Statistical Analysis Plan

Title: Statistical Analysis Plan for Protocol SL03-OHD-101: Phase 1 Dose Escalation Study of the Agonist Redirected Checkpoint, SL-172154 (SIRPα-Fc-CD40L) Administered Intravenously in Subjects with Ovarian Cancer

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LIST OF ABBREVIATIONS

ADA	Anti-drug antibodies
AE	Adverse event
ALP	Alkaline phosphatase
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical
AUC	Area under the serum concentration time curve
BLQ	Below the limit of quantification
C1D1	Cycle 1 day 1
CBR	Clinical benefit rate
CD40	Cluster of differentiation 40
CD40L	Cluster of differentiation 40 ligand
CI	Confidence interval
CL	Clearance
Cmax	Maximum observed concentration
Cmin	Minimum observed concentration
CR	Complete response
CV	Coefficient of variation
CTCAE	Common terminology criteria for adverse event
DAT	Direct antiglobulin test
DLT(s)	Dose-limiting toxicity(ies)
DOR	Duration of response
ECG	Electrocardiogram
ECHO	Echocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	Electronic Case Report Form
EOI	End of infusion
FIH	First in human
HRD	Homologous recombination deficiency
iBOR	Best overall response based on iRECIST
ICH	International Conference of Harmonisation
iCPD	Immune confirmed progression of disease
iCR	Immune complete response
iPR	Immune partial response
irAE	Immune-related adverse event
iRECIST	Immune response evaluation criteria in solid tumors
iSD	Immune stable disease
iUPD	Immune unconfirmed progression of disease
Kg	Kilogram
MAD	Maximum administered dose
MedDRA	Medical Dictionary for Regulatory Activities
mg	Milligrams
mg/kg	Milligrams per kilogram
MTD	Maximum tolerated dose
mTPI-2	Modified toxicity probability interval 2
NCA	Non-compartmental analysis
NCI	National Cancer Institute
NE	Not evaluable
ORR	Objective response rate
OS	Overall survival
PBMC	Peripheral blood mononuclear cell
PD	Progressive Disease

PFS	Progression-free survival
PK	Pharmacokinetic
PK/PD	Pharmacokinetic/pharmacodynamic
PR	Partial response
PT	Preferred term
RECIST	Response evaluation criteria in solid tumors
RO	Receptor occupancy
RP2D	Recommended phase 2 dose
SAE	Serious Adverse Event
SAP	Statistical analysis plan
SD	Stable disease
SD	Standard deviation
SIRPα	Signal regulatory protein alpha
SL-172154	SIRPα-Fc-CD40L agonist redirected checkpoint
SMC	Safety Monitoring Committee
SOC	System organ class
SOI	Start of infusion
t½	terminal elimination half-life
TEAE	Treatment-emergent adverse event
T_{max}	Time of maximum observed concentration
TTR	Time to response
ULN	Upper limit of normal
Vz	Volume of distribution
WHO	World Health Organization

1. INTRODUCTION

This statistical analysis plan (SAP) outlines the planned analyses for Protocol SL03-OHD-101, Phase 1 Dose Escalation Study of the Agonist Redirected Checkpoint, SL-172154 (SIRPα-Fc-CD40L) Administered Intravenously in Subjects with Ovarian Cancer:

Protocol Version	Approval date
Original Version v0.0	24 January 2020
Amendment Version v1.0	03 March 2020
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Amendment Version v6.0	24 August 2021

The purpose of this analysis plan is to provide specific guidelines for the analysis of data mainly obtained from the study electronic case report forms (eCRFs). A separate analysis plan will be provided for the pharmacodynamic (PD)/biomarker data. All decisions regarding data analysis, as defined in this document, have been made prior to Database Freeze of the study data. Any deviations from these guidelines will be documented in the clinical study report.

2. STUDY OBJECTIVES AND OUTCOME MEASURES

Objective	Outcome Measure
Primary Objectives	
To evaluate the safety and tolerability of SL-172154 and to identify the maximum tolerated dose (MTD) or maximum administered dose (MAD) of SL-172154 in subjects with platinum-ineligible ovarian, fallopian tube, or primary peritoneal cancers	▪ Safety/tolerability outcomes include: incidence of all adverse events (AEs) and immune-related adverse events (irAE), serious adverse events (SAEs), fatal SAEs, dose limiting toxicity (DLT), AEs and irAEs leading to discontinuation, and changes in safety assessments (e.g., laboratory parameters, vital signs etc.) per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE – version 5.0). ▪ The MTD is defined based on the rate of DLTs and the MAD is the highest dose administered.
Secondary Objectives	
To select the recommended Phase 2 dose (RP2D) for SL-172154.	▪ Based on review of all data collected during dose escalation, dose expansion, and pharma-codynamic cohorts including safety,

	tolerability, pharmacokinetic (PK), anti-tumor activity, and pharmacodynamic effects.
To assess preliminary evidence of anti-tumor activity of SL-172154	Disease assessment per investigator assessment according to Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1). ▪ Objective response rate (ORR) (proportion of subjects whose best response is a complete response [CR] or partial response [PR]) ▪ Clinical benefit rate (CBR): proportion of subjects whose best overall response is a CR, PR or stable disease (SD) ≥ 16 weeks ▪ Time to response (TTR): time from the first dose until the first response (CR or PR, whichever is recorded first) that is subsequently confirmed ▪ Duration of response (DOR): time between first response (CR or PR, whichever is recorded first) that is subsequently confirmed and date of disease progression
To evaluate immunogenicity to SL-172154 during and after treatment.	▪ Number/proportion of subjects with positive ADA titer ▪ ADA duration ▪ Transient vs. persistent ADA
To characterize the pharmacokinetics (PK) of SL-172154.	▪ Maximum observed concentration (Cmax) and time at which the maximum concentration is observed (Tmax) and minimum observed concentration (Cmin) following single and multiple doses of SL-172154 ▪ Area under the serum concentration-time curve (AUC) ▪ Terminal elimination half-life ($t_{½}$), Clearance (CL) and Volume of Distribution (Vz)
Exploratory Objectives	
To assess target engagement of cluster of differentiation 40 (CD40) on peripheral blood mononuclear cells (PBMCs) prior to and following SL-172154 administration.	▪ Free/total receptor occupancy (RO) of CD40
To assess target engagement of CD47 on RBCs and PBMCs prior to and following SL-172154 administration.	▪ Free/total RO of CD47

To assess pharmacodynamic biomarkers in blood prior to, on-treatment and following SL-172154 administration.	Pharmacodynamic biomarkers in blood: ▪ Changes from baseline in cytokine/chemokine levels potentially including (but not confined to) interleukin (IL)-17α, interferon alpha (IFNα), tumor necrosis factor alpha (TNFα), IL-7, IL-8, IL-15, IL-10, IL-12p70, chemokine ligand CXCL9, CXCL10 ▪ Changes from baseline in cell counts and percentages of circulating immune cells including T cell subsets, B cell subsets, and myeloid cells ▪ Circulating immunoglobulin (Ig) levels ▪ Complement activation by assessment of SC5b-9 terminal fragment
To assess pharmacodynamic biomarkers in tumor tissue prior to, on-treatment and following SL-172154 administration.	Pharmacodynamic biomarkers in tumor tissue including: ▪ Changes in T cells subsets, B cells and myeloid cells. ▪ CD47 and CD40 expression ▪ Programmed cell death ligand 1 (PD-L1) expression
To evaluate binding of SL-172154 to RBCs	Presence of SL-172154 on RBCs
To estimate progression-free survival (PFS) and overall survival (OS)	▪ PFS based on investigator assessment: time from first dose to progression by RECIST v1.1 or death, whichever comes first ▪ OS: time from first dose to death
To evaluate efficacy using immune related response criteria.	▪ ORR, CBR, TTR, DOR and PFS based on investigator assessment per immune Response Evaluation Criteria (iRECIST)

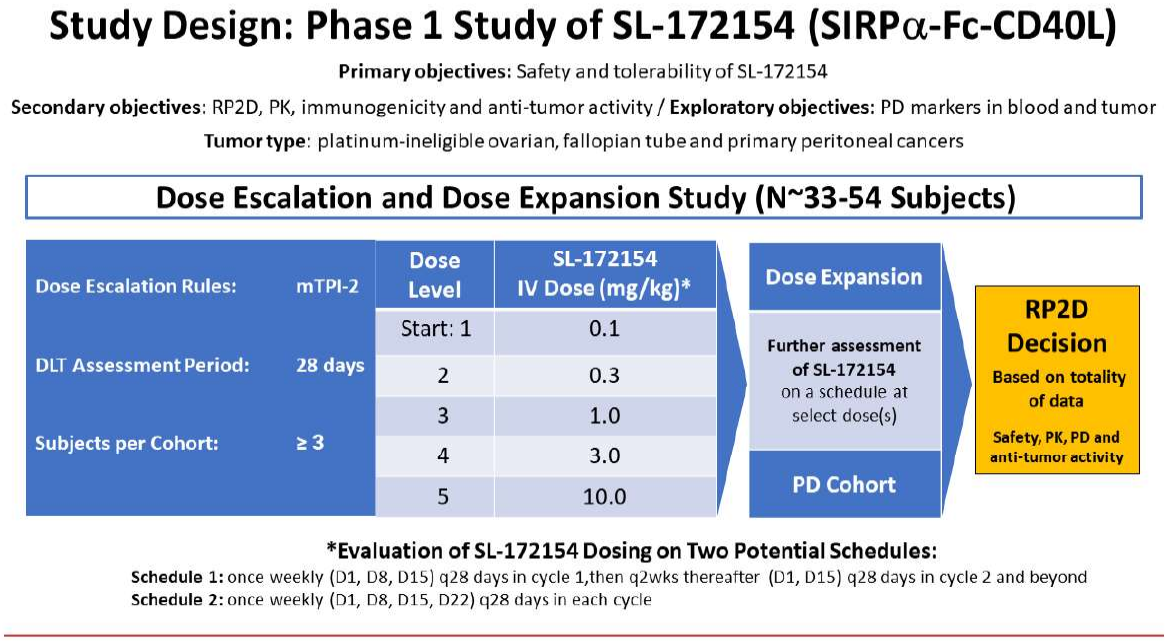
3. STUDY DESIGN

This clinical trial is a Phase 1 first in human (FIH), open label, multi-center, dose escalation study to evaluate the safety, PK, pharmacodynamic effects, and anti-tumor activity of SL-172154 (SIRPα-Fc-CD40L) in subjects with platinum-ineligible ovarian, fallopian tube, and primary peritoneal cancers.

3.1 Study Design

This Phase 1 FIH study is to evaluate the safety, PK, pharmacodynamic effects, and anti-tumor activity of SL-172154 monotherapy. Subjects with platinum ineligible ovarian, fallopian tube, and

primary peritoneal cancers are eligible for treatment. This study includes dose escalation, pharmacodynamic, and dose expansion cohorts (see Schema below).



Abbreviations: D = day; DLT = dose limiting toxicity; IV = intravenous; mTPI-2 = modified toxicity probability interval-2; PD = pharmacodynamic; PK = pharmacokinetics; q2wks = once every 2 weeks; RP2D = recommended phase 2 dose

Dose Escalation Cohorts

During dose escalation, two possible schedules (Schedule 1 and Schedule 2) for administration of SL-172154 may be explored as outlined below:

- Schedule 1: SL-172154 is given on days 1, 8 and 15 in cycle 1 (28 days for each cycle) and then every 2 weeks thereafter on days 1 and 15 in cycles >=2
- Schedule 2: SL-172154 is given on days 1, 8, 15 and 22 each 28-day cycle

Dose escalation for Schedule 1 and Schedule 2 will utilize the modified Toxicity Probability Interval (mTPI-2) design as described by Guo et al. with target DLT rate of 30% for the MTD. Subjects will be enrolled in cohorts of approximately 3 subjects into sequential dose levels of SL-172154 and evaluated for DLT during the 28-day DLT evaluation period starting from the first dose of SL-172154. At each dose level, a minimum 3-day stagger between dosing the first and second subject is required.

Schedule 1 will be evaluated first. A transition to Schedule 2 may be implemented if pharmacodynamic effects are not present or detectable in Schedule 1, or pharmacokinetic parameters from Schedule 1 may suggest that a more frequent dosing schedule is warranted. If Schedule 2 is opened for enrollment, the enrollment on Schedule 1 will be paused. Schedule 2 may stop enrollment earlier (e.g., based on safety) and enrollment in Schedule 1 may be resumed. The

MTD or MAD may be determined for either Schedule 1 or Schedule 2. Alternatively, a less intensive dosing schedule may be instituted if safety, pharmacokinetic and/or pharmacodynamic data on Schedule 1 support less frequent dosing of SL-172154.

The planned dose escalation is in half-log increments as outlined in Table 1.

Table 1: SL-172154 Dose Escalation Plan in Phase 1

Dose Level	IV Dose of SL-172154 (mg/kg)[a,b,c,d]	Duration of Infusion[e]
Level 1 - starting dose	0.1	30 minutes (+/- 10 minutes)
Level 2	0.3	30 minutes (+/- 10 minutes)
Level 3	1.0	30 minutes (+/- 10 minutes)
Level 4	3.0	60 minutes (+/- 15 minutes)
Level 5	10.0	60 minutes (+/- 15 minutes)

a) Dosing will begin on Schedule 1 with SL-172154 administered in 28-day cycles on days 1, 8, and 15 in cycle 1 and then on days 1 and 15 in cycles ≥ 2.
b) Dose escalation on Schedule 2 may be tested. If Schedule 2 is opened, SL-172154 may be administered once weekly on days 1, 8, 15 and 22 of each 28-day cycle.
c) Intermediate or higher dose levels may be tested based on emerging safety and pharmacodynamic data.
d) The actual body weight in kilograms (kg) will be used for dose calculation in all subjects whose body weight is ≤100 kg. For subjects with body weight >100 kg, the dose to be administered should be the same as that calculated for a subject weighing 100 kg.
e) Infusion time may change based on final drug volume needed for administration, safety and tolerability of the infusion for the subject and/or observed safety findings during the study. Protocol Clarification Memo dated on 04MAR2022 clarified that the duration of infusion was to be increased from 60 minutes to 120 minutes (± 20 minutes) for 10 mg/kg dose level. Protocol Clarification Memo dated on 3JUN2022 clarified that the duration of infusion was to be increased from 60 minutes to 120 minutes (± 15 minutes) for 3 mg/kg dose level.

For each dose level evaluated at Schedule 1 or Schedule 2, the minimum number of subjects evaluable for DLT (see Section 4 for definition of DLT evaluable subject) will be 3 unless unacceptable toxicity is observed prior to enrollment of 3 subjects (e.g., the first 2 subjects experience a DLT before the third subject enrolls). The maximum number of subjects evaluable for DLT at a dose level will be 12 (e.g., this may be reached by sequential enrollment of 4 cohorts of 3 subjects) assuming the dose decision is to stay at the current dose from the first 3 cohorts. Section 3.2 details the statistical design and rules for dose escalation.

During dose escalation, a review of available safety data for all subjects will be undertaken by the Safety Monitoring Committee (SMC) approximately every four weeks and a decision made regarding the safety profile of the current and prior dose levels.

Intrasubject dose escalation(s) may be considered on a case-by-case basis, provided that the subject has completed at least 2 cycles at the originally assigned dose, has tolerated treatment well, and experienced ≤Grade 1 toxicity on the most recent cycle of SL-172154 treatment. A subject's dose may be increased to a dose level that has completed evaluation for safety and has not exceeded the MTD.

Pharmacodynamic Cohorts
The Sponsor, in consultation with the SMC, may elect to open a pharmacodynamic cohort to obtain additional pharmacodynamic data from a total of approximately 6 additional subjects at one or more dose levels or one or more dosing schedules that have completed evaluation for safety without exceeding the MTD on the selected schedule. Subjects in the pharmacodynamic cohort must have tumor accessible for biopsy without excessive safety risk and must consent to providing paired biopsies for translational research. Subjects enrolled in the pharmacodynamic cohort will not inform dose escalation decisions but the pharmacodynamic information gathered from these additional subjects will inform selection of doses for further evaluation and the RP2D determination.

Dose Expansion Cohort
Approximately 6 subjects will be enrolled in the dose expansion cohort on a selected schedule. Subjects may be enrolled at one or more dose levels to further characterize safety, tolerability, PK, anti-tumor activity, and pharmacodynamic data to inform the selection of a RP2D. The number of subjects in dose expansion will vary depending on the number of subjects enrolled in both dose escalation and the pharmacodynamic cohort at a potential RP2D. The goal is to enroll approximately 6-12 subjects at the potential RP2D, including subjects in dose escalation, pharmacodynamic cohort, and dose expansion.

Selection of the Recommended Phase 2 Dose

Selection of the RP2D and schedule for SL-172154 monotherapy will be based upon the totality of the data in subjects treated in dose escalation, dose expansion and pharmacodynamic cohorts. Approximately 6-12 subjects (inclusive of the subjects enrolled at this dose in the Dose Escalation, Pharmacodynamic cohort, and Dose Expansion) may be treated at the RP2D.

3.2 Statistical Design for Dose Escalation

The dose escalation will utilize a mTPI-2 design with target DLT rate of 30% for the MTD. The mTPI-2 design employs a simple Beta-Binomial Bayesian model with decision rules based on the unit probability mass from the posterior probability of DLT rate. With the target DLT rate of 30%, the posterior probability of DLT rate unit interval (0, 1) is divided into subintervals with equal length of 0.1 that correspond to different dose escalation decisions: subinterval of (0.25, 0.35) is to stay at the current dose, subintervals below 0.25 is to escalate to next higher dose, and subintervals above 0.35 is to de-escalate to the next lower dose. Subjects will be enrolled in cohorts of approximately 3 subjects during the dose escalation. After each cohort of approximately 3 subjects, the posterior unit probability for subintervals will be calculated based on a noninformative prior distribution for the DLT rate (Beta(1,1)) and the total number of subjects with DLTs and DLT evaluable subjects for the current dose. A dose escalation/stay/de-escalation decision that corresponds to the subinterval with the highest unit probability mass will be selected. A minimum of 3 DLT evaluable subjects will be enrolled to a dose level and evaluated for DLT before a dose escalation/stay/de-escalation decision can be made unless unacceptable toxicity is observed prior to the enrollment of 3 subjects e.g., two subjects experience DLT before the third subject enrolls. A dose level will be considered unsafe, with unacceptable toxicity and no

additional subjects enrolled at that dose level and above, if it has an estimated 95% or more probability of exceeding the target DLT rate of 30%. The maximum number of subjects evaluated for DLT for each dose level will be 12 subjects (about 4 cohorts of 3 subjects) if the dose escalation decision is to stay at the current dose from the first 3 cohorts.

Based on the above design, the dose escalation decision rules are as the following for each dose level:

- When the number of DLT evaluable subject is <12 subjects:
  - Dose escalate if the observed DLT rate <25%;
  - Stay at the current dose if the observed DLT rate between 25%-33%;
  - Dose de-escalate if the observed DLT rate >33%;
- After reaching the maximum 12 subjects, the dose escalation decision will be either escalate or de-escalate as the following:
  - Dose escalate if the observed DLT rate ≤25%;
  - Dose de-escalate if the observed DLT rate ≥33%;

See Table 2 for dose escalation decision rules based on the total number of subjects evaluable for DLT and the number of subjects with DLT observed.

Table 2 Dose Escalation Decision Rules for Each Dose Level based on mTPI-2

Number of Subjects with DLTs	Number of Subjects in DLT Evaluable Population									
	3	4	5	6	7	8	9	10	11	12
0	E	E	E	E	E	E	E	E	E	E
1	S	S	E	E	E	E	E	E	E	E
2	D	D	D	S	S	S	E	E	E	E
3	DU	DU	D	D	D	D	S	S	S	E
4	.	DU	DU	DU	D	D	D	D	D	D
5	.	.	DU	DU	DU	DU	DU	D	D	D
6	.	.	.	DU	DU	DU	DU	DU	DU	D
7	.	.	.	.	DU	DU	DU	DU	DU	DU
8	.	.	.	.	.	DU	DU	DU	DU	DU

E = escalate to the next higher dose level	S = stay at the current dose level
D = de-escalate to the next lower dose level	DU = de-escalate to the next lower dose level and current dose level will never be used again due to unacceptable toxicity

3.3 Sample Size

If only Schedule 1 is evaluated, the planned total sample size is 21 for dose escalation. If Schedule 1 and Schedule 2 are both fully evaluated in dose escalation, the maximum planned sample size for dose escalation is 42. This sample size assumes evaluation of approximately 21 subjects across 5 dose levels in dose escalation on Schedule 1 and approximately 21 subjects across 5 dose levels on Schedule 2. Approximately 6 subjects may be enrolled in an optional pharmacodynamic cohort. After a dose and schedule are selected, approximately 6 subjects will be included in the dose expansion cohort. The number of subjects in dose expansion will vary depending on the number of subjects enrolled in both the dose escalation and pharmacodynamic cohorts at a potential RP2D. The goal is to enroll approximately 6-12 subjects at the potential RP2D, including subjects in the dose escalation, pharmacodynamic, and dose expansion cohorts. Overall, the total sample size estimate for this study is 33 subjects assuming only Schedule 1 is evaluated, and 54 subjects if both Schedule 1 and Schedule 2 are fully evaluated.

3.4 Duration of Study Treatment

The planned treatment duration with IP is for a maximum of two years. In the absence of treatment delays due to AE(s), treatment may continue until two years or until one of the following criteria applies:

- Disease progression per RECISTv1.1 (unless eligible for treatment beyond progression).
- Death
- Intercurrent illness that prevents further administration of treatment
- Unacceptable AE(s)
- Participant decides to withdraw from the study
- General or specific changes in the participant's condition that render the participant unacceptable for further treatment in the judgment of the investigator
- Participant non-compliance
- Pregnancy
- Termination of the study by Sponsor

Subjects with confirmed CR may elect to discontinue treatment after a minimum of 48 weeks of treatment and continue with all relevant study assessments including disease assessments until disease progression or start of another anticancer therapy.

Subjects who permanently discontinue study treatment for reasons other than progression will continue with disease assessments until progression or start of another anti-cancer therapy.

3.5 Duration of Follow-up

Subjects who are withdrawn from study for unacceptable AE(s) will be followed until resolution or stabilization of the AE. Participants who permanently discontinue study treatment for reasons other than progression will continue with disease assessments until progression or start of another anti-cancer therapy. Subjects who discontinue study treatment for any reason other than

withdrawal of consent will be followed for survival for approximately 18 months post treatment discontinuation or until death or the end of the study, whichever occurs first. During survival follow-up, the date of the first anticancer therapy will also be collected.

3.6 End of Study

End of Study is defined as approximately 2 years after the last subject is dosed on cycle 1, day 1 (C1D1) or the date the study is closed by the sponsor, whichever occurs first.

3.7 Study Assessments and Procedures

The detailed study assessments and procedures are described in Section 6 of the protocol.

4. ANALYSIS POPULATIONS

Population	Description
Screened	All subjects who have signed the main study inform consent form.
Screen Failures	All subjects who have signed the informed consent but have not received any dose of SL-172154.
All Treated	All subjects who receive at least one dose of SL-172154. Safety data will be evaluated based on this population.
DLT Evaluable	All subjects enrolled in the dose escalation cohorts 1) who have received ≥2 of the 3 scheduled doses of SL-172154 on Schedule 1 or who have received ≥2 of the 4 scheduled dose of SL-172154 on Schedule 2 during cycle 1 and completed the safety follow up through DLT evaluation period; or 2) who experienced any DLT during the DLT evaluation period. The DLT evaluation period is defined as the first 28 days. The DLT evaluable population will be used to guide dose escalation and to determine the MTD or MAD.
Response Evaluable	All subjects in the All Treated population who have a baseline disease assessment and have at least one post-baseline disease assessment or have progressed or died before the first post-baseline disease
PK Population	Subjects in the All Treated Population who have at least one postdose PK sample obtained and analyzed. The PK population will be used for the PK analysis.

5. GENERAL ANALYSIS CONSIDERATIONS

5.1 Interim Analyses

During the dose escalation, the number of subjects with DLTs will be determined after each cohort of approximately 3 subjects has been evaluated for DLT. The summary of DLTs for each dose level in Schedule 1 and Schedule 2 will be based on the number of subjects with DLTs from all subjects dosed and evaluated at the corresponding dose level who meet the definition of the DLT Evaluable Population. Select AE summary tables and listings may be provided during dose escalation to support dose escalation decisions.

5.2 Reporting Conventions

The statistical analyses will be reported using summary tables, figures, and data listings. The International Conference on Harmonisation (ICH) numbering convention will be used for tables, listings, and figures.

Data from all participating sites will be pooled prior to data summary or analysis. It is anticipated that subject accrual will be spread thinly across sites and summaries of data by site will not be informative and therefore, will not be provided.

Unless specified otherwise, all summary tables will be presented by dose schedule/level for all subjects in the analysis population, and subjects from dose escalation, pharmacodynamic and dose expansion cohorts will be pooled. Summaries will also be provided for subjects at the same dose level pooled across schedules. Select safety summary tables may be provided for the dose escalation cohorts.

All individual subject data listings will be presented by dose level, dose schedule and subject, unless specified otherwise. Data from all assessments, whether scheduled or unscheduled, will be included in the listings. Listings will present the data in their original format (without any imputation), unless specified otherwise.

Summaries by planned time point will include data from scheduled assessments and all data will be reported according to the nominal visit for which it will be recorded (i.e., no visit windows will be applied). Unscheduled data, when summarized, will be included only in calculation of the maximum or minimum value over time such as worst-case post-baseline. If multiple assessments are reported on the same date for the same scheduled planned time, the worst-case result will be analyzed.

Continuous variables will be summarized with means, standard deviations, medians, minimums, and maximums. The precision of the original measurements will be maintained in summaries and listings, when possible. Generally, means and medians will be presented to one more decimal place than the raw data, and the standard deviations will be presented to two more decimal places than the raw data.

Categorical variables will be summarized by counts and by percentages of subjects in the corresponding categories. Percentages are routinely based on the total number of the specified population N if not otherwise specified. For frequency counts, categories whose counts are zero will be displayed for the sake of completeness. For example, if none of the subjects discontinue due to "lost to follow-up," this reason will be included in the table with a count of 0. Categories with zero counts will not have zero percentages displayed.

All confidence intervals (CIs) will be constructed at the 95% confidence level, unless specified otherwise.

All analyses and tabulations will be performed using SAS® v9.4 or above.

5.3 Data Handling

The following sections provide a general description of the derived and transformed variables used to describe and analyze the data.

5.3.1 Premature Withdrawal and Missing Data

Subjects who prematurely withdraw from the study will be included in analyses up to the time of withdrawal, regardless of the duration of treatment and survival follow-up.

Missing data occurs when any requested data is not provided, leading to blank field on the collection instrument. Answers such as "Not applicable", "Not evaluable", etc. are not considered to be missing data and should be displayed as such.

For the time to event endpoints including DOR, PFS and OS, the missing data handling method will be censoring. Censoring mechanisms for these endpoints are described in Section 7.

The length of study treatment for each subject will depend on the safety, tolerability and efficacy of the treatment, so the duration of treatment will vary across subjects. Similarly, the duration of follow up for survival will also vary. All time to event endpoints will be analyzed using suitable statistical methods.

In the event that the study is prematurely discontinued, the study team will review the data to assess which statistical analyses are still considered appropriate.

5.3.2 Baseline and Change from Baseline

Unless otherwise specified, the baseline value is defined as the last value obtained on or before the date and time of the first SL-172154 dose on Cycle 1 Day (C1D1). Post-baseline values are defined as value obtained after the first dose of SL-172154.

Change from baseline is calculated as:

- Post-baseline value - baseline value

The percent change from baseline is calculated as:

- (Post-baseline value - baseline value)*100/baseline value

If either baseline or post-baseline value is missing, the change from baseline and percent change from baseline will be missing.

5.3.3 Study Day, Duration, and Time from Event

The reference date for age calculation is the date of consent form signed as age is an eligibility requirement. The reference date for safety, efficacy and other data analyses is the date of the first dose.

- **Study Day –** Study Day 1 is defined as the date of the first dose; the day before the first dose is defined as Study Day -1. There is no study day 0. For a given event date, Study Day is calculated relative to the date of first dose of study drug.

  Study Day = [Event Date – First Dose Date] (in days) + 1 day,
  where the event date is on or after the first dose date.

  Study Day = [Event Date – First Dose Date] (in days),
  where the event date is before the first dose date.

- **Duration (Days) –** A duration is calculated as the stop date minus the start date plus one.

  Duration (days) = [Stop Date – Start Date] (in days) + 1 day.

- **Time since an event -**Time since an event (e.g. time since initial diagnosis) is calculated as the reference date minus the event date. For time since initial diagnosis, the reference date is the first dose of study treatment.
- **Time to an event-** Time to an event (e.g. time to response, PFS, OS) is calculated as the event date minus the reference date+1. For time to response, PFS and OS, the first dose of study treatment is the reference date.

To convert days to months, divide the number of days by 30.4375 (365.24/12) and round to one decimal place.

5.3.4 Imputation of Partial Date

In general, imputed partial dates will not be used to derive study day or duration variables, unless otherwise specified. In addition, imputed partial dates are not used for time to event endpoint analysis. However, partial dates may be imputed for exploratory analysis. The imputed partial data will be flagged in the dataset to indicate the level of imputation. Imputed dates will not be displayed in the data listings.

6. STUDY POPULATION

Unless specified otherwise, all summary tables and data listings for this section will be based on the All Treated Population.

6.1 Subject Disposition

Summaries of study population and subject disposition will include the number of subjects in each analysis population and the primary reason for end of study participation. Study population and subject disposition information will be presented in a data listing. Both summary table and listing will be based on the Screened population.

Summaries of study treatment status will include the number of subjects by treatment status, and the primary reason for study treatment discontinuation. Subject treatment discontinuation information will be presented in a data listing.

6.2 Protocol Deviations

Number of subjects for each protocol deviation type and subtype will be summarized for key deviations, non-key deviations, and all deviations, respectively. A listing with deviation details will be provided for all protocol deviations. A separate listing will be provided for subjects with inclusion and exclusion criteria deviation. Other select categories of protocol deviations including but not limited to COVID-19 related deviations may be listed or summarized.

6.3 Demographic and Baseline Characteristics

Demographic variables include age, sex, ethnicity, race, weight and height. Descriptive statistics will be presented for age, weight, and height. Frequency counts and percentages will be presented for age groups (18-<65 years, 65-<75 years and ≥75 years), sex, ethnicity, race, and baseline Eastern Cooperative Oncology Group (ECOG) score (0 or 1). All demographic and baseline characteristics data will be presented in data listings for All Treated and Screen Failure population, respectively.

6.4 Study Cancer History

Study cancer history including the type of cancer, FIGO stage at study entry, grade, World Health Organization (WHO) histologic classification of cancer, BRCA mutation status and homologous recombination deficiency (HRD) status will be summarized in a table. Time since initial diagnosis will also be summarized. All study cancer history data will be presented in a data listing.

6.5 General Medical and Surgical History

General medical history and surgical history along with start/end date and ongoing status at study entry will be presented in a data listing.

6.6 Prior Anti-Cancer Treatment

Prior study cancer systemic treatment drugs will be coded using the WHO Drug Dictionary. Prior study cancer systemic treatment including regimen number, drug name, start/end date, intent, regimen best response, and data of progression will be presented in a data listing. Time since progression on the most recent regimen, and number of prior systemic regimens will be included in the summary table.

Prior anti-cancer surgical treatment including the date and intent of procedure will be presented in a data listing.

Prior anti-cancer radiotherapy including start/end date and intent of radiotherapy will be presented in a data listing.

6.7 Study Drug Exposure

The individual subject SL-172154 administration including total dose administered, infusion concentration, infusion volume, rate of infusion, start and end time, duration of infusion, and infusion outcome for each infusion will be presented in a data listing.

Total number of doses received, duration of treatment, average dose received, and dose compliance will be summarized.

Subject average dose is calculated as the cumulative dose (mg) that a subject received divided by the total number of doses received.

Duration of SL-172154 treatment is defined as:

- Minimum of (date of death plus 1 day, data cutoff date plus 1 day, and date of last dose + 14 days if last dose is C1D15 or beyond or + 7 days if last dose is C1D1 or C1D8) minus date of first study drug administration for subjects in Schedule 1.
- Minimum of (date of death plus 1 day, data cutoff date plus 1 day, and date of last dose + 7 days) minus date of first study drug administration for subjects in Schedule 2.

In addition to mean, median, minimum and maximum, duration on treatment will also be summarized in the following categories: <= 4 weeks, > 4 - 8 weeks, > 8 - 12 weeks, > 12 - 16 weeks, > 16 weeks.

Dose compliance is defined as the total mg of SL-172154 infused divided by the total mg of SL-172154 assigned, expressed as a percentage.

Duration of SL-172154 treatment will be plotted by subject using a horizontal bar graph with information regarding the time of first PR/CR and the first progressive disease (PD), dose level, best response (RECIST 1.1) and treatment discontinuation information for each subject.

6.8 Prior and Concomitant Medications

Prior and concomitant medications will be coded to Anatomical Therapeutic Chemical (ATC) class and Generic Drug Names using the WHO Drug Dictionary.

Prior medications are defined as medications that end prior to the date of the first dose of study treatment. Concomitant medications are defined as medications taken at any time on or after the date of the first dose of study drug. Medications that start prior to the date of the first dose but continue beyond the date of first dose will be categorized as concomitant medications. Prior and concomitant medications along with dose, route, start/end date, and indication for each medication will be presented in a data listing. If both the start and end dates are completely missing, the medication will be considered concomitant.

6.9 Concomitant Procedure

Concomitant procedures include cancer-related or treatment-related procedure or palliative radiotherapy. Concomitant procedures along with start/end date, and indication for the procedure will be presented in a data listing.

7. EFFICACY ANALYSES

The efficacy endpoints include ORR, CBR, TTR, DOR, PFS, and OS. The efficacy endpoints ORR, CBR, TTR, DOR, and PFS will be based on the investigator disease assessment per RECIST 1.1. Exploratory analyses of these endpoints will be based on the investigator disease assessment per iRECIST (iORR, iCBR, iTTR, iDOR and iPFS).

The efficacy analyses will be based on the All Treated population and/or Response Evaluable population, as appropriate. Subjects who do not have any post-baseline disease assessment will be considered as non-responders in the calculation of response rate.

Disease response will be evaluated and documented in CRF based on RECIST 1.1 until the first PD per RECIST 1.1, and then will be evaluated and documented in CRF based on iRECIST. Disease assessment will be performed at baseline (screening visit) and at the following intervals until disease progression: every 8 weeks until week 24 and every 12 weeks thereafter until year 2 and every 6 months until study conclusion. Confirmatory scans should be performed at least 4 weeks (>28 days) after initial documentation of an objective response. If subjects discontinue study treatment prior to progressive disease, they should continue to be followed with radiologic disease assessments until disease progression, start of a new anti-cancer therapy, withdrawal of consent or death, whichever is earliest.

7.1 Objective Response Rate

The ORR is defined as the proportion of subjects whose best overall response is a confirmed CR or confirmed PR based on investigator assessment according to RECIST 1.1. The ORR will be estimated with a 95% CI using the exact probability method. The number and percent of subjects with the best overall response of CR, PR, SD, PD and not evaluable (NE) will be summarized.

Summary of objective response will be provided for the All Treated population and Response Evaluable population, respectively.

The best overall response based on RECIST 1.1 is defined as the best overall response among all post-baseline time point assessments until the first PD per RECIST 1.1 or start of new anti-cancer therapy, whichever is earlier. For subjects who have not met the criteria for PD per RECIST1.1 or have not started a new anti-cancer therapy, the best overall response is defined as the best overall response among all post-baseline timepoint assessments.

Based on the investigator assessment of overall response per RECIST 1.1 at post-baseline assessments, the best overall response will be determined programmatically as the following and Table 3:

- CR > PR > SD > PD > NE
- CR = at least two determinations of CR with at least 4 weeks apart before progression.
- PR = at least two determinations of PR or better with at least 4 weeks apart before progression (and not qualifying for CR).
- SD = at least one SD or better ≥ 49 days after the first dose and before progression (and not qualifying for a CR or PR). The minimum interval from the first dose date for the best response of SD is 8 weeks minus 7 days to allow for visit windows of ± 7 days (49 days).
- If the minimum interval for SD is not met, the best response will depend on the subsequent assessments. See table below for details.
- PD is considered the best overall response when PD is documented and a best overall response of CR, PR, or SD could not be established before documentation of PD. Clinical deterioration will not be considered as documented disease progression in the determination of the best overall response.
- NE is considered the best overall response when PD has not been documented and a best response of CR, PR or SD could not be established.

Table 3. Best overall response when confirmation of CR and PR required.

Overall response First time point	**Overall response Subsequent time point**	**BEST overall response**
CR	CR	CR
CR	PR	SD, PD or PR[a]
CR	SD	SD provided minimum criteria for SD duration met, otherwise, PD
CR	PD	SD provided minimum criteria for SD duration met, otherwise, PD
CR	NE	SD provided minimum criteria for SD duration met, otherwise, NE
PR	CR	PR
PR	PR	PR
PR	SD	SD, provided minimum criteria for SD duration met, otherwise, PD

Overall response First time point	Overall response Subsequent time point	BEST overall response
PR	PD	SD provided minimum criteria for SD duration met, otherwise, PD
PR	NE	SD provided minimum criteria for SD duration met, otherwise, NE
NE	NE	NE

CR = complete response, PR = partial response, SD = stable disease, PD = progressive disease,
NE = not evaluable.
[a] If a CR is truly met at first time point, then any disease seen at a subsequent time point, even disease meeting PR criteria relative to baseline, makes the 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 patient 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.

Disease assessment at baseline including sum of target lesion diameters, number of target lesions, number of subjects with target lesions and non-target lesions will be summarized. The percent change from baseline in target lesion sum of diameters for all post-baseline disease assessments will be presented by subject using spider plot. The best percent change from baseline in target lesion sum of diameters is defined as the largest reduction or smallest increase (in the case where a reduction does not occur) from baseline observed over all post-baseline disease assessments up to and including the first PD and will be presented using a waterfall plot. Target lesion, non-target lesion, new lesion and response assessments will be presented in data listings. The percent change from baseline/nadir in target lesion sum of diameters will be displayed with 2 decimal places (xx.xx%) without rounding in the data listing.

7.2 Clinical Benefit Rate

The CBR based on RECIST 1.1 is defined as the proportion of subjects whose best overall response is a confirmed CR, confirmed PR or SD ≥ 16 weeks, where SD ≥ 16 weeks is defined as at least one SD or better for ≥ 15 weeks (16 weeks with 1 week visit window) and not qualifying for a confirmed CR or PR as the following:

Response at week 8 assessment	Response at week 16 assessment	Response at week 24 assessment	SD ≥ 16 weeks
SD	SD/PR/CR	Any	Yes
SD	PD	Any	No
SD	NE/missing	SD/PR/CR	Yes
SD	NE/missing	PD/NE/missing	No
CR/PR	PD	Any	No
PR	SD	Any	Yes
NE	SD	Any	Yes

The CBR will be estimated with a 95% CI using the exact probability method. Summary of CBR will be provided for the All Treated population and Response Evaluable population.

7.3 Time to Response

The TTR based on RECIST 1.1 is defined as the time from the first dose until the first documentation of a subsequently confirmed objective response (confirmed CR or confirmed PR). Only subjects who have achieved confirmed objective response will be evaluated for TTR, and individual TTR will be presented in a data listing. If data warrants, TTR will be summarized descriptively and graphically using Kaplan-Meier methods. The Kaplan-Meier estimate for the median TTR along with 95% confidence intervals and the first and third quartiles will be determined. Brookmeyer-Crowley method will be used for the confidence interval calculation. Kaplan-Meier estimate of TTR rate at 8 weeks, 16 weeks, and other timepoints of interest will be included in the summary table.

7.4 Duration of Response

The DOR based on RECIST 1.1 is defined as the time from the date of the first CR or PR (confirmed at least 28 days later) to the date of first documented disease progression per RECIST 1.1 or death, whichever occurs first. Only subjects who have achieved a confirmed CR or confirmed PR will be evaluated for DOR, and individual DOR will be presented in a data listing.

If a disease progression does not occur, DOR will be censored as of the date of the last evaluable disease assessment. The evaluable disease assessment is defined as an assessment for which the overall response can be determined. The censoring guidance and the date of PD/death or censoring are same as those for PFS in Section 7.5. If data warrants, DOR will be summarized descriptively and graphically using Kaplan-Meier methods. The Kaplan-Meier estimate for the median DOR along with 95% confidence intervals and the first and third quartiles will be determined. Brookmeyer-Crowley method will be used for the confidence interval calculation. Kaplan-Meier estimate of DOR rate at 8 weeks, 16 weeks, and other timepoints of interest will be included in the summary table.

7.5 Progression Free Survival

The PFS based on RECIST 1.1 is defined as time from the first day of treatment to the first documented disease progression per RECIST 1.1 or death from any cause, whichever occurs first. Subjects who have not progressed at the time of analysis will be censored at the date of their last evaluable disease assessment. Subjects who start new anticancer therapy prior to the documented PD will be censored at the last evaluable disease assessment prior to the start of new anticancer therapy. The censoring guidance and the date of PD/death or censoring are given in the Table 4 below.

Table 4. Summary of Censoring Guidelines for PFS based on RECIST1.1

Situation	Date of PD/Death or Censoring	PFS Outcome
Documented PD or death from any cause	Date of the PD or death, whichever comes first	Event (unless the censoring rule specified below)
Start new anticancer therapy before documented PD	Date of last evaluable disease assessment prior to the start of new anticancer therapy	Censored
Death or PD immediately after ≥ 2 consecutive missed or non-evaluable disease assessments[1] as per the protocol specified assessment schedule	Date of last evaluable disease assessment prior to missed or non-evaluable assessments, or the first dose of investigational product, whichever occurred last	Censored
No PD or death at time of analysis or lost to follow-up	Date of last evaluable post-baseline disease assessment	Censored
(No baseline disease assessment OR no post-baseline disease assessment) AND no death	Date of first dose with a duration of 1 day	Censored

[1] Two or more consecutive disease assessments is defined as ≥ 16+1 weeks for the first 6 months or ≥ 24+1 weeks for 6-24 months (two disease assessments as per protocol plus a one week visit window) after the last evaluable post-baseline disease assessment. If a subject has two or more consecutive missed or non-evaluable assessments followed by an assessment showing no radiologic disease progression, then the assumption will be that the subject did not progress during the missed or non-evaluable assessments.

If data warrants, PFS will be summarized descriptively and graphically using Kaplan-Meier methods. The Kaplan-Meier estimate for the median PFS along with approximate 95% confidence intervals and the first and third quartiles will be determined. Brookmeyer-Crowley method will be used for the confidence interval calculation. Kaplan-Meier estimate of PFS rate at 8 weeks, 16 weeks, 24 weeks, 48 weeks, and other timepoints of interest will be included in the summary table. PFS will be summarized and listed for the All Treated population.

7.6 Overall Survival

The OS is defined as time from the first day of treatment to the date of death. A subject alive at the end of study or lost to follow-up will be censored for OS at the last date when the subject was known to be alive, i.e., the last date on study.

If data warrants, the median and quartiles of OS and their 95% CIs will be assessed using the Kaplan-Meier method and Brookmeyer and Crowley method, respectively. The proportion of subjects alive at 12 weeks, 24 weeks, 48 weeks, 72 weeks, and other timepoints of interest will be estimated using the Kaplan-Meier method. OS will be summarized and listed for the All Treated population.

7.7 Exploratory Analysis

Exploratory analyses of ORR, CBR, TTR, DOR and PFS will be based on the investigator disease assessment per iRECIST (iORR, iCBR, iTTR, iDOR and iPFS).

Disease response will be evaluated and documented in CRF based on RECIST 1.1 until the first PD per RECIST 1.1, and then will be evaluated and documented in CRF based on iRECIST. The iRECIST responses at the timepoint assessments before and on the assessment of first PD per RECIST 1.1 are derived based on RECIST 1.1 assessment as in Table 5.

Table 5. Derivation of iRECIST response for assessments before or on PD per RECIST 1.1

Timepoint response per RECIST	Timepoint response per iRECIST
CR	iCR
PR	iPR
SD	iSD
PD	iUPD
NE	iNE

If data warrants, analysis of iORR, iCBR, iTTR, iDoR, and iPFS based on iRECIST will be performed similarly as those based on RECIST 1.1 (Section 7.1, 7.2, 7.4 and 7.5) except the following:

- The best overall response based on iRECIST (iBOR) is defined as the best overall response among all post-baseline timepoint assessments until the first confirmed PD per iRECIST (iCPD) or the last disease assessment if an iCPD has not been observed.
- The TTR based on RECIST 1.1 (iTTR) is defined as the time from the first dose until the first documentation of a subsequently confirmed objective response per iRECIST (iCR or iPR). Only subjects who have achieved objective response (iCR or iPR) will be evaluated for iTTR.
- The DOR based on iRECIST (iDOR) is defined as time from the date of the first iCR or iPR (confirmed at least 28 days later) to the date of the first documented iUPD that was subsequently confirmed as CPD or death due to any cause, whichever occurs first. Only subjects who have achieved objective response (iCR or iPR) will be evaluated for iDOR.
- PFS based on iRECIST (iPFS) is defined as time from the first day of treatment to the first documented iUPD that was subsequently confirmed as iCPD or death due to any cause, whichever occurs first.
- The following will be applied for both iPFS and iDOR:
    - If an unconfirmed PD per iRECIST (iUPD) occurs but is disregarded because of later iSD, iPR or iCR, then the iUPD date should not be used as the progression event for iPFS/iDOR.
    - If an iUPD is not confirmed and there is no subsequent iSD, iPR or iCR, then the iUPD date should still be used as progression event for iPFS/iDOR.
    - If an iUPD is not confirmed and the next timepoint responses are iUPDs but are not confirmed, then the last iUPD of the sequential iUPDs will be used as progression event for iPFS/iDOR.
    - Subjects who have not progressed at the time of analysis will be censored at their last evaluable iRECIST assessment.

7.8 CA-125

The CA-125 at baseline and post-baseline assessments, and maximum changes in CA-125 from baseline among all post baseline assessments will be summarized. Number of subjects with >=50%, >=75% and 100% decreases or increase from baseline will be summarized. The percent change from baseline in CA-125 for all post-baseline assessments will be plotted by subject. The CA-125 test results along with change from baseline will be presented in a data listing.

8. SAFETY ANALYSES

Unless specified otherwise, all safety data summaries will be presented by dose schedule/level, and all subjects based on the All Treated population. Summaries will also be provided for pooled subjects at the same dose level. safety summary will be provided for DLT evaluable populations.

8.1 Maximum Tolerated Dose Evaluation

The MTD evaluation will be based on the DLT Evaluable Population. The number and percentage of subjects with DLT will be presented by dose schedule and level for dose escalation cohorts. The MTD level will be indicated in the summary.

The MTD will be estimated using isotonic regression (based on the DLTs observed in the DLT evaluable subjects). A MAD will be reported if the DLT rate never reaches ≥25%. Otherwise, an MTD will be reported. Isotonic regression is a way to estimate the MTD under the assumption that toxicity increases with dose. When using isotonic regression, the first step is to identify the doses where the dose-toxicity monotonicity assumption is violated. The DLT estimate is then adjusted for the violators such that the final estimate of the DLT rate increases with the dose. The target DLT rate is then used to select the MTD. For example, suppose that when the trial is completed, the observed DLT rates [# subjects who experienced DLT]/[# evaluable subjects] at five dose levels are (0/3, 1/3, 0/3, 4/15, 2/4). In this example the observed DLT rate at Dose Level 2 (i.e., 1/3=33%) is higher than the observed DLT rate at Dose Level 3 (i.e., 0/3=0%). To adjust for this violation, the DLT estimates are replaced with their average, i.e., (1/3+0/3)/2=1/6, resulting in the isotonic regression DLT estimates (0/3, 1/6, 1/6, 4/15, 2/4) = (0%, 16.7%, 16.7%, 26.7%, 50%), which monotonically increases with the dose level. Based on this isotonic estimate, assuming that the trial goal is to find the dose with the DLT rate of 30%, Dose Level 4 will be selected as the MTD. If there are no violators of the dose-toxicity monotonicity assumption, isotonic regression directly uses the observed DLT rates as the final estimates for MTD selection. For subjects who undergo intra-subject dose escalation, only DLTs that occur during the DLT period on the subject's initial dose level the assignment will be used for MTD determination.

In the case of dose levels with estimated toxicity of equal distance (tied dose levels) from the target toxicity of 30%, the following approach will be used: among all tied dose levels the highest dose level with target toxicity ≤ 30% will be selected, unless all tied dose levels have estimated toxicity > 30%, in which case the lowest dose level will be selected.

8.2 Adverse Events

The AE terms on the eCRFs will be mapped to the preferred terms (PT) and system organ classes (SOC) using the Medical Dictionary for Regulatory Activities (MedDRA). Drug-related AEs are defined as AEs with relationship to study treatment being related or possible related. A worst-case scenario approach will be taken to handle missing data, i.e. AEs with the relationship to study treatment as missing will be treated as drug-related AEs.

All AEs with onset dates on or after the first dose of study treatment are defined as treatment-emergent adverse events (TEAEs). Only TEAEs will be included in AE tables.

An overview summary of TEAEs will be produced to include counts and percentages of subjects with any TEAE, drug-related TEAEs, DLT, serious TEAEs, drug-related serious TEAEs, fatal TEAEs, immune related TEAEs, infusion related reaction AEs, Grade 3 or 4 TEAEs, and TEAEs leading to drug withdrawn, drug interrupted, dose not given/held, and infusion interrupted.

The TEAE by maximum toxicity grade summary tables will use the following algorithms for counting subjects:

- **PT rows:** each subject is counted once within each unique PT at the maximum grade. For example, if a subject has two headaches, the subject is counted only once under the PT "Headache". Subjects experiencing the same TEAE PT several times with different grades will only be counted once with the maximum grade.
- **Any event row**: each subject with at least one TEAE will be counted only once at the maximum grade no matter how many events they have.

All TEAEs and drug-related TEAEs will be summarized by MedDRA PT and maximum toxicity grade. The PT will be ordered by descending order of the subject incidence based on all subjects in the analysis population. A table of all TEAEs by SOC and PT will also be provided.

The following summary tables will be presented by MedDRA PT, in which the PT will be sorted by descending order of subject incidence of PT based on all subjects in the analysis population:

- Summary of all TEAEs.
- Summary of drug-related TEAEs.
- Summary of Grade 3 or 4 TEAEs.
- Summary of DLT.
- Summary of TEAEs leading to drug interrupted, dose not given/held, infusion interrupted, and drug withdrawn.
- Summary of serious TEAEs.
- Summary of drug-related serious TEAEs.
- Summary of immune related TEAEs.

Additional summaries for drug-related IRR AE (toxicity grade, seriousness, number of events, action taken) at event-level, at subject-level, and number of subjects with IRR at each dosing visit among the first two cycles and during all subsequent cycles combined will be provided.

All AEs, immune related AEs, drug-related AEs, Grade 3 or 4 AEs, drug-related Grade 3 or 4 AEs, DLTs, SAEs, fatal AEs, AEs leading to dose not given/held, infusion interruption, dose increased or dose reduced, and drug withdrawal, and infusion related reaction signs and symptoms will be presented in data listings. Pretreatment AE, defined as AEs that start prior to the first dose of the study treatment, will be flagged in relevant listings. All AEs for the Screen Failures population will also be presented in a data listing.

8.3 Clinical Laboratory Evaluation

The clinical laboratory evaluation includes the following:

- Hematology: hemoglobin, hematocrit, platelet count, red blood cell count, white blood cell count, neutrophils, lymphocytes, monocytes, eosinophils and basophils.
- Clinical chemistry: blood urea nitrogen, creatinine, glucose, sodium, potassium, calcium, magnesium, phosphorus, total protein, albumin, lactate dehydrogenase, bicarbonate, haptoglobin, ferritin, C reactive protein and liver panel [alanine aminotransferase (ALT), aspartate aminotransferase (AST), total and direct bilirubin, and alkaline phosphatase (ALP)].
- Coagulation: prothrombin time, international normalized ratio, activated partial thromboplastin time, fibrinogen, and D-dimer.
- Thyroid: thyroid stimulating hormone and free thyroxine 4.

The clinical laboratory grades will be reported using the CTCAE v5.0. Separate listings will be provided for hematology, clinical chemistry, coagulation and thyroid tests. For each listing, baseline value will be specified for each subject.

Clinical laboratory results (hematology, clinical chemistry, coagulation, thyroid) will be summarized for worst case shift from baseline toxicity grade. Frequencies of maximum observed Grade 0-4 toxicity, as defined by the NCI CTCAE v5.0, will be presented for each laboratory parameter. The determination of the maximum grade post-baseline takes into account both planned and unscheduled assessments. Separate summaries indicating hyper- and hypo- directionality of change will be produced, where appropriate.

All laboratory values will be categorized as “low”, “normal”, or “high” relative to the normal ranges, or “unknown” if no valid result is available. For those laboratory parameters that do not have NCI CTCAE v5.0 grading criteria, worst case shift from baseline to post-baseline will be summarized. If a subject has worst case shifts to both “low” and “high”, the subject will be counted in both categories.

Subjects with elevated worst post-baseline ALT, AST, total bilirubin, or ALP values that fall into the following categories will be identified and summarized:

- ALT in the categories of <=1x upper limit of normal range (ULN), >1x ULN, >3x ULN;

- AST in the categories of <=1x ULN, >1x ULN, >3x ULN;
- total bilirubin in the categories of <=1x ULN, >1x ULN, >2x ULN
- ALP in the categories of <=1x ULN, >1x ULN, >1.5x ULN, >2x ULN
- Potential Hy's law, defined as at least one case of post-dose total bilirubin > 2 x ULN occurred at the same day or after the first incidence date of ALT or AST > 3 x ULN post treatment.

Additionally, C1D2 change from C1D1, C1D16 change from C1D15, C2D2 change from C2D1, and C2D16 change from C2D15 will be summarized for select laboratory tests (hemoglobin, platelet, lymphocytes, neutrophil).

All laboratory results will be presented by subject in data listings.

8.4 Death

All death records will be presented in a data listing. Subject incidence of deaths within and outside of 30 days of last dose and the cause of death will be summarized.

8.5 Vital Signs and Pulse Oximetry

Vital signs (blood pressure, heart rate, respiration rate, temperature), body weight (with percent change from baseline) and pulse oximetry will be presented in a data listing.

8.6 Cardiac Assessments

Cardiac assessments including electrocardiogram (ECG) and echocardiogram (ECHO) assessment date and results along with clinically significance will be presented in data listings.hriv

8.7 ECOG Performance Status

ECOG performance status scores will be summarized for baseline, and worst-case shift from baseline in a table and presented in a data listing.

8.8 Blood Phenotype and Direct Antiglobulin Test

Blood phenotype and direct antiglobulin test (DAT) assessment date and result will be presented in a data listing.

8.9 Transfusion

Transfusions data will be presented in a data listing.

9. PHARMACOKINETIC ANALYSES

The merge of SL-172154 serum concentration with CRF data will be performed after database lock by Shattuck Labs to generate a dataset with actual PK sampling times, actual time relative to

the start of infusion, and SL-172154 concentrations. Derivation of PK parameters will be performed by [redacted] using Phoenix WinNonlin (Version 8.2 or higher).

Unless otherwise specified, all PK data analysis will be based on the PK population and summarized by dose levels regardless of dosing schedules. Subjects who have infusion outcome as "Not Completed" on the PK sample collection day will be included in the summary of dose normalized concentration and PK parameter but will be excluded from other summary by dose level for the corresponding PK sample collection day.

9.1 Data Handling

The nominal time relative to the start of infusion will be calculated as the planned time relative to the end of infusion plus the planned infusion duration. The actual time relative to the start of infusion will be calculated as the actual sampling time relative to the start of infusion (SOI) or the SOI of the first infusion period if with infusion interruption(s). Missing PK sampling time will be handled as the following when calculating the actual time relative to SOI:

- If a sampling time is missing and no infusion interruption, the actual time relative to SOI will be calculated as time from SOI to end of infusion (EOI) plus planned time relative EOI.
- If a sampling time is missing and there is interruption(s) during the infusion, the actual time relative to SOI will be calculated as time from the SOI of first infusion period to the EOI of the last infusion period plus planned infusion time relative to EOI.

Concentration values that are below the limit of quantification (BLQ) will be handled as the following:

- If a BLQ value occurs at the predose, the BLQ value will be assigned as zero concentration. If one or more BLQ values occur in a profile after infusion but before the first measurable concentration, the BLQ values will be assigned a value of zero concentration. For linear plots, zero concentration value(s) will be included in the plot. For log-linear plots, zero concentration value(s) will be assigned a missing value.
- If a BLQ value occurs after a measurable concentration in a profile and is followed by a measurable concentration, then the BLQ will be set as missing.
- If a BLQ value occurs after the last measurable concentration in a profile, then the BLQ values will be set as missing.
- If two or more BLQ values occur in succession after a measurable concentration, the profile will be deemed to have terminated at the first BLQ value (BLQ values will be set to missing) and any subsequent concentration will be set as missing.
- BLQ values that are set to be missing will be omitted from PK parameter generation, concentration summary, and the individual PK profile plots.
- For the time point that all concentrations are BLQ and all BLQ results are imputed to be zero, then the mean/median concentration will be reported as zero.
- For the time point that only some concentrations are BLQ and BLQ values are imputed to be zero, the mean/median will be reported unless the mean/median value is below the LLQ (10 ng/ml), in which case the value will be assigned as BLQ.

9.2 SL-172154 Concentration Measures

SL-172154 concentration values will be sorted by dose level, dosing schedule, sample collection day, and nominal time points in the listing. All SL-172154 concentration values including BLQ will be listed in the same precision as the source data.

SL-172154 concentration will be summarized by dose level for each nominal time point relative to the EOI. Standard summary statistics will be calculated (i.e., mean, standard deviation [SD], median, minimum, maximum, coefficient of variation (CV%), geometric mean, geometric CV%).

Individual subject concentration-time profiles and median/mean profiles by dose level will be plotted for C1D1, C1D15 and C2D1, using the actual time from SOI for individual plots and the nominal time from EOI for medina/mean profiles. Each of the figures will contain one plot on the untransformed scale (i.e. linear plot) and one plot on the log transformed scale (i.e. semi-log plot). For mean concentration profile plot, mean+/- SD for each dose level will be plotted. For median concentration profile plot, median along with minimum and maximum for each dose level will be plotted. Individual subject concentration-time profiles using actual time from SOI (semi-log plot) will also be plotted along with infusion actual start and end time (including any interruptions) for each dose level at C1D1, C1D15 and C2D1.

Dose normalized concentration will be calculated by dividing total administered dose (mg). Mean (SD) dose normalized concentration time profile will be plotted for each dose level at C1D1, C1D15 and C2D1.

9.3 PK Parameters

The PK parameters will be derived from the concentration-time data using the actual collection time from SOI. The PK parameters will be calculated by standard non-compartmental analysis (NCA) as data permits. At least one post-dose concentration is required for C_{max} calculation, and at least three consecutive post-dose concentrations are required for AUC parameter calculation.

Table 6 SL-172154 PK Parameters

C_{max}	Maximum observed concentration over a dosing interval
C_{trough}	Observed concentration at the end of a dosing interval.
T_{max}	Time of maximum observed concentration
$AUC_{0\text{-}last}$	The area under the serum concentration time curve, from time 0 to the last quantifiable concentration, calculated by a combination of linear and logarithmic trapezoidal methods (Linear up/log down method).
$AUC_{0\text{-}inf}$	Area under the serum concentration time curve from time 0 extrapolated to infinity, calculated as $AUC_{last} + C_{last}$/terminal elimination rate constant (λ_z). Reliability of $AUC_{0\text{-}inf}$ values is contingent on the percent of the total area obtained by extrapolation: $AUC_{0\text{-}inf}$ values with <20% of the total area coming from C_{last}/λ_z are considered acceptable. Any exceptions to the above procedures will be clearly documented/justified in the PK report.

AUC_{tau}	The area under the serum concentration time curve over the dosing interval, calculated by a combination of linear and logarithmic trapezoidal methods (Linear up/log down method).
$\%AUC_{ext}$	Percentage of $AUC_{0\text{-}inf}$ due to extrapolation from T_{last} to infinity
$t_{½}$	Terminal elimination half-life, estimated using the equation $[\ln(2)/\lambda_z]$
CL	Clearance; calculated as Dose/$AUC_{0\text{-}inf}$ for C1D1 and Dose/AUC_{tau} for later time unless specified otherwise
Vz	Volume of distribution, calculated as Dose/(λ_z * $AUC_{0\text{-}inf}$) for C1D1 and Dose/(λ_z * AUC_{tau}) for later time unless specified otherwise
AR_{AUCtau}	Accumulation ratio of AUC_{tau} (C1D15/C1D1 and C2D1/C1D1).
AR_{Cmax}	Accumulation ratio of C_{max} (C1D15/C1D1and C2D1/ C1D1).

The elimination rate constant (λ_z) will be determined if the log-linear terminal elimination phase is apparent and excludes C_{max}. The λ_z will only be considered reliable if the adjusted coefficient of determination (adj-R^2) is greater than or equal to 0.8. Parameters dependent on λ_z (i.e., $t_{1/2}$, $AUC_{0\text{-}inf}$, $AUC_{\%ext}$, CL, Vz) will not be presented if λ_z cannot be estimated.

The following PK parameters will be calculated for diagnostic purposes and listed but not be summarized:

- λ_z lower: Lower limit of time (h) included in the calculation of λ_z
- λ_z N: Number of data points used in the calculation of λ_z
- λ_z upper: Upper limit of time (h) included in the calculation of λ_z
- Adjusted-R^2: Regression coefficient for calculation of λ_z

All PK parameters will be sorted by dose level/schedule in the listing and summarized by dose level for each PK sample collection day. For each of the PK parameters, except T_{max}, the following summary statistics will be calculated: median, minimum, maximum, arithmetic mean, standard deviation, CV%, geometric mean, and geometric CV%. For T_{max}, median, minimum, and maximum will be calculated. All PK parameters will be reported with the same precision as the source concentration data except that T_{max} and $t_{1/2}$ will be reported with 2 decimal places and λ_z will be reported with at least 3 significant figures.

Box plots of $AUC_{0\text{-}inf}$, $AUC_{0\text{-}last}$, AUC_{tau}, C_{max}, and C_{trough} for each dose level will be produced for C1D1, C1D15 and C2D1 as data permit.

To graphically examine the accumulation over time, box plots of C_{max} and $AUC_{0\text{-}last}$ as a function of time (in day) will be produced for each dose level. Mean C_{trough} with SD will be presented on linear scale as a function time (in day) for each dose level.

9.4 Assessment of Dose Proportionality

An assessment of dose proportionality will not be based strictly on statistical rule criteria but rather, several factors will be considered when assessing dose proportionality, such as results derived from a Power Model (e.g., the slope estimate, and the width of the 95% confidence intervals), graphical evaluation (box plots of dose-normalized PK parameters) and descriptive statistics of PK parameters by dose, as data permit.

Dose normalized PK parameters will be calculated by dividing total administered dose (mg) for $AUC_{0\text{-}inf}$, $AUC_{0\text{-}last}$, AUC_{tau}, C_{max}, and C_{trough}. Additional dose normalized PK parameters may be calculated, if appropriate and as data permit. Dose proportionality will be evaluated graphically using box plots of dose normalized PK parameters ($AUC_{0\text{-}inf}$, $AUC_{0\text{-}last}$, AUC_{tau}, C_{max}, and C_{trough}) by dose level for C1D1, C1D15 and C2D1.

Dose proportionality will also be evaluated for the $AUC_{0\text{-}inf}$, $AUC_{0\text{-}last}$, AUC_{tau}, C_{max}, and C_{trough} using the power model as data permit. A statistical linear relationship between the ln-transformed PK parameters and the ln-transformed actual dose received in mg will be fitted by using a mixed effect model with ln-transformed dose as a fixed effect and subject as random effect. Additional predictors may be included in the model. The general form of the power mode is described as:

$$\text{Ln}(Y) = \beta_0 + \beta \text{ Ln (Dose)} + \varepsilon$$

where Y represents the pharmacokinetic parameter. Note that $\beta = 1$ would correspond to perfect dose proportionality.

10. PHARMACODYNAMIC AND BIOMARKER ANALYSES

The analysis plan for pharmacodynamic and biomarker data will be provided in a separate analysis plan.

11. CHANGE FROM PROTOCOL-SPECIFIED ANALYSES

There are four changes from protocol-specified analyses:
1. Protocol Section 9.2.3 states that tabular summaries will be presented by dose levels/schedule/cohorts. Due to the limited enrollment, data from different cohorts will be pooled and summarized by schedule/dose level.
2. It is clarified in SAP Section 4 that the DLT Evaluable Population derivation is for the subjects enrolled in the dose escalation cohorts.
3. It is clarified in SAP Section 4 that all subjects who have signed the main study inform consent form are defined as Screened population, instead of Enrolled population.
4. “postdose” was added in SAP Section 4 for the definition of PK Population.

12. LITERATURE REFERENCES

1. National Cancer Institute Common Terminology Criteria for Adverse Events v5.0, NCI, NIH, DHHS, November 27, 2017.
2. 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;45:228-47.
3. Seymour L, Bogaerts J, Perrone A, et al. iRECIST: guidelines for response criteria for use in trials testing immunotherapeutics. Lancet Oncol 2017;18:e143-e52.
4. Brookmeyer, R. and Crowley, J. (1982). A confidence interval for the median survival time. Biometrics 38 29-41.
5. Guo W, Wang SJ, Yang S, Lynn H, Ji Y. A Bayesian interval dose-finding design addressing Ockham's razor: mTPI-2. Contemp Clin Trials 2017;58:23-33.

13. APPENDIX: LIST OF TABLES, FIGURES AND LISTINGS

13.1 List of Tables

ICH Heading	Table Number	Table Description	Analysis Population
14.1		**Demographics**	
	14.1.1	Study Populations and Subject Disposition	All Screened
	14.1.2	Study Treatment Status	All Treated
	14.1.3	Protocol Deviations	All Treated
	14.1.4	Demographic and Baseline Characteristics	All Treated
	14.1.5	Study Cancer History	All Treated
	14.1.6	Prior Anti-Cancer Treatment	All Treated
14.2		**Efficacy**	
	14.2.1	Objective Response with Confirmation Based on RECIST 1.1	All Treated
	14.2.2	Objective Response with Confirmation Based on RECIST1.1	Response Evaluable
	14.2.3	Objective Response with Confirmation Based on iRECIST	All Treated
	14.2.4	Time to Response and Duration of Response Based on RECIST 1.1	Response Evaluable
	14.2.5	Time to Response and Duration of Response Based on iRECIST	Response Evaluable
	14.2.6	Progression-Free Survival Based on RECIST 1.1	All Treated
	14.2.7	Progression-Free Survival Based on iRECIST	All Treated
	14.2.8	Overall Survival	All Treated
	14.2.9	Tumor Assessment at Baseline	All Treated
	14.2.10	CA-125	All Treated
14.3		**Safety**	
14.3.1		**Study drug exposure/adverse event**	
	14.3.1.1	Study Drug Exposure	All Treated
	14.3.1.2	Overall Summary of Treatment-Emergent Adverse Events	All Treated
	14.3.1.3	All Treatment-Emergent Adverse Events by System Organ Class and Preferred Term	All Treated
	14.3.1.4	All Treatment-Emergent Adverse Events by Preferred Term and Maximum Toxicity Grade	All Treated
	14.3.1.5	Drug-Related Treatment-Emergent Adverse Events by Preferred Term and Maximum Toxicity Grade	All Treated
	14.3.1.6	All Treatment-Emergent Adverse Events by Preferred Term	All Treated
	14.3.1.7	Serious Treatment-Emergent Adverse Events by Preferred Term	All Treated
	14.3.1.8	Immune Related Treatment-Emergent Adverse Events by Preferred Term	All Treated

ICH Heading	Table Number	Table Description	Analysis Population
	14.3.1.9	Drug-Related Treatment-Emergent Adverse Events by Preferred Term	All Treated
	14.3.1.10	Drug-Related Serious Treatment-Emergent Adverse Events by Preferred Term	All Treated
	14.3.1.11	Treatment-Emergent Adverse Events with Toxicity Grade 3 or 4 by Preferred Term	All Treated
	14.3.1.12	Dose Limiting Toxicities	DLT Evaluable
	14.3.1.13.1	Treatment-Emergent Adverse Events leading to Infusion Interrupted by Preferred Term	All Treated
	14.3.1.13.2	Treatment-Emergent Adverse Events Leading to Dose Not Given/Held by Preferred Term	All Treated
	14.3.1.13.3	Treatment-Emergent Adverse Events Leading to Drug Interrupted by Preferred Term	All Treated
	14.3.1.14	Treatment-Emergent Adverse Events leading to Drug Withdrawn by Preferred Term	All Treated
	14.3.1.15	Summary of Drug-Related Infusion Related Reaction at Subject Level	All Treated
	14.3.1.16	Summary of Drug-Related Infusion Related Reaction at Event Level	All Treated
	14.3.1.17	Summary of Drug-Related Infusion Related Reaction by Dosing Visit	All Treated
	14.3.1.18	Deaths	
14.3.5		**Laboratory**	
	14.3.5.1	Hematology – Maximum CTCAE Grade Shift from Baseline	All Treated
	14.3.5.2	Chemistry – Maximum CTCAE Grade Shift from Baseline	All Treated
	14.3.5.3	Coagulation and Thyroid Function Test – Maximum CTCAE Grade Shift from Baseline	All Treated
	14.3.5.4	Laboratory Tests without CTCAE - Maximum Shift from Baseline with Respect to Normal Range	All Treated
	14.3.5.5	Post-Baseline Potential Serious Hepatoxicity	All Treated
	14.3.5.6	Summary of Change for Select Laboratory Tests	All Treated
14.3.6		**Other Safety Data**	
	14.3.6.1	ECOG Performance Status – Maximum Shift from Baseline	All Treated
14.3.7		PK	
	14.3.7.1	SL-172154 Serum Concentration-Time Data	PK
	14.3.7.2	SL-172154 PK Parameters	PK

13.2 List of Figures

ICH Heading	Figure Number	Figure Description	Analysis Population
14.2	14.2.1	Horizontal Bar Plot of Duration on Treatment by Response	All Treated
	14.2.2	Waterfall Plot of Target Lesions Maximum Reduction in Sum of Lesion Diameters	All Treated
	14.2.3	Plot of Target Lesions Percent Change from Baseline Sum of Lesion Diameters Over Time	All Treated
	14.2.4	Kaplan-Meier Plot of Time to Response Based on RECIST 1.1 and iRECIST	Response Evaluable
	14.2.5	Kaplan-Meier Plot of Duration of Response Based on RECIST1.1 and iRECIST	Response Evaluable
	14.2.6	Kaplan-Meier Plot of Progression-Free Survival Based on RECIST1.1 and iRECIST	All Treated
	14.2.7	Kaplan-Meier Plot of Overall Survival	All Treated
	14.2.8	Plot of Percent Change from Baseline for CA-125 Over Time	All Treated
14.3	14.3.7.1	Plot of Individual SL-172154 Concentration-time Profiles by Dose Level (Linear and Semi-log)	PK
	14.3.7.2	Plot of Individual SL-172154 Concentration-time Profiles with Infusion Time by Dose Level (Semi-log)	PK
	14.3.7.3	Plot of Mean (+/-SD) SL-172154 Concentration-time Profile by Dose Level (Linear and Semi-log)	PK
	14.3.7.4	Plot of Median (Min-Max) SL-172154 Concentration-time Profile by Dose Level (Linear and Semi-log)	PK
	14.3.7.5	Plot of Mean (+/-SD) Dose Normalized SL-172154 Concentration-time Profile by Dose Level (Linear and Semi-log)	PK
	14.3.7.6	Box Plot of C_{max} by Dose Level	PK
	14.3.7.7	Box Plot of Dose Normalized C_{max} versus Dose Level	PK
	14.3.7.8	Box Plot of $AUC_{0\text{-last}}$ versus Dose Level	PK
	14.3.7.9	Box Plot of Dose Normalized $AUC_{0\text{-last}}$ versus Dose Level	PK
	14.3.7.10	Box Plot of C_{max} versus Visit for Each Dose Level	PK
	14.3.7.11	Box Plot of $AUC_{0\text{-last}}$ versus Visit for Each Dose Level	PK
	14.3.7.12	Box Plot of Dose Normalized $AUC_{0\text{-inf}}$ versus Dose Level	PK
	14.3.7.13	Box Plot of Dose Normalized AUC_{tau} versus Dose Level	PK
	14.3.7.14	Box Plot of Dose Normalized C_{trough} versus Dose Level	PK

13.3 List of Data Listings

ICH Heading	Listing Number	Listing Description	Analysis Population
16.2		**SUBJECT DATA LISTINGS**	

ICH Heading	Listing Number	Listing Description	Analysis Population
16.2.1		**Discontinued subjects**	
	16.2.1.1	Study Population and Subject Disposition	All Screened
	16.2.1.2	Study Treatment Discontinuation	All Treated
	16.2.1.3	Informed Consent and Protocol Amendment Re-Consent	All Treated
16.2.2		**Protocol deviations**	
	16.2.2.1	Protocol Deviations	All Treated
	16.2.2.2	COVID-19 Related Protocol Deviations	All Treated
	16.2.2.3	Inclusion and Exclusion Criteria Deviation	All Treated
16.2.4		**Demographics**	
	16.2.4.1	Demographic and Baseline Characteristics	All Treated
	16.2.4.2	Medical and Surgical History	All Treated
	16.2.4.3	Study Cancer History	All Treated
	16.2.4.4	Prior Anti-Cancer Systemic Treatment	All Treated
	16.2.4.5	Prior Radiotherapy	All Treated
	16.2.4.6	Prior Surgery Treatment	All Treated
	16.2.4.7	Prior and Concomitant Medications	All Treated
	16.2.4.8	Concomitant Procedures	All Treated
	16.2.4.9	Demographic and Baseline Characteristics for Screen Failure Subjects	Screen Failure
16.2.5		**Study Drug Exposure**	
	16.2.5.1	Study Drug Administration	All Treated
	16.2.5.2	SL-172154 Serum Concentration-Time Data	PK
	16.2.5.3	SL-172154 PK Parameters	PK
16.2.6		**Individual efficacy response data**	
	16.2.6.1	Tumor Assessment: Target Lesions	All Treated
	16.2.6.2	Tumor Assessment: Non-Target Lesions	All Treated
	16.2.6.3	Tumor Assessment: New Lesions	All Treated
	16.2.6.4.1	Tumor Responses Based on RECIST 1.1	All Treated
	16.2.6.4.2	Tumor Responses Based on iRECIST	All Treated
	16.2.6.5	Time to Response and Duration of Response Based on RECIST 1.1 and iRECIST	Response Evaluable
	16.2.6.6.1	Progression-Free Survival Based on RECIST 1.1	All Treated
	16.2.6.6.2	Progression-Free Survival Based on iRECIST	All Treated
	16.2.6.7	Overall Survival	All Treated
	16.2.6.8	Summary of CA-125	All Treated

ICH Heading	Listing Number	Listing Description	Analysis Population
16.2.7		**Adverse Event Listings**	
	16.2.7.1	All Adverse Events	All Treated
	16.2.7.2	Dose Limiting Toxicities	DLT evaluable
	16.2.7.3	Drug-Related Adverse Events	All Treated
	16.2.7.4	Adverse Events with Toxicity Grade 3 or 4	All Treated
	16.2.7.5	Drug-Related Adverse Events with Toxicity Grade 3 or 4	All Treated
	16.2.7.6	Fatal Adverse Event	All Treated
	16.2.7.7	Serious Adverse Events	All Treated
	16.2.7.8	Immune Related Adverse Events	All Treated
	16.2.7.9	Infusion Related Reaction Adverse Events	All Treated
	16.2.7.10	Adverse Events Leading to Infusion Interrupted	All Treated
	16.2.7.11	Adverse Events Leading to Dose Increased or Dose Reduced	All Treated
	16.2.7.12	Adverse Events Leading to Dose not given/Held	All Treated
	16.2.7.13	Adverse Events Leading to Drug Withdrawn	All Treated
	16.2.7.14	Infusion Reaction Signs and Symptoms	All Treated
	16.2.7.15	Death	All Treated
	16.2.7.16	All Adverse Events for Screen Failure Subjects	Screen Failure
16.2.8		**Individual Laboratory Measurements**	
	16.2.8.1	Hematology	All Treated
	16.2.8.2	Clinical Chemistry (including ferritin and haptoglobin)	All Treated
	16.2.8.3	Coagulation and Thyroid Function	All Treated
16.2.9		**Listing of other safety data**	
	16.2.9.1	Vital Signs and Pulse Oximetry	All Treated
	16.2.9.2	ECOG Performance Status	All Treated
	16.2.9.3	Cardiac Assessments: ECG	All Treated
	16.2.9.4	Cardiac Assessments: ECHO	All Treated
	16.2.9.5	Blood Phenotyping and Direct Antiglobulin Test	All Treated
	16.2.9.6	Transfusions	All Treated