Form
CRO	Contract Research Organization
CSR	Clinical Study Report
CTCAE	Common Terminology Criteria for Adverse Events
DCR	Disease Control Rate
DDI	Drug-Drug Interaction
DLT	Dose-Limiting Toxicity
DOR	Duration of Response
ECG	Electrocardiogram
ECHO	Echocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
EOC	Epithelial Ovarian Cancer
EOS	End of Study
EOT	End of Treatment
FDA	United States Food and Drug Administration
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
h	hour
ICF	Informed Consent Form
ICH	International Council for Harmonisation
IRB	Institutional Review Board
IU	International Units

IV	Intravenous
L	liter(s)
m^2	squared meter(s)
mAb	monoclonal antibody
MedDRA	Medical Dictionary for Regulatory Activities
mg/mL	Milligrams per milliliter
min	minute(s)
MTD	Maximum Tolerated Dose
NA	Not Available
NAb	Neutralizing antibodies
NCI	National Cancer Institute
NE	Not Evaluable
ORR	Objective Response Rate
OS	Overall Survival
PD	Progressive Disease; Pharmacodynamics
PLD	Pegylated Liposomal Doxorubicin
PFS	Progression-Free Survival
PI	Principal Investigator
PK	Pharmacokinetics
PP	Per Protocol
PR	Partial Response
PT	Preferred Term
RECIST	Response Evaluation Criteria in Solid Tumors
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Stable Disease
SOC	System Organ Class
SOP	Standard Operating Procedure
TEAE	Treatment Emergent Adverse Events
TLF	Tables, Listings, and Figures
WHO	World Health Organization
WHO-DD	World Health Organization Drug Dictionary

1. INTRODUCTION

1.1. Protocol and Amendment History

This Statistical Analysis Plan (SAP) is based on version 2.0 of Protocol C4971002 (TTI-622-02) (07DEC2022).

Protocol Version	Approval Date
1.0	28JUL2021
2.0	07DEC2022

The study protocol describes the general approach to analysis of data from the study. This SAP describes additional detail needed to complete such an analysis and will govern the final analysis of data from this study. The plan may be modified prior to the clinical database lock. Any deviations from this analysis plan, including any after the time of final analysis, will be documented as such in the study report.

1.2. Changes to Planned Analyses from Protocol

No changes to the planned analyses in the protocol are noted.

1.3. Revision History of the Statistical Analysis Plan

Version	Approval Date	Changes from Previous Version
1.0	18SEP2023	n/a

2. STUDY OBJECTIVES

2.1. Primary Objective

The protocol lists the following primary objectives:

- To evaluate dose-limiting toxicities (DLT), safety and tolerability of escalating dose levels of Maplirpacept (PF-07901801) when administered in combination with 40 mg/m^2 pegylated liposomal doxorubicin (PLD) in 28-day cycles and establish the maximum tolerated dose (MTD) and recommended phase 2 dose (RP2D) combination regimen (Phase 1 portion of study)
- To assess a preliminary evidence of anti-tumor activity of Maplirpacept (PF-07901801) in combination with 40 mg/m^2 PLD (Phase 2 portion of study)

2.2. Secondary Objectives

The protocol lists the following secondary objectives:

- To further assess the overall safety profile of Maplirpacept (PF-07901801) administered in combination with 40 mg/m^2 PLD
- To assess additional efficacy outcomes

2.3. Exploratory Objectives

The protocol lists the following exploratory objectives:

- To assess effect of treatment with Maplirpacept (PF-07901801) in combination with PLD on CA-125 levels
- To characterize the Maplirpacept (PF-07901801) concentration in serum when administered in combination with PLD
- To characterize the PLD concentration in plasma when administered in combination with PF-07901801
- To assess drug-drug interaction (DDI) potential between Maplirpacept (PF-07901801) and PLD
- To evaluate development of antibodies directed against Maplirpacept (PF-07901801)
- To explore possible relationships between Maplirpacept (PF-07901801) exposure and clinical outcome, safety and pharmacodynamics observations.
- To understand the relationship between the therapeutic intervention(s) being studied and the biology of the participant's disease.

3. STUDY ENDPOINTS

3.1. Primary Endpoint

The primary endpoints are:

- Phase 1: DLTs during the DLT observation period (28 days following cycle 1 day 1)
- Phase 2: Objective response (CR, PR) as defined by RECIST v1.1 criteria

3.2. Secondary Endpoints

The protocol describes as secondary endpoints the following:

- Overall safety profile as assessed by the type, frequency, severity, timing and causal relationship of any adverse events, changes in vital signs, ECG, serum chemistry or other laboratory assessment, treatment delays or discontinuations
- PFS, OS, disease control (DC [CR or PR or SD]), and DOR

3.3. Exploratory Endpoints

The protocol describes as exploratory endpoints the following:

- CA-125 levels in serial blood samples
- Measurements of biomarkers/pharmacodynamics, which may consist of DNA, RNA, protein or defined cell types, resulting from analyses of peripheral blood and/or tumor tissue biospecimen obtained at baseline, on treatment and/or at end of study
- Immunogenicity: Incidence and titers of ADA and neutralizing antibodies against PF-07901801
- PF-07901801 PK: Single and multiple dose C_{max}, CCI , C_{trough}, and clearance
- PLD PK: Single and multiple dose C_{max} and C_{trough}

4. STUDY DESIGN

4.1. Design Overview

This is a multi-center, open-label study designed to evaluate Maplirpacept (PF-07901801) administered in combination with PLD in participants with platinum-resistant recurrent epithelial ovarian cancer (EOC), including ovarian, peritoneal and fallopian tube malignancy, and for whom PLD is a reasonable treatment option. The study will consist of a 28-day screening period, a treatment period in which participants will receive PF-07901801 in combination with PLD in 28-day cycles until documentation of objective disease progression or development of unacceptable toxicity, and a long-term follow-up period to assess overall survival.

In the phase 1 dose escalation portion of the study, the primary objective is to assess DLTs, safety and tolerability of escalating dose levels of PF-07901801 in combination with PLD at the standard dose of 40 mg/m^2. Up to approximately 18 participants are planned to be enrolled in this portion of the study to evaluate three dose levels of PF-07901801 12 mg/kg (Dose Level 1), 24 mg/kg (Dose Level 2) and 48 mg/kg (Dose Level 3). In Cycle 1 for dose levels 1 and 2, PF-07901801 will be administered on Day 1, Day 8, Day 15, and Day 22 in combination with PLD on Day 1 of 28-day cycle. Beginning with Cycle 2 at dose levels 1 and 2, PF-07901801 will be administered on Day 1 and Day 15 in combination with PLD on Day 1 of 28-day cycles. The enhanced dosing in Cycle 1 represents a loading cycle and is intended to allow PF-07901801 levels to reach steady state more quickly. For dose level 3, PF-07901801 will be administered on Day 1 and Day 15 in combination with PLD on Day 1 of 28-day cycles. Loading doses (Day 8 and Day 22) may be considered for Cycle 1 at the 48 mg/kg dose (Dose Level 3) if found to be safe and offer clinical benefit for participants. If Cycle 1 loading doses are implemented, all dosing and lab draw schedules for the 48 mg/kg dose will follow the schedules for dose levels 12 mg/kg and 24 mg/kg.
One dose level combination will be selected for further evaluation in the phase 2 expansion portion of the study. The primary objective of the phase 2 expansion portion of the study is investigation of clinical activity of the combination of PLD and PF-07901801, assessed using the overall response by RECIST v1.1.

4.2. Sample Size

In the Phase 1 dose escalation phase of the study, the number of participants will depend on the number of dose cohorts that will be enrolled before reaching the MTD. It is anticipated that the study will evaluate three dose levels of PF-07901801 given in combination with a fixed dose of PLD. On the basis of emerging safety and/or clinical activity data, additional dose levels may be added. The size and design of the phase 1 is consistent with standard 3+3 design with the objective of determining the safety of escalating doses of PF-07901801 in combination with fixed-dose PLD and establishing PF-07901801 doses for further evaluation in the intended participant population. Based on a standard 3+3 design, up to approximately six DLT-evaluable participants may be enrolled in each dose level cohort during the phase 1; a minimum of nine and a maximum of 18 DLT-evaluable participants is anticipated.

In the phase 2 expansion phase of the study, a cohort is planned to evaluate a selected PF-07901801 dose level in combination with a fixed dose of PLD. In this hypothesis-generating study, assuming an objective response rate of 10% with PLD monotherapy and an alternative of 30%, a power of 80% and one-sided type 1 error set at 0.05, the combination will be considered worthy of further study if at least six responses are observed a 25 treated participant cohort. If the dose level combination selected for further phase 2 is determined to be not optimal or not well tolerated, an intermediate dose level, not to exceed the dose levels evaluated in phase 1, may be implemented. Secondary endpoints, such as disease control, duration of response, progression-free survival and overall survival will be analyzed descriptively.

5. General Analytical Considerations

5.1. Data Sources

All reported study data will be recorded on the electronic case report forms (eCRF) using Medidata Rave. During the data collection process, automated quality assurance programs will be used to identify missing data, out-of-range data, and other data inconsistencies. Lab data (chemistry and hematology) will come from local labs through the EDC.

5.2. Definition of Baseline

Baseline is defined as the last measurement taken prior to the first infusion of study medication (Cycle 1 Day 1). If an assessment is planned to be performed prior to the first dose of study treatment in the protocol and the assessment is performed on the same day as the first dose of study treatment, it will be assumed that it was performed prior to study treatment administration, if assessment time point is not collected or is missing.

The average of the pre-infusion results will be considered as the baseline value for vital signs taken at different timepoints on the same pre-infusion day.

5.3. Analysis Visits and Windows

The participation in the study includes the following planned visits (window) with respect to the first dose of study treatment:

- Screening Visit (Day -28 to -1)
- Cycle 1: Day 1, Day 8, Day 15, and Day 22
- Cycle 2 and 3: Day 1, Day 8, Day 15, and Day 22 (±3)
- Cycle 4 and subsequent cycles: Day 1, and Day 15 (±3)
- End of Treatment (7 ± 3 days after last administration of study treatment)
- Safety Follow-Up (30 + 5 days after last administration of study treatment)
- Long-Term Follow-Up (assessed every 12 ± 2 weeks)

The protocol provides additional details in table 28. Schedule of Assessment. Timepoints and its windows for PK analysis of PF-07901801 and PLD concentrations are described in section 10 of this SAP, and in tables 29 and 30 of the protocol.

In case of out-of-window visits, these data will be analyzed separately at the time the input as recorded.

5.4. Missing Data

Due to the study design, data will be reported as collected and no imputation methods of missing values will be performed, except for partial dates. Below it is addressed how missing information will be handled for partial/missing dates and incomplete disease assessments.

5.4.1. Partial and Missing Dates

Partial dates are allowed on the eCRF for prior disease therapy start and stop dates, adverse event (AE) onset and end dates, concomitant medication start and stop dates, and concomitant procedure, procedure dates. An entry for the year is required in the eCRF system for each of these dates. Only the month and day may be entered as unknown. Dates from these forms will be reported in listings as collected. Every effort will be made to query missing dates. The following rules will be used for imputation of partial and missing AE dates:

- AE onset dates with missing day and non-missing month will be assumed to occur on the first day of the non-missing month, except for AEs occurring in the month and year of first dosing, in which case the date will be imputed using the date of first dosing.
- AE onset dates with missing day and month will be assumed to occur on the first day of the non-missing year (i.e., January 1), except for AEs occurring in the year of first dosing, in which case the date will be imputed using the date of the first dosing.
- AEs that are not ongoing and have an end date with missing day and non-missing month, they will

be assumed to occur on the last day of the month, except when the end of study date or date of death is prior to the last day of the month. The date will be imputed as end of study date, or death date, whichever happens the earliest.

- AEs that are not ongoing and have missing month in the end date, the imputed end date should be set to the last day of the year (31DECYYYY), except when the end of study date or date of death is prior to the last day of the year. The date will be imputed as end of study date, or death date, whichever happens the earliest.

For records with missing AE onset date, the following procedure will be employed for use in determining whether the AE is treatment-emergent:

Start Date	End Date	Rule
Known	Known	If start date < study medication start date, then non-TEAE; If start date ≥ study medication start date, then TEAE
	Partial	
	Missing	
Partial (known parts indicating AE are not on or after study medication start date)	Known	Non-TEAE
	Partial	
	Missing	
Partial (known parts indicating AE are on or after study medication start date) OR Missing	Known	If end date < study medication start date, then non-TEAE; If end date ≥ study medication start date, then TEAE
	Partial	Assume end date as latest possible date (i.e., last day of month if day unknown or 31st December if day and month are unknown), then: If end date < study medication start date, then non-TEAE; If end date ≥ study medication start date, then TEAE
	Missing	TEAE

For records with a missing medication start and/or stop date, the following date imputation rule will be applied:

- Medication start dates with a missing day and non-missing month will be assumed to occur on the first day of the non-missing month, except for medications occurring in the month of first dosing, in which case the date will be the date of first dosing.
- Medication start dates with missing day and month will be assumed to occur on the first day of the non-missing year (i.e., January 1), except for medications occurring in the year of first dosing, in which case the date will be the date of first dosing.
- Medications that are not ongoing and have a medication stop date with a missing day and non-missing month will be assumed to occur on the last day of the non-missing month.

- Medications that are not ongoing and have a medication stop date with missing day and month will be assumed to occur on the last day of the non-missing year (i.e., December 31).

The following algorithm will be employed for determining whether the medication is prior or concomitant:

Start Date	End Date	Rule
Known/ Partial/ Missing	Known	If end date < study medication start date, then prior; If end date ≥ study medication start date, then concomitant
	Partial	Assume end date as latest possible date (i.e., last day of month if day unknown or 31st December if day and month are unknown), then: If end date < study medication start date, then prior; If end date ≥ study medication start date, then concomitant
	Missing	Concomitant

For records with a missing procedure date, the following procedure will be employed for use in determining whether the procedure is prior or concomitant:

- Procedure dates with a missing day and non-missing month will be assumed to occur on the first day of the non-missing month, except for procedures occurring in the month of first dosing, in which case the date will be the date of first dosing.
- Procedure dates with missing day and month will be assumed to occur on the first day of the non-missing year (i.e., January 1), except for procedures occurring in the year of first dosing, in which case the date will be the date of first dosing.

For records with a missing disease progression date from prior therapy, the following procedure will be employed for use in analyzing time to event endpoints:

- If the disease progression date is completely missing OR only the year is available, set as missing.
- If both year and month of disease progression date from are available and only day is missing, the date of disease progression will be imputed by the last day of the month.

For records with a partial death date, the death date will be imputed by the earliest possible date that is not contradicting with any other available data in the database.

5.4.2. Exposure

No imputation will be done for first dose date. Date of last dose of study drug, if unknown or partially unknown, will be imputed as follows:

- If the last date of study drug is completely missing and there is no End of Treatment eCRF page and no

death date, the participant should be considered to be ongoing and use the cut-off date for the analysis as the last dosing date

• If the last date of study drug is completely or partially missing and there is EITHER an End of Treatment eCRF page OR a death date available (within the cut-off date), then imputed last dose date is:

- = 31DECYYYY, if only Year is available and Year < Year of min (EOT date, death date)
- = Last day of the month, if both Year and Month are available and Year = Year of min (EOT date, death date) and Month < the month of min (EOT date, death date)
- = min (EOT date, death date), for all other cases.

5.4.3. Last Known Alive Date

The last known alive date will be derived for participants not known to have died at the time of analysis using the latest complete date among the following:

- All patient assessment dates (blood draws (laboratory, PK), vital signs, performance status, ECG, tumor assessments)
- Start and end dates of anti-cancer therapies administered after study treatment discontinuation
- AE start and end dates
- Last date collected on the 'Survival status' eCRF
- Study drug start and end dates
- Withdrawal of consent date
- Date of treatment or study discontinuation (do not use if reason for discontinuation is lost to follow-up).

Only dates associated with actual examinations of the participant will be used in the derivation. Dates associated with a technical operation unrelated to participant status such as the date a blood sample was processed will not be used. Assessment dates after the cut-off date will not be applied to derive the last contact date.

5.5. Timing of Analyses

This is an exploratory study, so analyses may be performed as the study progresses, such as for the trial phase 2 transition. Efficacy and safety analysis for safety review/evaluation, and/or publication purposes might be produced before the final analysis (*e.g.* reporting for Phase 1 and Phase 2, separately).

5.6. Analysis Populations

5.6.1. Safety Analysis Set (SAS)

The safety analysis set will include participants who were enrolled and received at least one dose of PF-07901801. This analysis population will be the primary population for the analysis of safety and efficacy endpoints. For reporting response rate prior to study completion, the analysis population will include all patients with a baseline disease

assessment, a follow-up assessment at least 4 weeks after the first dose and participants who have discontinued the study for any reason.

In Phase 1, each participant will be classified to a dose cohort if the initially planned PF-07901801 dose was received at least once any time on study. If the initially planned dose is never received by a participant, then the participant will be classified to the cohort based on highest PF-07901801 dose received.

For participants who received a wrong study dose, they would be recoded as protocol deviation, as described in section 6.3.

5.6.2. DLT-Evaluable Population (DLP)

The DLT-evaluable population is applicable to phase 1 dose-escalation participants only who either experience DLT after at least one dose of PF-07901801 or did not experience a DLT and received the full dose of PLD, at least two infusions of PF-07901801 and completed safety evaluations during the 28-day Cycle 1 DLT period.

5.6.3. PF-07901801 / PLD Concentration Analysis Population (PCP)

The PCP will include participants who received at least one dose of PF-07901801 and/or PLD and have at least one evaluable blood sample for analysis collected.

5.6.4. Immunogenicity Analysis Population (IAP)

The IAP will include participants who received at least one dose of PF-07901801 and with at least 1 anti-PF-07901801 antibody (ADA) and neutralizing anti-PF-07901801 antibody (NAb) sample analyzed (pre-dose or post-treatment).

If a subject has only pre-dose assessment and no post-treatment immunogenicity data, this subject is not evaluable for subject-level ADA and NAb evaluation, and should not be included in subject-level data analysis (*e.g.,* overall ADA/NAb incidence, duration of ADA/NAb response).

5.6.5. Pharmacodynamics Analysis Population (PDP)

The PDP will include participants who received at least one dose of PF-07901801 and have at least one evaluable blood sample collected for specific biomarker and pharmacodynamics analysis (pre-dose or post-treatment).

If a subject has only pre-dose assessment and no post-treatment biomarkers and pharmacodynamics data, this subject is not evaluable for subject-level evaluation, and should not be included in the subject-level data analysis.

5.7. Data Display Characteristics

Data displays produced for this study will include three types—summary tables, data listings, and figures. Summary tables and figures will be produced when specified in sections to follow.

Data listings will list the data recorded on the CRF or derived for each subject. As needed, they can be produced by dose cohort, site, subject number, and time of assessment, and additional levels of ordering hierarchy may reflect subsets of assessments within subject. Subject-level identifiers appear on the first line of data, and identifiers for subgroups within subject appear only on the first line of each subgroup value.

Tables will display summary statistics calculated for each dose cohorts per study phase (escalation/expansion), unless described otherwise in the following sections. For most summary tables, the dose group will be presented in columns and the summary statistics of interest will be presented in rows.

The summary statistics displayed will be a function of the type of data associated with the summarized assessment. Unless stated otherwise in relevant sections to follow, continuous data will be summarized with the number of non-missing values, mean, standard deviation, minimum, median, and maximum. Categorical data will be summarized with the number of non-missing values and the numbers of values equal to each of the possible values. Percentages of subjects with each of the possible values will be calculated from the number of subjects in the corresponding analysis population, unless stated otherwise, and those percentages will be presented with one decimal (XX.X%). Some continuous variables may also be grouped into categorical levels and evaluated in frequency tables.

Dates in the clinical database are classified into the categories of procedure dates, log dates, milestone dates, outcome dates, and special dates:

- Procedure Dates (TARGET DATE): Dates on which given protocol-specified procedure are performed. They include the dates of laboratory testing, physical examinations, disease assessments, etc. They should be present whenever data for a protocol-specified procedure is present and should only be missing when a procedure is marked as NOT DONE in the database. Procedure dates will not be imputed.
- Log Dates: Dates recorded in CRF data logs. Specifically, they are the start and end dates for adverse events and concomitant medications/procedures. They should not be missing unless an event or medication is marked as ongoing in the database. Otherwise, incomplete log dates will be imputed according to the rules in Section 5.4.1 above. However, in listings, log dates will be shown as recorded without imputation.
- Milestone Dates: Dates of protocol milestones such as study drug start date, study drug termination date, study closure date, etc. They should not be missing if the milestone occurs for a subject. They will not be imputed.
- Outcome Dates: Dates corresponding to study endpoints such as survival, progression, etc. In most cases, they are derived either from a milestone (e.g., the survival date is derived from the death

date), or a procedure date (e.g., the progression date is derived from the date of the tumor scan that was used to determine progression). They may be subject to endpoint-specific censoring rules if the outcome did not occur but are not otherwise subject to imputation.

- Special Dates: Dates that cannot be classified in any of the above categories and they include the date of birth. They may be subject to variable-specific censoring and imputation rules.

Calculations using dates (e.g., subject's age or relative day after the first dose of study medication) will adhere to the following conventions:

- Trial Day 1 of Cycle 1 is defined as the day on which the dose of PLD and PF-07901801 is administered after screening. Study days after trial day 1 will be calculated as the difference between the date of interest and the first date of dosing of study medication plus 1 day. The generalized calculation algorithm for relative day: STUDY DAY = [(TARGET DATE – DSTART) + 1 where DSTART = the start day of study drug].
- For dates of interest before the first date of dosing of study medication, the study day will be calculated as: STUDY DAY = TARGET DATE – DSTART. Negative study days are reflective of observations obtained prior to first study drug administration. Note: Partial date for the first study drug is not imputed in general. All effort should be tried to avoid incomplete study drug start date.
- Age (years) at informed consent will be calculated as: (Date of informed consent – date of birth + 1) / 365.25, and then truncated to an integer. In case of partial birth date: impute missing day as 15th of the month; impute missing month as July (7th month); set missing age in case of missing year.
- Duration will be calculated by the difference of start and stop date + 1. AE duration (days) = AE end date – AE start date +1
- Study drug exposure duration (weeks) is detailed in section 8.1. Exposure.
- Time since disease diagnosis (months) will be calculated as (Informed Consent Date – Diagnosis Date + 1) / 30.4167.
- The time to event will be calculated as date of event minus reference date + 1. The specific censoring rules on time to event endpoints will follow Section 7.1.1. Secondary Efficacy Outcome Analysis, and Section 8.7. ECOG Performance Status.
- The following conversion factors will be used to convert days to months or years:
  - 1 month = 30.4167 days
  - 1 week = 7 days
  - 1 year = 365.25 days

5.7.1. Multiple Assessments for the Same Assessment Time Point

In the case of multiple observations (e.g., scheduled vs. unscheduled) at a specific visit, the first non-missing measurement will be used for analysis, unless multiple study assessments are expected (e.g., pre-dose vs. post-dose). When multiple study assessments are expected (*e.g.* ECG), the average of the replicate measurements should be

determined after the derivation of the individual parameter at same time point.

5.8. Software Version

All statistical analyses will be conducted using SAS® version 9.4 or higher (SAS Institute, Inc., Cary, North Carolina).

Non-compartmental Pk parameter calculations will be performed using Phoenix® WinNonlin® 8.3 or higher (Certara, Princeton, New Jersey). Graphics may be prepared using the same versions of SAS®, and/or Phoenix WinNonlin).

6. SUBJECT ACCOUNTABILITY

6.1. Subject Characteristics

Subject characteristics will be summarized by phase (dose escalation and expansion phase) and by dose cohort, based on the SAS, which consist of all participants who received at least one dose of study treatment.

6.1.1. Demography

Data collected about the following subject characteristics at the screening visit will be summarized:

- Age (in years). Age will be calculated as the number of years elapsed between birth date and the date of the screening visit.
- Age strata:
  - < 65 years
  - >= 65 years
  - 65 - 74 years
  - 75 - 84 years
  - ≥ 85 years
- Sex
- Race. If more than one race selected, summarize race as multiple.
- Ethnicity
- Height
- Weight
- BSA
- ECOG
- Number of prior regimens (1 vs 2, 3 or 4)
- Disease stage

6.1.2. Medical History

Medical histories will be summarized as the numbers and percentages of subjects with histories significant for each of the medical-history elements recorded on the Medical History (MH) CRF form. Coding will be performed using Medical Dictionary for Regulatory Activities (MedDRA), latest version. System Organ Class (SOC) and Preferred Term (PT) will be summarized by number and percentage of participants having at least one occurrence of a disease. All MH information, including diagnosis and start/end date will be listed for the SAS.

6.1.3. Cancer History

Cancer histories will be summarized as the numbers and percentages of subjects with significant medical-history elements recorded on the Disease History CRF form. Disease History information, including histology information, stages, disease site and progressive disease date will be listed.

6.1.4. Prior Surgeries

Prior surgeries for the current diagnosis will be summarized in a table organized to display the type of surgery, displaying counts and percentages of participants who reported at least one surgery in each group, by SOC and PT according to the MedDRA current version.

6.1.5. Prior Anti-cancer Treatments

Prior treatment for the current cancer diagnosis will be captured in the eCRF form 'Prior Treatments for Disease Under Study Diagnosis' and will be coded using WHO Drug Dictionary (WHO-DD) current version. A summary table will be organized to display the therapeutic subgroup and preferred names of each coded medication. The summary table will display counts and percentages of participants who reported using at least one medication in each represented therapeutic subgroup and preferred term. All information recorded in the CRF, including start/end date, best response for that regime, and reason for discontinuation, will be listed.

6.1.6. Concomitant Medications

Concomitant medication (CM) is defined as any medication with a start date prior to the date of the first dose of study treatment (before baseline) and continuing after the first dose of study treatment or with a start date between the dates of the first and last dose of study treatment. Any medication with a start date after the date of the last dose of study treatment will not be considered a CM. Any medication with a stop date prior to the first dose of study treatment (baseline) is defined as a prior treatment.

CM will be coded using the WHO-DD current version and will be summarized by the anatomical main class (1st level) of each coded medication and, within that, pharmacological subgroup (3rd level) of the coded medication. Participants are counted only once in each therapeutic class category. Concomitant medication will be summarized using the SAS

and be tabulated for each dose level using frequencies and percentages. Percentages will be based on the number of participants in each dose level. A listing will be produced displaying the CM indication, dose, units, frequency, route, start/end date of the medication.

6.1.7. Concomitant Procedures

Concomitant procedure is defined as any procedure with a start date prior to the date of the first dose of study treatment (before baseline) and continuing after the first dose of study treatment or with a start date between the dates of the first and last dose of study treatment. Any procedure with a start date after the date of the last dose of study treatment will not be considered a concomitant procedure. Any procedure with a stop date prior to the first dose of study treatment is defined as a prior procedure.

Concomitant procedure will be coded using the MedDRA current version. SOC and PT will be summarized by number and percentage of participants having at least one occurrence of a concomitant procedure. A listing will be provided to display the procedure reason, location, and date.

6.2. Disposition

Counts and percentages will be calculated using the number of participants in SAS in the relevant cohort as the denominator. Screen failure is defined as a participant who signs informed consent but does not qualify for enrollment into the study. Screen failures and reasons will be reported on screen log and be summarized for all participants who sign informed consent.

For SAS, a summary of subjects will display the numbers and percentages of participants in each dose level by phase, total for escalation group, total for expansion group, and total for patients from escalation and expansion groups treated at the dose used in expansion.

End of Treatment (EOT) form will record the subject's status (completed or discontinued treatment), as well as the reason for discontinuation of each study drug (PLD and PF-07901801 are on separated forms) based on SAS.

End of Study (EOS) form will record participants who permanently discontinued the study, as well as the reasons, based on SAS.

6.3. Protocol Deviations

A listing will identify subjects who were enrolled even though they did not meet one or more eligibility criteria, or any other situations that were not compliant with the protocol. This data will be classified as major or minor deviation by the clinical team, that will review periodically the protocol deviations and finalize the deviations prior to the database lock and efficacy analyses.

7. EFFICACY ANALYSES

Efficacy analyses will use data from the SAS (for all efficacy endpoints). For reporting response rate prior to study completion, the analysis population will include all patients with a baseline disease assessment, a follow-up assessment at least 4 weeks after the first dose and participants who have discontinued the study for any reason. Efficacy analyses will be descriptive in nature. Summary tables and figures will be presented by dose cohorts within the dose escalation and expansion phases, and combined, as applicable.

7.1. Efficacy Outcomes

For the efficacy endpoint, the clinical anti-tumor efficacy of PF-07901801 in combination with PLD will be evaluated by tumor response as assessed by the investigators using RECIST v1.1, according to protocol appendix B (Eisenhauer, 2009).

The response categories of target lesions and its definitions are described below:

Complete Response (CR)	Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to < 10 mm.
Partial Response (PR)	At least a 30% decrease in the sum of the longest diameter (LD) of target lesions, taking as reference the baseline sum LD.
Stable Disease (SD)	Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for PD, taking as reference the smallest sum LD since the treatment started.
Progressive Disease (PD)	At least a 20% increase in the sum of the LD of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. The appearance of one or more new lesions is also considered PD.
Not Evaluable (NE)	No imaging/measurement is done at all at a particular time point. If only a subset of lesion measurements is made at an assessment, usually the case is also considered NE at that time point, unless a convincing argument can be made that the contribution of the individual missing lesion(s) would not change the assigned time point response, which is most likely to occur in the case of PD.

The response categories of non-target lesions and its definitions are described below:

Complete Response (CR)	Disappearance of all non-target lesions and normalization of tumor marker level.
Stable Disease/ Incomplete Response (Non-CR/Non-PD)	Persistence of one or more non-target lesion(s) or/and maintenance of tumor marker level above the normal limits.
Progressive Disease (PD)	Appearance of one or more new lesions and/or unequivocal progression of existing non-target lesions.

The tumor responses are required to be confirmed by radiographic tumor assessments. If an initial CR or PR is noted, confirmatory scans must be performed at least 4 weeks later. In the case of SD, follow-up measurements must have met the SD criteria at least once after study entry at a minimum interval of no less than 4 weeks.

The table below summarizes how the overall response will be calculated at each timepoint based on target and non-target lesion assessment:

Target Lesions	Non-target Lesions	New Lesions	Overall Response
CR	CR	No	CR
CR	Non-CR/non-PD	No	PR
CR	Not Evaluated	No	PR
PR	Non-PD or not evaluated	No	PR
SD	Non-PD or not evaluated	No	SD
Not Evaluated	Non-PD	No	NE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD
Any	Any	Yes	PD

Objective Response Rate (ORR) is defined as the percentage of participants in the treatment group who have a confirmed CR or PR to the treatment within the study period. The ORR will be summarized taking all target lesion, non-target lesion, and new lesion, into consideration.

The table below summarizes the overall response algorithm based on non-target lesion assessment only:

Non-target Lesions	New Lesions	Overall Response
CR	No	CR [a]
Non-CR/non-PD	No	Non-CR/non-PD
Not all evaluated	No	NE
Unequivocal PD	Any	PD
Any	Yes	PD

[a] *Best Response for this category also requires normalization of tumor markers, tumor nodes < 10 mm.*

Best Overall Response (BOR) is defined as the best response recorded (CR, PR, SD, PD, NE per RECIST) from the start of the treatment until disease progression, recurrence, start of new anti-cancer therapy or death, whichever is earlier, taking as reference for PD the smallest measurements recorded since the treatment started. The participant's best response assignment will depend on the achievement of both measurement and confirmation criteria. The evaluation of BOR will be determined according to the table below when confirmation of CR and PR is required:

Overall Response (OR)		Best Overall Response (BOR)
First Timepoint	Subsequent Timepoint	
CR	CR	CR
CR	PR	SD, PD or PR [a]

CR	SD	SD provided minimum criteria for SD duration met (≥4 weeks), otherwise, PD
CR	PD	SD provided minimum criteria for SD duration met (≥4 weeks), otherwise, PD
CR	NE	SD provided minimum criteria for SD duration met (≥4 weeks), otherwise, NE
PR	CR	PR
PR	PR	PR
PR	SD	SD
PR	PD	SD provided minimum criteria for SD duration met (≥4 weeks), otherwise, PD
PR	NE	SD provided minimum criteria for SD duration met (≥4 weeks), otherwise, NE
NE	NE	NE

[a] *If a CR is truly met at first timepoint, then any disease seen at a subsequent timepoint, even disease meeting PR criteria relative to baseline, makes this disease PD at that point (since disease must have reappeared after CR). Best response would depend on whether minimum duration for SD was met. However sometimes 'CR' may be claimed when subsequent scans suggest small lesions were likely still present and in fact the participant had PR, not CR at the first time point. Under these circumstances, the original CR should be changed to PR and the best response is PR.*

For participants with asymptomatic progression and in the absence of unacceptable toxicity, the participant should continue treatment and a confirmation scan should be conducted at least four weeks later to document objective progression prior to removing the participant from study treatment.

7.1.1. Primary Efficacy Outcome Analysis

Objective Response Rate (ORR), defined as the proportion of participants' best overall response achieving a confirmed CR or PR, per investigator, at any time on the study, will be summarized descriptively by dose cohort within the dose escalation and expansion phases. Baseline documentation of "target" and "non-target" lesions (lesion count and maximum lesion length) will be recorded in listings. The sum of diameters will be calculated for all target lesions at baseline and at each subsequent tumor assessment as a measure of tumor burden. The baseline lesion size or the smallest measurement on study value will be used as reference by which to characterize the lesion response.

Per RECIST criteria, target lesions considered 'too small to measure' will be assigned a default value of 5 mm and

those identified as 'not present' will be assigned 0 mm for purposes of analysis.

For efficacy response parameters, a 95% confidence interval (CI) using Wilson's score method will be presented for the phase 2 expansion cohorts, or combined data from phase 1 and phase 2 at the common dose used in the expansion cohort. All SAS participants will be included in the denominators for percentage, even if the participant had a NE response. The Objective Response Rate and BOR (CR, PR, SD, PD, NE) will be summarized descriptively for RECIST assessment method, for both phase 1 dose escalation and phase 2 expansion cohorts, and combined for the common dose.

Similarly, the proportion of participants with a BOR as CR and the proportion of participants with a BOR as PR at any time during the study will be summarized as part of the BOR.

Overall tumor response assessment data will be presented in listings.

7.1.2. Secondary Efficacy Outcome Analysis

Duration of response (DOR) will be calculated for participants who achieve a confirmed CR or confirmed PR, and is defined as the time from the date of first documented response (CR or PR) to the date of documented progression or death of any cause after achieving response. Participants who complete or discontinue the study without disease progression or death, as well as participants who receive alternate anti-cancer therapy prior to disease progression, will be censored at their last adequate response assessment date or last adequate assessment prior to the start date of alternate anti-cancer therapy. The number of events and the number of censored participants will be summarized, and the median time to PD or death event (reported in days), its 95% confidence interval (using Brookmeyer-Crowley method), and the 25th and 75th percentiles on the time to event for cohort will be summarized.

Disease Control Rate (DCR) is defined as the percentage of participants who have achieved CR, PR, or SD lasting at least 12 weeks. DCR at any time during the study will be summarized, as per the RECIST assessment method.

Progression Free Survival (PFS) is defined as the time from the first PF-07901801 injection (Cycle 1 Day 1) to PD or death of any cause, whichever is first. Participants who complete or discontinue the study without disease progression or death, as well as participants who receive alternate anti-cancer therapy prior to disease progression, will be censored at their last adequate response assessment date or last adequate assessment prior to the start date of alternate anti-cancer therapy. If date of progression occurs on the same date as the start of new anticancer therapy, the progression will be counted as an event. If there is PD or death after missing 2 planned assessments, the participant will be censored at the last non-PD assessment. Censoring reasons will be summarized in the PFS output.

For participants who do not have an adequate baseline tumor assessment or who do not have any postbaseline tumor assessments, censoring will occur on the date of first dose unless death occurred on or before the time of the second planned tumor assessment in which case the death will be considered an event. Note for participants who died without

any post baseline assessments and meet the definition of 2 or more missing assessment, the reason for censoring will be documented as 2 or more missed assessments and censoring will occur on the date of first dose.

The number of events and the number of censored participants will be summarized. PFS rate at selected times, as well as the median time to event (reported in days), its 95% confidence interval (using Brookmeyer-Crowley method), and the 25th and 75th percentiles on the time to event for cohort will be summarized. Kaplan-Meier plot of PFS will also be provided.

Overall Survival (OS) is defined as the time from the first PF-07901801 injection (Cycle 1 Day 1) to death of any cause. Participants without death date at the time of analysis will be censored at their last known alive date. Kaplan-Meier methodology similar to the PFS analysis will be used to summarize the results.

Waterfall plot for target lesion tumor response by individual will be presented, indicating best tumor response (maximum reduction of the sum of longest diameters from baseline) at any time point for each subject. The plot will have one bar per subject sorted from worst to best response with color by dose administered. Tumor response will be calculated based on the type of cancer that the participant has, with the appropriate measure using RECIST.

Spaghetti plots for target lesion tumor response by time will be presented for all participants at all visits, by dose. One line will be drawn per subject with color by response type. The horizontal axis will be the time and the vertical axis will be the percent change from baseline in tumor response. One set of spaghetti plots will be generated for RECIST assessment and only participants with non-missing tumor assessments will be shown.

Swimmer plots for tumor response will be generated with RECIST assessment. The plots will have one horizontal bar per subject firstly sorted by Best Response, and then sorted from earliest to latest time to start of response for CR and PR; within categories of SD, PD and NE, participants will be sorted by maximum observation duration. Symbols within the swimmer plot will indicate time to start and end of each new level of response (if the end of one response is the start of a new type of response by definition, only the start will be shown). The plots will also show the length of treatment duration a participant had.

8. SAFETY ANALYSES

Summary of AEs and other safety parameters will be based on the safety analysis set (SAS) by phase and dose cohort, except for the DLT, which will be based on DLT-Evaluable Population (DLP) by dose cohort.

8.1. Exposure

On Day 1 of each cycle, PLD will precede administration of PF-07901801. An observation period between completion of PLD infusion and initiation of PF-07901801 infusion is not mandated. Cohorts/dose levels for phase 1 escalation

part of the study with the intravenous exposure to study drugs PLD and PF-07901801 (after PLD) and its schedule of administration per 28-day cycle is summarized below:

Cohort / Dose Level (DL)	PLD Dose [mg/m^2] *Schedule of administration*	PF-07901801 Dose [mg/kg] *Schedule of administration*
1	**40** *Day 1 of every 28 day-cycle*	**12** *Cycle 1: Day 1, Day 8, Day 15, and Day 22* *Cycle 2 and above: Day 1 and Day 15*
2	**40** *Day 1 of every 28 day-cycle*	**24** *Cycle 1: Day 1, Day 8, Day 15, and Day 22* *Cycle 2 and above: Day 1 and Day 15*
3	**40** *Day 1 of every 28 day-cycle*	**48** *Any cycle: Day 1 and Day 15* [a]

The following rules apply during dose escalation:

- Starting dose at dose level 1 is 12 mg/kg.
- At least 3 participants will be enrolled at each dose level. When all participants at a dose level complete DLT assessments, the study will escalate to the next dose level and another 3 participants will be recruited in this order until MTD/RP2D.
- If agreed upon by the investigators and Pfizer (*eg*, based on safety, incidence of DLT, PK and dose-exposure data from prior and current cohorts) that increasing the dose further may not yield additional benefit, the dose may stay at the current dose level, be de-escalated to any dose, or no future escalation may be made, even if the dose escalation rule indicates to escalate.
- The need for dose escalation to a specific dose beyond 48 mg/kg or de-escalation to an intermediate dose level will be evaluated jointly by investigators and Pfizer based on cumulative clinical safety, PK, and preliminary efficacy data.

A participant who completes at least four cycles of treatment with PF-07901801 in combination with PLD and requires discontinuation of PLD due to PLD-related toxicity and who is receiving disease control may continue on study receiving PF-07901801 monotherapy beginning with the next cycle provided the participant has not experienced disease progression and PF-07901801 re-treatment guidelines as described in Section 9.1.2 of the protocol are met.

Exposure to PF-07901801 and PLD will be summarized with descriptive statistics for the number of non-zero doses received, duration of dosing (weeks), total cumulative dose (mg/kg for PF-07901801, mg/m^2 for PLD), and overall relative intensity.

Duration of treatment is defined as the time (in weeks) from first dose of study drug in cycle 1 to the last dose of study drug in the last cycle a participant had.

Total cumulative dose is the sum of the actual doses of PF-07901801 or PLD received.

The calculation algorithm for duration of exposure (in weeks) for each drug and intended duration of PF-07901801 treatment will be:

- Duration of PLD exposure (weeks) = (Last PLD dose date – first PLD dose date + 28) / 7
- Duration of PF-07901801 exposure (weeks)
  - DL1 and DL2 → If the last dose occurs during cycle 1: (Last PF-07901801 dose date – first PF-07901801 dose date + 7) / 7
  - DL1 and DL2 → If the last dose occurs during cycle 2 and beyond: (Last PF-07901801 dose date – first PF-07901801 dose date + 14) / 7
  - DL3: (Last PF-07901801 dose date – first PF-07901801 dose date + 14) / 7

Overall relative intensity (in %) for each drug is calculated as 100 × cumulative dose received divided by cumulative dose planned, where:

- Cumulative dose of PLD planned (mg/m^2) = Planned PLD dose/cycle (40) × Duration of PLD exposure (weeks)
- Cumulative dose of PLD received (mg/m^2) = Sum of all PLD doses (mg/m^2) actually received.
- Relative Dose Intensity (%) of PLD = Cumulative dose of PLD planned (mg/m^2) / Cumulative dose of PLD received (mg/m^2) × 100%
- Cumulative dose of PF-07901801 planned (mg/kg), where D = planned dose for the participants according to the DL (12, 24 or 48 mg/kg) and C = number of treatment cycles:
  - DL1 and DL2: (planned PF-07901801 dose/cycle × cycle 1 × number of planned administrations of PF-07901801 in cycle 1) + (planned PF-07901801 dose/cycle × number of cycles of PF-07901801 after cycle 1 × number of planned administrations of PF-07901801 per cycle) = (D × 1 × 4) + (D × [C-1] × 2)
  - DL3: planned dose/cycle × number of cycles of PF-07901801 × number of planned administrations of PF-07901801 per cycle = 48 × C × 2
- Cumulative dose of PF-07901801 received (mg/kg) = Sum of all PF-07901801 doses (mg/kg) actually received.
- Relative Dose Intensity (%) of PF-07901801 = Cumulative dose of PF-07901801 planned (mg/m^2) / Cumulative dose of PLD received (mg/m^2) × 100%

The number of drug administrations with dose reduction, infusion held or permanently withdrawn will also be

summarized descriptively by cohort, for each study drug (PF-07901801 and PLD).

In addition, the planned dosing date and the actual dosing date will be listed. Listings will be provided with the information from all the study drug administration eCRFs. Reasons for missed doses of PF-07901801 and PLD will be listed.

8.2. Treatment Compliance

8.2.1. Dose Delays

Dose delay is the difference between the actual time between two consecutive non-zero doses and the planned time between the same two consecutive non-zero doses.

> Dose delay for dose x (days) = Date of dose x – Date of dose (x-1) – Planned days between two consecutive doses.

Dose delays will be grouped into the following categories:

- No delay
  - 0 days delay
  - 1-3 days delay
- 4-6 days delay
- 7 or more days delay

For example, for PF-07901801, initially administered on a weekly schedule, if one participant receives PF-07901801 on Day 1, then the next PF-07901801 administration date will be on Day 8; however, if the participant receives PF-07901801 at Day 9 or 10, this is considered as 1-3 days delay.

The number and percentage of participants with delayed study drug administration and maximum length of delay, *i.e.*, the worst case of delay if participants have multiple dose delays will be summarized for the overall study.

8.2.2. Dose Reductions

Dose reduction is defined as actual non-zero dose < 90% of the planned dose. The number and percentage of participants with at least one dose reduction as well as a breakdown of the number of dose reductions (1, 2, 3, ≥4) will be summarized.

8.2.3. Infusion Interruptions

An infusion interruption is defined as an infusion that is stopped and re-started on the same day (*i.e.,* for a visit more than one infusion start time and infusion end time are recorded).

The number and percentage of participants with at least one infusion interruption as well as the frequency of participants with 1, 2, 3, or ≥4 infusion interruptions will be summarized.

8.3. Dose-limiting toxicity

Dose-limiting toxicity (DLT) is defined as CCI and/or CCI treatment-emergent adverse event that occurs during the 28-day Cycle 1 and are judged by the investigator as related to PF-07901801 or the combination of PF-07901801 and PLD. Adverse events that are in the opinion of the investigator attributable exclusively to intravenous infusion of PLD or any PLD prophylaxis medication will not be considered a DLT. AEs to be considered as DLT are listed in the study protocol. A patient without DLT must receive at least two doses of PFS to be called DLT-free.

These DLT will be summarized, including number and percentage of participants, in the DLT-evaluable population (DLP). A participant who withdraws from the study during cycle 1 in the absence of DLT-evaluable (*i.e.*, not receiving PLD and at least two doses of PF- 07901801) will be replaced.

AEs and Serious AEs (SAE) will be determined to be dose-limiting if they occur with cycle 1 and meet the described criteria above. AEs or SAEs experienced after the end of cycle 1 will not be reported as DLTs but will be documented.

8.4. Adverse Events

Adverse events (AEs) will be documented on the AE eCRF and monitored continuously throughout the study. Adverse events will be coded using the Medical Dictionary for Regulatory Activities (MedDRA), latest version, associating lower-level terms with PT and SOC by the primary hierarchy.

Treatment-Emergent Adverse Events (TEAE) are defined as any event that occurs or worsens on or after the day study treatment PF-07901801 is initiated through minimum (30 days + last dose of study treatment, start day of new anti-cancer drug therapy – 1 day), defined as on-treatment period. The tables will display counts and percentages of participants who reported at least one TEAE in each SOC represented in the AE data. Within each SOC, the tables will display the counts and percentages of participants reporting at least one TEAE, as designated by the PT.

The severity of adverse events will be graded using the NCI Common Toxicity Criteria for Adverse Events (CTCAE version 5.0). The intensity is assigned a grade of 1 through 5 using the following CTCAE guidelines: Grade 1 – Mild; Grade 2 – Moderate; Grade 3 – Severe; Grade 4 – Life-threatening; Grade 5 – Death.

The causality of AE is reported as either related to study drug or not related to study drug for each study drug (PF-07901801 and PLD). If the relationship to a treatment is missing, it will be considered as "related".

If a participant has multiple occurrences of an adverse event, the strongest level of relationship to study drug and the worst toxicity grade a participant experiences for a given AE will be used in these tables. No imputation will be performed for missing toxicity grade.

AEs that have missing onset dates will be considered as TEAE unless the stop date is known to be prior to the first administration of the study medication. If the AE onset date is partial, the date will be correlated as far as possible with the date of first dose of study medication. AE will be assumed to be TEAE, unless there is clear evidence (through comparison of partial dates) to suggest that the adverse event started prior to the first dose of study medication. Detailed date imputation rules can be found in section 5.4.1. If participants died during the study and experienced AEs at the time of death, the AEs that lead to death will use death date as the AE end date; otherwise, AEs that do not lead to death will be reported as ongoing.

There are no Adverse Events of Special Interest (AESI) related to the study drugs in this protocol.

The following TEAE summary tables will be produced by dose cohort, and overall:

- An overall summary of safety will summarize the numbers (and percentages) of participants with the following:
  - TEAEs
  - Grade ≥ 3 TEAEs
  - Related TEAEs [related to PF-07901801 only, PLD only, any study drug, and both drugs]
  - Related grade ≥ 3 TEAEs [related to PF-07901801 only, PLD only, any study drug, and both drugs]
  - Serious TEAEs
  - Related Serious TEAEs [related to PF-07901801 only, PLD only, any study drug, and both drugs]
  - TEAEs leading to dose reduction (of PF-07901801 and PLD, separately)
  - TEAEs leading to drug interruption (of PF-07901801 and PLD, separately)
  - TEAEs leading to permanently discontinued study drug (PF-07901801, PLD, any drug, and both)
  - Related TEAEs [related to PF-07901801 only] leading to permanent discontinuation of PF-07901801
  - Related TEAEs (related to PLD only) leading to permanent discontinuation of PLD
  - Related TEAEs (related to both drugs) leading to permanent discontinuation of both drugs
  - TEAEs leading to death
  - Related TEAEs [related to PF-07901801 only, PLD only, any study drug, and both drugs] leading to death

- Separate summaries of TEAEs by SOC and PT, as follows:
  - All TEAEs (any grade)
  - All grade ≥ 3 TEAEs
  - Related TEAEs [related to PF-07901801 only, PLD only, any study drug, and both drugs] (any grade)

- Related TEAEs [related to PF-07901801 only, PLD only, any study drug, and both drugs] (grade ≥ 3)
- All Serious TEAEs
- Related Serious TEAEs [related to PF-07901801 only, PLD only, any study drug, and both drugs]
- All TEAEs leading to dose reduction (of PF-07901801 and PLD, separately)
- All TEAEs leading to drug interruption (of PF-07901801 and PLD, separately)
- Related TEAEs [related to PF-07901801 only] leading to permanent discontinuation of PF-07901801
- Related TEAEs (related to PLD only) leading to permanent discontinuation of PLD
- Related TEAEs (related to both drugs) leading to permanent discontinuation of both drugs
- All TEAEs leading to death
- All related TEAEs [related to PF-07901801 only, PLD only, any study drug, and both drugs] leading to death

- Summary of infusion related reactions (any grade and Grade ≥ 3) by PT
- All TEAEs by SOC, PT, and maximum severity (CTCAE toxicity grade)
- DLTs by SOC, PT, and maximum severity (CTCAE toxicity grade)

The following AE listings will be produced, sorted by dose cohort, participant, and timing, with relevant information:

- All AEs
- All DLTs
- AEs leading to death

8.5. Deaths

The frequency (number and percentage) of subjects in the SAS who died and who died within 30 days after last dose of study treatment as well as the reason for death, will be tabulated:

- All deaths
- Deaths within 30 days after last dose of study treatment
- Cause of death

In addition, date and cause of death will be provided in individual participant data listing together with selected dosing information (study treatment received, date of first / last administration, dose) and will include the following information:

- AEs with fatal outcome (Listing of PTs of AEs with outcome=Fatal, as well as AEs of Grade 5)
- Flag for death within 30 days of last dose of study treatment.

8.6. Clinical Laboratory Results

Clinical laboratory tests (serum chemistry and hematology) will be performed at screening and, generally, each day receiving a PF-0790180 dose, unless otherwise specified in table 28. Schedule of Assessment, of the protocol. Baseline laboratory measurements do not need to be repeated if screening measurements were performed within 3 days prior to Cycle 1 Day 1. All laboratory data will be converted to standardized conventional units for reporting purposes.

Serum chemistry tests include determination of the following parameters: glucose, sodium, potassium, calcium, chloride, phosphate, bicarbonate, blood urea nitrogen or urea, creatinine, total protein, albumin, alkaline phosphatase, aspartate aminotransferase (AST), alanine aminotransferase (ALT), total bilirubin, indirect bilirubin, uric acid, calcium, magnesium, and lactate dehydrogenase (LDH).

Hematology tests include determination of the following parameters: Hemoglobin, hematocrit, platelets, white blood cells (WBC), neutrophils, lymphocytes, eosinophils, basophils, monocytes, WBC with automated 5-part differential, red blood cells (RBC), absolute reticulocytes, reticulocytes %, Erythrocyte Mean Corpuscular Hemoglobin (MCH), Erythrocyte Mean Corpuscular Volume (MCV), and Red Cell Distribution Width (RDW).

Summaries of baseline values and changes from baseline will be presented by dose level for each assessment time point.

Serum chemistry and hematology evaluations which cannot be graded per CTCAE criteria will be summarized as counts and percentages of participants who were normal at baseline, but who became abnormal subsequently.

For serum chemistry and hematology evaluations which can be graded per CTCAE v5.0, the following summary table will be created:

- Shift summary of baseline CTCAE grade versus the worst on-treatment CTCAE grade (The highest CTCAE grade during the on-treatment period is considered as the worst grade [Grade 0, 1, 2, 3, or 4] for the summary)
- Shift summary from ≤ Grade 2 at baseline to ≥ Grade 3 postbaseline

Clinical laboratory results will be listed by participant. In addition, listings of abnormal values will be provided for hematology, chemistry, coagulation parameters. If there is at least one abnormal assessment for any parameter, all the data for that laboratory parameter will be included into the listing.

8.7. Vital Signs

Vital signs (weight, temperature, pulse, respiratory rate, systolic blood pressure, and diastolic blood pressure) will be summarized with continuous descriptive statistics at screening, on day 1 of each treatment cycle, at EOT/Early Termination, and at Safety Follow-up visit. Mean change from screening (baseline) will be calculated for each

cycle/cohort.

Vital Signs will be listed by participant and summarized by cohort and visit in the SAS.

8.8. ECOG Performance Status

ECOG Performance Status (ECOG PS) will be assessed with the scale described in the protocol Appendix A, at screening, on all study treatment day 1 of each cycle, and at Safety Follow-Up visit. ECOG PS at baseline will be summarized, including number and percentage of participants.

8.9. Electrocardiogram (ECG)

Supine position 12-lead ECGs will be performed at screening and reviewed locally at each visit. An overall interpretation of the ECG results will be made (normal/abnormal), and corrected QT intervals, will be summarized by visit.

9. EXPLORATORY ANALYSIS

9.1. Efficacy analysis by demographic subgroups

ORR (primary efficacy outcome) as defined in section 7.1.1 will be analysed by the following demographic subgrouping:

- Age strata:
  - < 65 years
  - >= 65 years
- Sex
- Race
- ECOG
- Number of prior regimens (1 vs 2, 3 and 4)
- Disease stage

9.2. CA-125 Analysis

Final individual subject results from the CA-125 assay, as applicable, will be presented in the listings and the concentrations will be summarized by descriptive statistics in tabular form by dose cohort for day 1 and 15 on cycles 1-3, and day 1 for cycle 4 and further, including Safety Follow-Up visit.

9.3. Biomarkers/Pharmacodynamic Analysis

Blood samples for determination of biomarkers and pharmacodynamics (PD) will be collected in accordance with the schedule specified in the table 32 of the protocol. Pharmacodynamics results include quantification of peripheral CD47 receptor occupancy and serum cytokines. This analysis will use data from the Pharmacodynamics Analysis Population (PDP).

Final individual subject results, as applicable, will be presented in the listings and the results will be summarized by descriptive statistics in tabular form by dose cohort for each cycle day 1, including Safety Follow-Up and Long-Term Follow-Up visits. A table for mean change from screening (baseline) per cycle will be produced with the applicable PD parameters.

9.4. Immunogenicity Analysis

Final individual subject results from the PF-07901801 ADA and NAb assay, as appropriate, will be presented in the listings and the incidence summarized by descriptive statistics in tabular form by cohort. This analysis will use data from the Immunogenicity Analysis Population (IAP).

Summary tables that show the number and percentage of subjects that fall into the following categories will also be produced by study phase and cohort:

Treatment-induced ADA	Baseline ADA titer is missing or negative and subject has ≥ 1 post-treatment positive ADA titer.
Treatment-boosted ADA	A positive ADA result at baseline and the titer ≥ 8×baseline titer at least once after treatment with PF-07901801
ADA-positive subject	A subject with ≥ 1 treatment-induced or treatment-boosted ADA response.
ADA-negative subject	An ADA evaluable subject without treatment-induced or treatment-boosted ADA response. Subject either has (1) all ADA-negative results throughout the study or (2) is ADA positive at baseline but did not become treatment-boosted post-dose.
ADA incidence	The percent of ADA-positive subjects in a treatment group/cohort or study.
ADA never-positive	No positive ADA results at any time point; ADA-negative patients (titer < cutpoint)
ADA ever-positive	At least one positive ADA result at any time point; ADA-positive patients (titer ≥ cutpoint)
Treatment-induced NAb	Baseline NAb titer is missing or negative or ADA-negative and subject has ≥ 1 post-treatment positive NAb titer.

Treatment-boosted NAb	A positive Nab result at baseline and the titer ≥ 8 × baseline titer at least once after treatment with PF-07901801
NAb-positive subject	An ADA-positive subject with ≥ 1 treatment-induced or treatment-boosted NAb response. For ADA-positive (treatment-boosted) subjects, subject is NAb positive only if the subject has ≥1 treatment-induced or treatment-boosted NAb response at the visit where the subject has a treatment-boosted ADA response. For visits where the subject did not show a boosted ADA response, the subject is classified as NAb-negative for the visit even if the subject has post-treatment positive NAb titer for that visit.
NAb-negative subject	NAb evaluable participant who is either (1) an ADA-negative subject or (2) an ADA-positive subject without treatment-induced or treatment-boosted NAb response (*i.e.*, subject has all NAb-negative results throughout the study or subject is NAb positive at baseline but did not become treatment-boosted post-dose). Note: in the event a subject is ADA-positive at baseline but did not show a boosted response post-treatment, subject is classified as ADA-negative and NAb-negative at the subject level even if the subject has post-treatment positive NAb titer. As such all ADA-negative subjects are NAb-negative regardless of NAb titer data.
NAb incidence	The percent of NAb-positive subjects in a treatment group/cohort or study.
NAb never-positive	No positive NAb results at any time point (including no positive ADA results at any time point and no NAb results)
NAb ever-positive	At least one positive NAb result at any time point
Transient ADA	An ADA-positive subject with (1) a treatment-induced or treatment-boosted ADA sample detected only at 1 sampling time (excluding the last time point) post-treatment, or (2) treatment-induced or treatment-boosted ADA samples detected at ≥ 2 time points where the first and last positive samples (irrespective of any negative samples in between) are separated by < 16 weeks, and the subject's last sample is ADA negative.
Persistent ADA	An ADA-positive subject with first and last positive ADA samples (treatment-induced or treatment-boosted) detected over a period of ≥ 16 weeks post-treatment, irrespective of any negative samples in between
Indeterminate ADA	An ADA-positive subject who is not persistent or transient
Transient NAb	
Persistent NAb	A NAb-positive subject with (1) a treatment-induced or treatment-boosted NAb sample detected only at 1 sampling time (excluding the last time point) post-treatment, or (2) treatment-induced or treatment-boosted NAb samples detected at ≥ 2 time points where the first and last positive samples (irrespective of any negative samples in between) are separated by < 16 weeks, and the
Indeterminate NAb	

subject's last sample is NAb negative or ADA negative

A NAb-positive subject with first and last positive NAb samples (treatment-induced or treatment-boosted) detected over a period of ≥ 16 weeks post-treatment, irrespective of any negative samples in between.

A NAb-positive subject who is not persistent or transient.

Titers will be reported as median, range and interquartile range.

Descriptive summaries (mean, standard deviation, median, and range) of time to ADA response will be presented by phase and cohort

9.5. Pharmacokinetic Analysis

9.5.1. PF-07901801 and PLD Serum Concentrations

Pharmacokinetic samples for determination of concentrations of serum PF-07901801 and plasma PLD will be collected in accordance with the regimen specified in the schedule table 28 and 29 of the protocol. The concentrations as reported by the bioanalytical lab will be used without rounding for all analyses.

For serum and plasma concentration data, all values below the limit of quantification (BLQ) will be set to zero irrespective of where they occur within a profile and indicated in a footnote. Individual BLQ results occurring between two quantifiable concentrations may be identified as anomalous concentrations and set to missing. BLQ will be excluded from the calculation of summary statistics. If the majority of concentrations within a treatment group are BLQ, the PK parameters may not be reported for the treatment group in question. For subjects with at least 1 quantifiable result, limited PK parameters will be reported: C_{max} and T_{max} will be reported based on only a single quantifiable concentration if all other samples in a profile are BLQ. A minimum of 3 quantifiable concentrations will be used to report CCI [redacted] will be reported as zero when all concentrations are zero as noted above.

CCI [redacted]

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

1. A concentration has been reported as ND (*i.e.,* not done) or NS (*i.e.,* no sample)
2. A deviation in sampling time is of sufficient concern or a concentration has been flagged as anomalous by the clinical pharmacologist. If this is performed, a footnote or other documentation in the clinical study report (CSR) detailing the exclusions will be provided.

For concentrations above the upper limit of quantification (ULOQ), Samples will be reported as (>ULQ) value as well as the dilution rate. Diluted ULQ samples that fall within assay detection limits will be included in summary statistics after correction with dilution factor. In the tables presenting summary statistics of concentration-time series, the total number of values (n) and the number of values that are ULQ will be presented to allow appropriate interpretation of the data. All values will be included in summaries.

Individual serum concentrations of PF-07901801 and PLD will be summarized at each time point using descriptive statistics. Individual concentration-time plots and median data by dose plots will be produced for PF-07901801. For PLD, boxplot summarizing the mean/median concentration by cycle, day and nominal time will be produced All graphs will be presented using both linear and semi-logarithmic scales. The above descriptive summary will be performed for the PF-07901801 and PLD Concentration Analysis Population (PCP). Summary statistics (mean, median, etc.) of concentration-time data will be based on nominal sampling times; samples outside of the collection window specified in the protocol table 29 (pre-dose: within 30 minutes prior to initiation of PLD and PF-07901801 infusion; EOI: up to 2 min after completion of PLD infusion and up to 5 minutes after completion of PF-07901801 infusion; other time points: within 15 min) will be considered as "missing" for the calculation of summary statistics only.

The below precision will be used for descriptive and statistical summary of serum PF-07901801 and plasma PLD concentrations:

- Geometric Means, Medians and their %CV and Confidence Intervals (CIs) – 1 more significant figure than the data
- Standard Deviation – 1 more significant figure than means
- CV% – whole numbers
- Minimum, Maximum – same significant figures as the data
- Ratios, CIs (log transformed data) – 2 decimal places

All serum PF-07901801 and plasma PLD concentrations will be presented in a by-participant listing. Additionally, time elapsed since dosing and deviation from scheduled time point will be presented. Individual and mean concentration-time plots for serum PF-07901801 and plasma PLD will be produced.

9.5.2. PF-07901801 and PLD Pharmacokinetic Parameters

Pharmacokinetic parameter estimation will be performed in Phoenix® WinNonlin® 8.3 or higher (Certara, Princeton, New Jersey) on individual serum/ plasma concentration-time data. The actual sampling times will be used for all calculations, except as noted above. For the PK parameter calculation, BLQ serum concentrations occurring before T_{max} will be set to 0, with the exception of a BLQ value occurring between two measurable concentrations, in which case it will be set to missing. BLQ concentrations occurring in pre-dose (trough) samples during the multiple dosing phase will be set to zero. Pharmacokinetic parameter estimates and summaries will be completed for patients in the PK Population having sufficient measurable concentrations to define the PK profile. For any patient whose

extrapolated CCI from the last time point where the concentration is above the limit of quantification to infinity exceeds 20% of the total CCI from the patient will be excluded from the calculation of the descriptive statistics.

Pharmacokinetic parameter estimates after the single dose will include C_{max}, T_{max}, CCI where appropriate and as data permit. For the multiple dosing phase, C_{max}, T_{max}, C_{min}, C_{avg}, CCI CL will be calculated if data permit. Additional PK parameters may be reported if appropriate.

The non-compartmental parameters will not be reported to any greater precision than that of the concentration data. All parameters will be reported to 3 significant figures. Parameter values will be rounded to the same precision used in data listings prior to any statistical analysis or descriptive summaries.

The below precision will be used for descriptive and statistical summary of PK parameters:

1. Geometric Means, Medians and their %CV and Confidence Intervals (CIs) – 1 more significant figure than the data
2. Standard Deviation – 1 more significant figure than means
3. CV% – whole numbers
4. Minimum, Maximum – same significant figures as the data
5. Ratios, CIs (log transformed data) – 2 decimal places

For parameters which are direct time observations, median and range will have the same significant figures as the data
The definitions and the associated rules for the PK parameter calculation are summarized in the table below:

C_{max}	Maximum observed concentration, occurring at time T_{max}. If all observations are below the limit of quantification (BLQ), C_{max} will be reported as zero.
T_{max}	Time of maximum observed concentration. If the maximum observed concentration is not unique, then the first maximum is used. If all observations are BLQ, T_{max} will be reported as not determined (ND).
CCI	
C_{min}	Minimum observed concentration occurring at time T_{min}.
CCI	
Rac (Multiple dosing)	Observed accumulation ratio will be calcluated as: Rac = AUCτ,ss / AUCτ,(first dose).
CL	An estimate of total body clearance computed from the steady state data, calculated as Dose/CCI .

C_{avg}	Average concentration during a dosing interval, calculated as CCI [redacted] divided by tau.

The calculated PK parameters will be summarized using descriptive statistics, including arithmetic and geometric means, SD, arithmetic and geometric %CV, median, minimum, and maximum. For T_{max} only the median and the range will be reported. All data will be summarized by subject, dose, cohort and the study phase.

Dose proportionality will also be assessed based on the data acquired during the dose escalation phase using descriptive statistics.

Exploratory analysis may be conducted on the relationship between PF-07901801 exposure and various PD, safety and efficacy variables.

PF-07901801 serum concentrations analyzed using population PK approaches. In addition, a model-based approach may be used to explore the potential relationship between PF-07901801 exposure metrics and efficacy, safety, and/or biomarker endpoints and reported separately. These analyses, if conducted, will be reported in separate report(s).

10. REFERENCES

Eisenhauer EA, Therasse P, Bogaerts J et al. New response evaluation criteria in solid tumours: revised RECIST guideline (version 1.1). Eur J Cancer 2009; 45:228-247.

11. APPENDIX 1: TABLE OF CONTENT OF TABLES, LISTINGS AND FIGURES

The following titles describe planned outputs (summary tables, listings, and figures) for the statistical analysis.

The convention followed in the list of titles is to include enough information to identify the outputs uniquely, and to indicate the analysis population from which the contributing data are drawn (if applicable). Commentary adds detail to aid the construction of the intended outputs when the title might not be sufficient to link the table, listing or figure with the relevant section of this SAP text or might not fully represent its content.

Outputs may be combined or divided, and title details may be modified during development, if spacing and appearance require doing so. Additional outputs may be produced if needed by collected data.

If an output in this appendix is not produced because it would not be informative (for example, when two analysis populations converge or no information is collected), that change in the set of data displays will be acknowledged in the CSR.

The Analysis Populations, as defined in Section 5.6, are Safety Analysis Set (SAS), DLT-Evaluable Population (DLP), PF-07901801 / PLD Concentration Analysis Population (PCP), Immunogenicity Analysis Population (IAP), and Pharmacodynamics Analysis Population (PDP).

Ref. #	Table Title and Subtitle	Analysis Population
1	Analysis Population, Number (%) of Participants	All screened
2	Participants Disposition, Number (%) of Participants	SAS
3	Demographic and Baseline Characteristics	SAS
4	Medical History, Number (%) of Participants	SAS
5	Cancer History, Number (%) of Participants	SAS
6	Prior Treatments for Current Diagnosis, Number (%) of Participants	SAS
7	Prior Surgeries for Current Diagnosis, Number (%) of Participants	SAS
8	Concomitant Medications, Number (%) of Participants	SAS
9	Concomitant Procedure, Number (%) of Participants	SAS
10	Exposure to PF-07901801	SAS
11	Exposure to PLD	SAS
12	Exposure to PF-07901801 (Subjects with Dose Reduction)	SAS
13	Exposure to PLD (Subjects with Dose Reduction)	SAS
14	Dose Delay, Reduction, Interruption or Permanent Withdrawal, Number (%) of Participants	SAS
15	Summary of BOR	SAS

16	Summary of Duration of Response	SAS
17	Summary of Progression Free Survival	SAS
18	Summary of Overall Survival	SAS
19	Summary of Dose Limiting Toxicity, by System Organ Class, Preferred Term, and Maximum Severity, Number (%) of Participants	DLP
20	Overall Summary of Treatment Emergent Adverse Events (TEAE), Number (%) of Participants	SAS
21	Incidence of Treatment Emergent Adverse Events (any grade and grade ≥ 3) by System Organ Class and Preferred Term, Number (%) of Participants	SAS
22	Incidence of Treatment Emergent Adverse Events (any grade and grade ≥ 3) by System Organ Class and Preferred Term – Related to PF-07901801 only, Number (%) of Participants	SAS
23	Incidence of Treatment Emergent Adverse Events (any grade and grade ≥ 3) by System Organ Class and Preferred Term – Related to PLD only, Number (%) of Participants	SAS
24	Incidence of Treatment Emergent Adverse Events (any grade and grade ≥ 3) by System Organ Class and Preferred Term – Related to Both PF-07901801 and PLD, Number (%) of Participants	SAS
25	Incidence of Treatment Emergent Adverse Events (any grade and grade ≥ 3) by System Organ Class and Preferred Term – Related to any Study Drug, Number (%) of Participants	SAS
26	Incidence of Serious Treatment Emergent Adverse Events by System Organ Class and Preferred Term, Number (%) of Participants	SAS
27	Incidence of Serious Treatment Emergent Adverse Events by System Organ Class and Preferred Term – Related to PF-07901801 only, Number (%) of Participants	SAS
28	Incidence of Serious Treatment Emergent Adverse Events by System Organ Class and Preferred Term – Related to PLD only, Number (%) of Participants	SAS
29	Incidence of Serious Treatment Emergent Adverse Events by System Organ Class and Preferred Term – Related to both PF-07901801 and PLD, Number (%) of Participants	SAS
30	Incidence of Serious Treatment Emergent Adverse Events by System Organ Class and Preferred Term – Related to any study drug, Number (%) of Participants	SAS
31	Incidence of Treatment Emergent Adverse Events Leading to Any Study Drug Permanent Discontinuation by System Organ Class and Preferred Term, Number (%) of Participants	SAS
32	Incidence of Treatment Emergent Adverse Events Leading to PF-07901801 Permanent Discontinuation by System Organ Class and Preferred Term, Number (%) of Participants	SAS
33	Incidence of Treatment Emergent Adverse Events Leading to PLD Permanent Discontinuation by System Organ Class and Preferred Term, Number (%) of Participants	SAS
34	Incidence of Treatment Emergent Adverse Events Leading to Permanent Discontinuation of PLD and PF-07901801 by System Organ Class and Preferred Term, Number (%) of Participants	SAS
35	Incidence of Treatment-related (related to PF-07901801 only) Treatment Emergent Adverse Events Leading to PF-07901801 Permanent Discontinuation by System Organ Class and Preferred Term, Number (%) of Participants	SAS
36	Incidence of Treatment-related (related to PLD only) Treatment Emergent Adverse Events Leading to PLD Permanent Discontinuation by System Organ Class and Preferred Term, Number (%) of Participants	SAS

37	Incidence of Treatment-related (to both drugs) Treatment Emergent Adverse Events Leading to Permanent Discontinuation of Both PLD and PF-07901801 by System Organ Class and Preferred Term, Number (%) of Participants	SAS
38	Incidence of Treatment Emergent Adverse Events Resulting in PF-07901801 Dose Interruption by System Organ Class and Preferred Term, Number (%) of Participants	SAS
39	Incidence of Treatment Emergent Adverse Events Resulting in PLD Dose Interruption by System Organ Class and Preferred Term, Number (%) of Participants	SAS
40	Incidence of Treatment Emergent Adverse Events Resulting in PF-07901801 Dose Reduction by System Organ Class and Preferred Term, Number (%) of Participants	SAS
41	Incidence of Treatment Emergent Adverse Events Resulting in PLD Dose Reduction by System Organ Class and Preferred Term, Number (%) of Participants	SAS
42	Incidence of Treatment Emergent Adverse Events Resulting in Death by System Organ Class and Preferred Term, Number (%) of Participants	SAS
43	Incidence of Treatment-related (Related to PF-07901801 only) Treatment Emergent Adverse Events Resulting in Death by System Organ Class and Preferred Term, Number (%) of Participants	SAS
44	Incidence of Treatment-related (Related to PLD only) Treatment Emergent Adverse Events Resulting in Death by System Organ Class and Preferred Term, Number (%) of Participants	SAS
45	Incidence of Treatment-related (Related to Both Drugs) Treatment Emergent Adverse Events Resulting in Death by System Organ Class and Preferred Term, Number (%) of Participants	SAS
46	Incidence of Treatment Emergent Adverse Events by System Organ Class, Preferred Term and Maximum Severity, Number (%) of Participants	SAS
47	Summary of Death	SAS
48	Shift Table from Baseline in Chemistry Parameters, Normal to Abnormal (no CTCAE graded parameters)	SAS
49	Shift Table from Baseline to Worst On-Treatment CTCAE Grade in Chemistry Parameters	SAS
50	Shift Table from CTCAE Grade ≤ 2 at Baseline to ≥ 3 Postbaseline in Chemistry Parameters	SAS
51	Shift Table from Baseline in Hematology Parameters, Normal to Abnormal (no CTCAE graded parameters)	SAS
52	Shift Table from Baseline to Worst On-Treatment CTCAE Grade in Hematology Parameters	SAS
53	Shift Table from CTCAE Grade ≤ 2 at Baseline to ≥ 3 Postbaseline in Hematology Parameters	SAS
54	Summary of Newly Occurring or Worsening (CTCAE grade) Abnormalities during the On-Treatment in Hematology Parameters	SAS
55	Mean and Change in Vital Signs Over Time	SAS
56	ECG Abnormalities, Number (%) of Participants	SAS
57	CA-125 Concentrations, by Dose Cohort and Cycle	PDP
58	Pharmacodynamic Biomarkers Concentrations, by Dose Cohort and Cycle	PDP
59	Mean Change in Pharmacodynamic Biomarkers, by Dose Cohort and Cycle	PDP
60	Incidence and Duration of ADA and NAb, by Dose Cohort	IAP
61	Serum PF-07901801 Concentrations, by Dose Cohort, Visit and Timepoint: Summary Statistics	PCP
62	Serum PLD Concentrations, by Dose Cohort, Visit and Timepoint: Summary Statistics	PCP

63	PF-07901801 PK Parameters, by Dose Cohort, Visit and Timepoint: Summary Statistics	PCP
64	PLD PK Parameters, by Dose Cohort, Visit and Timepoint: Summary Statistics	PCP

Ref. #	Listing Title	Analysis Population
1	Listing of Analysis Population	All screened
2	Listing of Participant Disposition	SAS
3	Listing of Protocol Deviations	SAS
4	Listing of Demographic Characteristics	SAS
5	Listing of Cancer History	SAS
6	Listing of Prior Treatments for Current Diagnosis	SAS
7	Listing of Concomitant Medications	SAS
8	Listing of Concomitant Procedures	SAS
9	Listing of Administration of PF-07901801	SAS
10	Listing of Administration of PLD	SAS
11	Listing of Reasons for Missed Doses	SAS
12	Listing of Tumor Response Assessments: Target, Non-Target and New Lesions	SAS
13	Listing of Tumor Response Assessment	SAS
14	Listing of Dose Limiting Toxicity	DLP
15	Listing of Adverse Events	SAS
16	Listing of Deaths	SAS
17	Listing of Adverse Events Leading to Death	SAS
18	Listing of Clinical Laboratory Test Results	SAS
19	Listing of ECOG	SAS
20	Listing of CA-125 Concentrations	PDP
21	Listing of Pharmacodynamic Biomarkers Concentrations	PDP
22	Listing of ADA and NAb	IAP
23	Listing of PF-07901801 Serum Concentrations	PCP
24	Listing of PLD Plasma Concentrations	PCP
25	Listing of PF-07901801 PK Parameters	PCP
26	Listing of PLD PK Parameters	PCP

Ref. #	Figures Title	Analysis Population
1	Waterfall Plot of Change in Tumor Size from Baseline to Participants' Best Tumor Response at Any Time Point	SAS
2	Swimmer Plot of Tumor Response	SAS
3	Spaghetti Plot of Tumor Response	SAS
4	Kaplan-Meier Analysis of Progression Free Survival	SAS
5	Kaplan-Meier Analysis of Overall Survival	SAS
6	Individual PF-07901801 Concentrations Over Time (Linear and Semi-log Plots)	PCP
7	Mean and Median PF-07901801 Concentrations Over Time by Dose Cohort (Linear and Semi-log Plots)	PCP
8	Individual PLD Concentrations Over Time (Linear and Semi-log Plots)	PCP
9	Mean and Median PLD Concentrations Over Time by Dose Cohort (Linear and Semi-log Plots)	PCP