STUDY CODE: STML-901-0119

STATISTICAL ANALYSIS PLAN (SAP)

A Phase 1, Open-label, Dose-escalation Study of the PI3K Inhibitor SL-901 in Patients with Advanced Solid Tumors

Sponsor:	Stemline Therapeutics, Inc. 750 Lexington Ave. 11th Floor New York, NY 10022
EudraCT-No.:	**2019-004135-22**
Investigational medicinal Product:	**SL-901**
Development Phase:	Phase I
Indication:	Advanced Solid Tumors
Date of First Patient In:	25MAR2021
Date of Last Patient Out:	24APR2023
SAP Version and date	1.0 21JUN2023
Protocol Version and date	2.0 06OCT2020

SIGNATURE PAGE

I have read this report and confirm that to the best of my knowledge it accurately describes the planned statistical analyses of the study.

Author	[redacted]	[redacted]	28JUN2023
	[redacted]	Signature	Date
Reviewer	[redacted]	[redacted]	28JUN2023
	[redacted]	Signature	Date
Approver	[redacted]	[redacted]	27JUN2023
	[redacted]	Signature	Date

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1. Version History

Version Date	Author	Description for Revision
1.0 23MAY2023	[redacted]	This is the first issue of this document

2. List of abbreviations

ADaM	Analysis Data Model
ADR	Adverse Drug Reaction
AE	Adverse Event
ALT	Alanine Aminotransferase
AML	Acute Myeloid Leukemia
ANC	Absolute Neutrophil Count
AST	Aspartate Aminotransferase
ATC	Anatomical Therapeutic Chemical Classification System
AUC	Area Under Curve
AUC_{inf}	AUC from time of dosing extrapolated to infinity
$\%AUC_{extrap}$	Percentage of AUC_{inf} due to extrapolation from T_{last} to infinity
AUC_{last}	Area under the curve from the time of dosing to the time of the last measurable concentration (T_{last})
AUC_{Tau}	The partial area from dosing time to dosing time plus dose interval (Tau)
b.i.d.	bis in die (twice daily)
BLQ	Below the Lower Limit of Quantification
BMI	Body Mass Index
BOR	Best Overall Response
BP	Blood Pressure
BR	Breath Rate
BUN	Blood Urea Nitrogen
CA	Competent Authority
C_{avg}	Average concentration
CDB	Clinical Database
CDISC	Clinical Data Interchange Standards Consortium
CHF	Congestive Heart Failure
CL_{ss}/F	Apparent Clearance at steady state
C_{last}	Observed concentration corresponding to T_{last}
C_{max}	Maximum observed concentration
C_{min}	Minimum observed concentration occurring at time T_{min}
CI	Confidence Interval
CR	Complete Response

CRC	Cohort Review Committee
CRF	Case Report Form
CRO	Contract Research Organization
CRR	Complete Response Rate
CS	Clinically Significant
CSP	Clinical Study Protocol
CTCAE	Common Terminology Criteria for Adverse Events
CTLS	Clinical Tumor Lysis Syndrome
CV	Coefficient of Variation
CYP	Cytochromes
DC	Disease Control
DCR	Disease Control Rate
DLT	Dose Limiting Toxicity
DM	Data Management
DOCR	Duration of Complete Response
DOR	Duration of Response
DRM	Data Review Meeting
DSM	Drug Safety Manager
DSRC	Data Safety Review Charter
DSUR	Development Safety Update Report
ECG	Electrocardiogram
ECOG	Eastern Cooperative Oncology Group
eCRF	electronic Case Report Form
EDC	Electronic Data Capture
EOT	End of Treatment
F	Bioavailability
FFPE	Formalin-Fixed Paraffin-Embedded
GCP	Good Clinical Practice
GGT	Gamma-Glutamyl Transpeptidase
GM	Geometric Mean
HDPE	High-Density Polyethylene
HM	Haematologic Malignancies
HR	Heart Rate
IB	Investigator's Brochure

ICF	Informed Consent Form
ICH	International Conference on Harmonisation
iDSMB	Independent Data Safety Monitoring Board
IMP	Investigational Medicinal Product
INR	International Normalized Ratio
IRB	Institutional Review Board
ITT	Intent-to-treat
IVRS	Interactive Voice Response System
IWRS	Interactive Web Response System
LDH	Lactate Dehydrogenase
LLT	Lowest Level Term
LOCF	Last observation carry forward
LTLS	Laboratory Tumor Lysis Syndrome
MedDRA	Medical Dictionary for Regulatory Activities
MTD	Maximum Tolerated Dose
NC	Not Calculated
NCI	National Cancer Institute
NE	Not Evaluable
NSADR	Non-serious Adverse Drug Reaction
NSAE	Non-serious Adverse Event
ODS	Output Delivery System
OR	Objective Response
ORR	Objective Response Rate
OS	Overall Survival
PBMC	Peripheral Blood Mononuclear Cell
PD	Pharmacodynamics
PD	Progressive Disease
PFS	Progression-free survival
PI3K	Phosphoinositide 3-kinase
PK	Pharmacokinetics
PP	Per-protocol
PR	Partial Response
PS	Performance Status
PT	Preferred Term

QA	Quality Assurance
q.d.	quaque die (every day)
QTcF	Fridericia-corrected QT interval
RBC	Red Blood Cells
RECIST	Response Evaluation Criteria in Solid Tumors
RO	Receptor Occupancy
SADR	Serious Adverse Drug Reaction
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAR	Statistical Analysis Report
SD	Stable Disease
SD	Standard Deviation
SDTM	Study Data Tabulation Model
SmPC	Summary of Product Characteristics
SOC	System Organ Class
SOP	Standard Operating Procedure
sUA	serum Uric Acid
SUSAR	Suspected Unexpected Serious Adverse Reaction
TA	Tumor Assessment
TEAE	Treatment Emergent Adverse Event
T_{last}	Time of last measurable observed concentration
TLS	Tumor Lysis Syndrome
T_{max}	Time of maximum observed concentration
TMF	Trial Master File
T_{min}	Time of minimum observed concentration
UA	Uric Acid
UGT	Uridine Diphosphate Glucuronosyltransferase
ULN	Upper Limit of Normal
V_z/F	Apparent volume of distribution based on the terminal phase
WBC	White Blood Cells
WHO	World Health Organization

3. Introduction

The purpose of this document is to provide further details about the statistical analysis methods specified in the final study protocol Version 2.0 dated 06OCT2020 and subsequent amendments. The SAP follows the principles of the guidelines ICH Topic E3 and E9 regarding the structure and content of clinical study reports and regarding statistical principles for clinical trials.

The SAP will be finalized and signed prior to locking the database.

The sponsor of the study is Menarini Stemline.

Section 4 provides a study overview and presents the study objectives. In Section 5 the study design and the endpoints are described in a detailed way and also the study flow chart, taken from the Clinical Study Protocol v2.0, is reported. Section 6 presents some general specifications for the data validation, the computer systems, software and coding systems used. All definitions and the general methodology for the study activities are reported in Sections 7 through 10, while the analyses and summaries that will be produced and detailed specifications on the statistical methodology are presented in Sections 11 and 12. Section 13 provides the complete index of tables, listings and figures for the Statistical Analysis Report that will be generated at the end of the study.

3.1. Changes from study protocol

Since the PK run-in period is included in the DLT assessment period, the DLT population definition has been modified so that in order to be considered DLT evaluable a patient must have taken also the full dose during the run-in period in addition to at least 75% of the planned SL-901 doses in Cycle 1.

4. Study overview

SL-901 is an orally bioavailable investigational anticancer drug aimed to treat patients whose cancers harbor an overactive phosphoinositide 3-kinase (PI3K) signaling.

This is a Phase I, open-label, dose-escalation and cohort expansion study in two parts: In Part 1a, escalating doses and 2 schedules of SL-901 will be evaluated in patients with advanced solid tumors, to identify the maximum tolerated dose (MTD) and determine the regimen for Part 1b. In Part 1b, the clinical activity of SL-901 at the selected dose and schedule will be further characterized in patients with advanced solid tumors known to have specific genetic alterations and who may derive benefit from treatment with a PI3K inhibitor.

The study was stopped early and Part 1b was not started.

4.1. Study objectives

4.1.1. Primary objective(s)

- To identify the MTD of SL-901;
- To identify an appropriate dosing regimen for further investigation of SL-901;
- To characterize the pharmacokinetics (PK) profile of SL-901;
- To generate clinical safety data and perform initial assessment of the safety profile of SL-901.

4.1.2. Secondary objective(s)

- To characterize the pharmacodynamics (PD) of SL-901;
- To assess preliminary clinical activity of SL-901.

4.1.3. Exploratory objective(s)

Not Applicable.

5. Investigational plan

5.1. Study configuration and structure

This clinical study includes 2 parts.

Dose-Escalation (Part 1a)

This is an open-label, dose-escalation, and regimen-finding study to investigate the safety, PK, and PD of SL-901 in patients with advanced solid tumors. In Part 1a, adverse events (AEs) occurring during the

first cycle of treatment will be considered for the assessment of Dose Limiting Toxicities (DLTs), with continued evaluation of AEs in subsequent treatment cycles for further characterization of the safety of SL-901. This part will follow a 3+3 dose-escalation design to determine the MTD of SL-901 when administered on both a QD and BID schedule; single and multiple dose PK assessments will be performed to characterize the exposure of SL-901. The dose-escalation scheme to be followed is based on a modified Fibonacci sequence schema, which also is commonly employed in Phase 1 dose-finding oncology studies.

The SL-901 starting dose will be 20 mg on both the QD and BID schedule. The QD and BID schedules are planned to be tested in parallel, with enrolment to the current cohort for each schedule conducted on an every other patient basis.

Table 1: Planned SL-901 Dose Levels in Part 1a

	Cohort						
	1	2	3	4	5	6	7
QD Dosing (mg/dose)	20	40	60	80	120	160	200
BID Dosing (mg/dose)	--	20	--	40	60	80	100
Total Daily Dose (mg/day)	20	40	60	80	120	160	200

QD = once daily, BID = twice daily

A DLT occurring during the Run-in PK period or in Cycle 1 is defined as any of the following AEs for which there is a reasonable possibility that SL-901 caused the event.

- Any ≥Grade 3 non-hematologic AEs, with the exceptions of:
  - Grade 3 nausea, vomiting, diarrhea, constipation, fever, fatigue, or skin rash that resolves to Grade <3 within 72 hours.
  - Grade 3 laboratory abnormalities that are not associated with symptoms and resolve to Grade 1 or baseline by C1D28 (unless otherwise specified).
- Grade 4 thrombocytopenia or Grade 3 thrombocytopenia with >Grade 1 bleeding or requirement for platelet transfusion.
- Grade 4 neutropenia lasting >5 days.
- Febrile neutropenia (absolute neutrophil count [ANC] <1×109/L with fever ≥38.5°C) of any duration.
- Persistent anemia (i.e., lasting >96 hours despite >2 red blood cell [RBC] transfusions).
- ≥Grade 3 transaminase (AST/ ALT) elevation.
- Any toxicity resulting in >7 held/skipped doses.

- Any other significant toxicity considered by the Investigator or the Sponsor to be dose-limiting (e.g., any toxicity considered at least possibly related to SL-901 that results in patient withdrawal during C1).

In situations in which DLTs have occurred that would prevent further dose-escalation and are severe but not life-threatening (i.e., persistent Grade 3 fever, malaise), re-evaluation of specific dose cohorts may be considered with co-administration of appropriate supportive care agents (e.g., corticosteroids, anti-depressants) concomitant with SL-901 therapy.

Patients who do not receive the complete run-in dose and at least 75% of the planned SL-901 doses in Cycle 1 and/or discontinue before completing study assessments through C2D1 for reasons other than DLT are to be replaced.

The MTD is defined as the highest dose level at which no more than 1 of 6 subjects experience a DLT during the DLT assessment window (Run-in PK period and C1). An MTD will be identified for each dosing schedule.

All dose-escalation steps and schedule recommendations will be made by a review committee, comprised of the study Investigators and Sponsor representatives, who will review the available safety and other relevant data to inform the decision.

Expansion Cohorts (Part 1b)

Up to 4 expansion cohorts at the MTD (or maximum tested dose if no MTD is identified, or dose below the MTD if there is evidence suggesting a more favorable risk/benefit profile) may be opened for enrolment with 6 to 12 patients in each cohort. Although decisions regarding dose-escalation will be made based on review of data from Part 1a, safety data will also be collected from all patients in Part 1b and reviewed periodically by the Sponsor and Investigators. Any detected cumulative toxicity may require later dose reductions or other action as appropriate, including further refinement of the MTD.

This part of the study was not started.

5.2. Schematic study design

Screening assessments are performed subsequent to the patient providing an informed consent and within 28 days before the first administration of SL-901 at the Run-in PK sampling day, unless otherwise specified.

In both study parts a treatment cycle is considered to be 28 days, with daily dosing throughout the cycle.

All patients will receive SL-901 as a single agent in an open-label fashion; study drug will be dispensed to patients at scheduled study center visits on a per-cycle basis. SL-901 capsules (20 mg and 60 mg) are packaged into 50-cc high-density polyethylene (HDPE) bottles, 14 capsules per bottle.

Tumor assessment will occur at Screening (for identification of baseline disease) and every 2 cycles of treatment thereafter. Response will be evaluated using Response Evaluation Criteria in Solid Tumors (RECIST) v1.1.

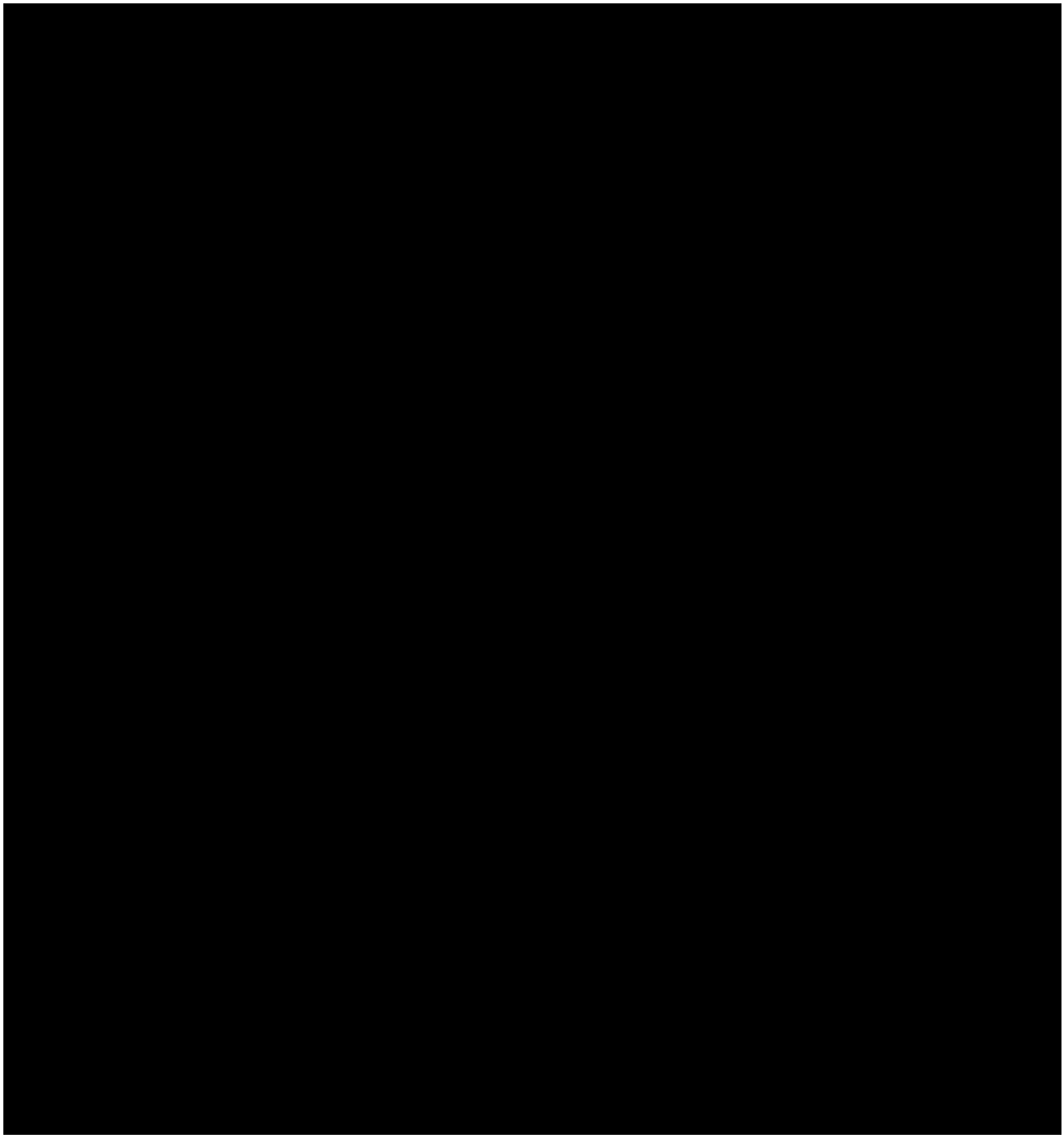
In Part 1a, a serially sampled PK profile will be obtained for a single dose (Run-in PK sampling) and at steady-state (C1D15); in Part 1b, the PK sample collection schedule will be informed by data collected in Part 1a.

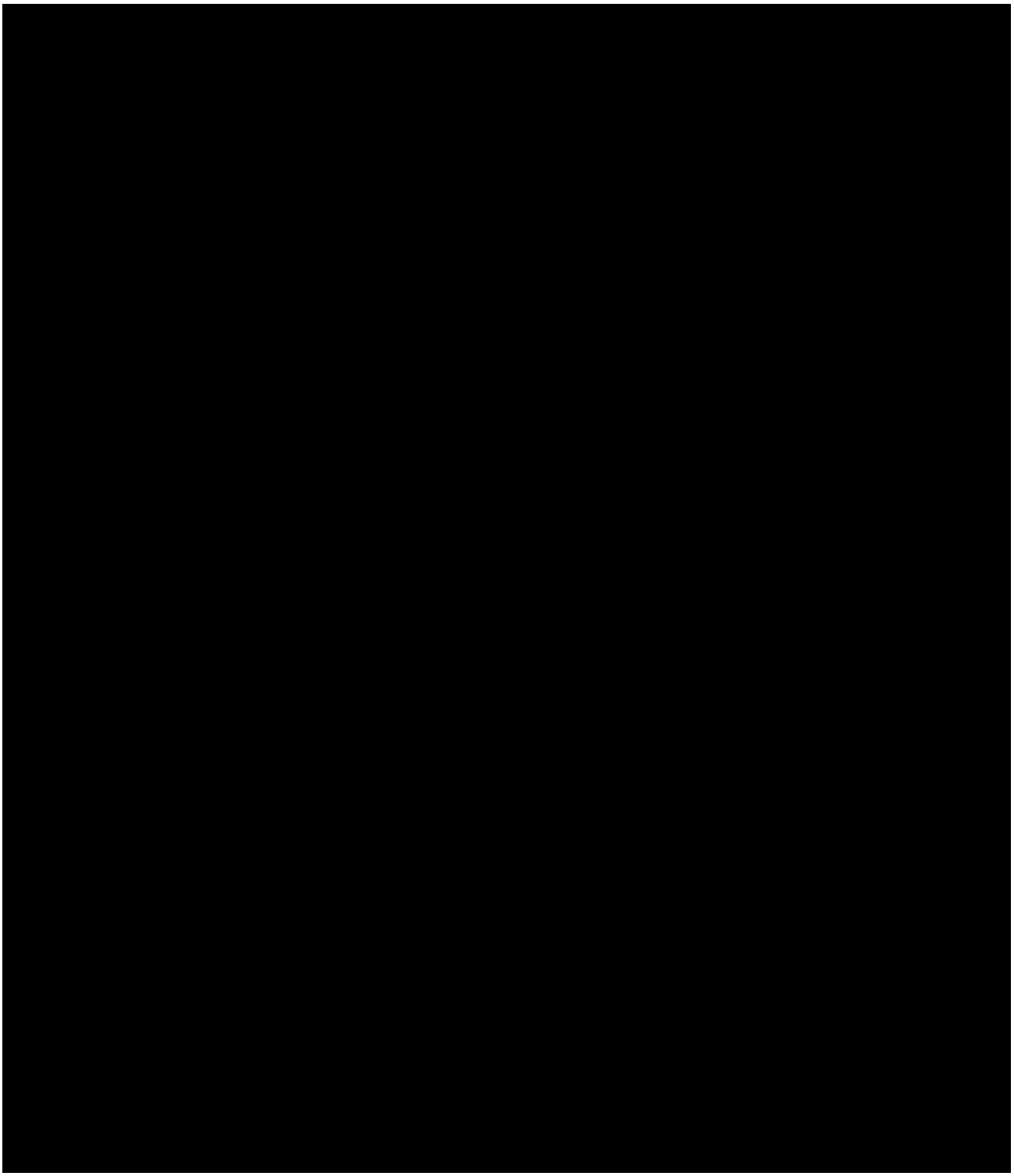
All Serious Adverse Events (SAEs) and non-SAEs will be recorded in the study's clinical database from the day of informed consent signature (SAEs) or from the day of first exposure to SL-901 (AEs) through 30 days after the last dose of SL-901.

After completion of the End of Treatment (EOT) visit, patients will then be followed every 90 days for survival status for 12 months. The survival follow-up may be by telephone contact. If the patient discontinued study drug for reasons other than progressive disease, disease assessments should continue to be performed on an every 8-week basis (±1 week) through 6 months after the first study drug dose and then on an every 90-day basis or until, in the judgment of the Investigator, there is evidence of relapsed or progressive disease.

5.3. Study flow chart

The schedule of assessments for the study is provided in Table 2 (Screening period, Run-in pharmacokinetic [PK] and Cycles 1-2) and Table 3 (Cycle 3 and beyond). PK assessment schedule is provided in Table 4.





5.4. Study Endpoints

5.4.1. Primary endpoints

- Safety endpoints include
  - identification of DLTs;
  - rate of treatment-emergent adverse events (TEAEs) and SAEs;
  - identification of abnormalities in physical examination, vital signs, clinical laboratory evaluations;
  - ECG findings.
- PK endpoints include
  - assessment of SL-901 plasma concentration over time;
  - assessment of any changes in the PK properties of SL-901 between initial administration and steady-state and between cycles of treatment;
  - explore the correlation between PK parameters and toxicity.

5.4.2. Secondary endpoints

- PD assessment of target phosphorylation will be performed using a PI3K pathway triple assay (p-AKT, p-p70S6K, and p-GSK3) in platelet-rich plasma and/or tumor tissue and using immunofluorescence for gamma H2AX in PBMCs.

- Clinical activity endpoints include
  - Objective Response Rate (ORR);
  - Disease Control Rate (DCR)
  - Complete Response Rate (CRR);
  - Duration of Response (DOR);
  - Duration of Complete Response (DOCR)
  - Progression-free survival (PFS);
  - Overall Survival (OS).

5.4.3. Exploratory endpoints

Not applicable.

5.4.4. Safety endpoints

The Safety endpoints are included among the planned primary endpoints. Please refer to paragraph 5.4.1.

6. General specifications

6.1. Data validation

Medidata Classic Rave ® 2020.3. 2 and following software release will be used as Electronic Data Capture (EDC) system for data entry, by site personnel and for data cleaning and data locking by the Menarini Ricerche Data Management team.
The eCRF data are elaborated to create the SDTM (v1.8) and ADaM (v2.1) CDISC standard datasets.

6.2. Computer system and software used

The software used for all summary statistics and statistical analyses will be SAS Studio ® 9.04.01 or higher (SAS Institute, Inc.). All tables and listings will be produced using PROC REPORT or procedure specific output displays using output delivery system (ODS). The summary tables and listings will use SAS monospace font of size 6. The default page type will be A4 and the default page orientation will be landscape.
The PK parameters will be determined from the individual plasma concentration time curves using non-compartmental methods with Phoenix™ WinNonlin® software, version 6.4 or higher (Pharsight Corp., Mountain View, California).

6.3. Coding systems

6.3.1. Clinical Terms

Concomitant diseases, medical procedures, and Adverse Events will be coded with MedDRA version 23.1 or subsequent versions.

6.3.2. Drugs

Drugs will be coded with WHO (ATC coding system) Drug version Mar-2021 or subsequent versions.

6.3.3. Classification criteria

Adverse Events will be graded for severity using the classifications of Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0 (November 27, 2017).

6.4. Report type, language, format

The statistical output will be in word and .pdf format and in English language.

Dates will be presented with the DDMMMYYYY format.

Counts and percentages:

<group 1> xxx (xx.xx%)

Counts and percentages including also the count of the event of interest will be displayed in two separated columns:

n (%)	No. of events
xx (xx.xx %)	xxx

Descriptive statistics:	n	xxx
	Mean	xxx.xx
	Median	xxx.xx
	SD	xxx.xxx
	Minimum	same precision as individual value
	Maximum	same precision as individual value

In general, the following rule will be applied for decimal place:

- Minimum, maximum: one decimal place
- Arithmetic mean and median: one more decimal than minimum/maximum

- o SD: one more decimal than arithmetic mean/median
- o N: no decimal places

Character values will be left aligned.
Numeric values will be decimal-point aligned.

6.5. Standard Operating Procedures (SOPs) to be followed

[1]Code	Title
MR-GCS-DMST-210_SOP	Statistical Analysis Plan (SAP)
MR-GCS-DMST-211_SOP	Statistical Programs Writing
MR-GCS-DMST-211.3_WI	TLF programming
MR-GCS-CP&P-504	Use and management of Phoenix® WinNonlin® and pharmacokinetic data flow
MR-GCS-CP&P-505	Standard methods for non-compartmental analysis of pharmacokinetic data

6.6. Data Transfer Agreements

Data not directly entered in eCRF like (and not limited to):
- PK concentrations – [redacted] "*STML_901_0119_PK_Concentrations_DTA V1.0"*
- PK analysis results – Clinical Pharmacology and Pharmacometrics team Menarini Ricerche S.p.A "*STML_901_0119_PK_DTA V1.0"*
- PD results - [redacted]

are transferred to the Sponsor based on specific Data Transfer Agreements (DTA).
For the details regarding DTAs and the management of the received data, please refer to the Clinical Data Management Plan.

7. Definitions and general methodology

7.1. Data quality assurance

All tables, figures and data listings to be included in the report will be independently checked for consistency, integrity and in accordance with Menarini Ricerche standard procedures.

7.2. General considerations and key definitions

7.2.1. General considerations

Study day is defined as the number of days from the date of first dose of SL-901 to the event/visit date. For dates equal to or later than the first dose of study drug, study day is calculated as follows:
Study Day = Event or Visit Date – First Dose Date + 1

For dates prior to the first dose of study drug, study day is calculated as follows:
Study Day = Event or Visit Date – First Dose Date

One (1) month will be considered to be equal to 30.4375 days when calculating durations or survival times in months.

7.2.2. Key definitions

Baseline

Baseline is defined as the last non-missing assessment prior to the date and time of the first SL-901 dose.

Change from Baseline

Change from Baseline (absolute value) = post-baseline value – baseline value.

Adverse Events (AEs)

An AE is any untoward medical occurrence in a study patient who is administered a medicinal product (study drug), regardless whether or not considered drug-related. An AE can therefore be any unfavorable and unintended sign including abnormal laboratory/examination findings, symptoms, or disease(s) temporally associated with the use of study drug, whether or not related to study drug. An AE can arise from any use of the drug (e.g., off-label use, use in combination with another drug) and from any route of administration, formulation, or dose, including an overdose.

Treatment-Emergent Adverse Events (TEAEs)

If an Adverse Event occurs for the first time or if it worsens in terms of grade, seriousness or severity on or after the first on or after the date and time of the first dose of SL-901 and up to 30 days after the last dose of SL-901, it will be classified as TEAE, otherwise it will be classified as non-TEAE. Where an AE date is partial or missing, and it is unclear whether the AE is treatment-emergent, the AE will be assumed to be treatment-emergent.

Adverse Drug Reactions (ADRs)

Untoward and unintended responses to an Investigational Medicinal Product (IMP) related to any dose administered. The definition also covers medication errors and uses outside what is foreseen in the protocol, including misuse and abuse of the product. The definition implies a 'reasonable possibility of a causal relationship between the event and the IMP. This means that there are facts (evidence) or arguments to suggest a causal relationship.

All AEs (including SAEs) are to be accurately recorded on the AE page of the patient's electronic case report form (eCRF). Each event will be graded for severity using the classifications of NCI CTCAE (see section 6.3.3).

- **Grade 1 / Mild** - AE that disappears or is easily tolerated on continuation of study drug;
- **Grade 2 / Moderate** – AE that disappears or is easily tolerated on continuation of study drug;
- **Grade 3 / Severe** - AE sufficiently discomforting to cause interference with usual work activities;
- **Grade 4 / Life-threatening** - AE that is potentially life-threatening.
- **Grade 5 / Fatal** - Results in the patient's death.

A severe event is not necessarily a serious event. For example, a headache may be severe (interferes significantly with patient's usual function) but would not be classified as serious unless it met one of the criteria for serious events as defined below.

Serious Adverse Event (SAE) / Serious Adverse Drug Reaction (SADR)

Any untoward medical occurrence or effect that at any dose:

- Results in death.

- Is life-threatening. Life-threatening means that the patient was at immediate risk of death from the reaction as it occurred (i.e., it does not include a reaction which hypothetically might have caused death had it occurred in a more severe form).
- Requires in-patient hospitalization or prolongation of existing hospitalization. Hospitalization admissions and/or surgical operations scheduled to occur during the study period, but planned before study entry are not considered adverse events if the illness or disease existed before the patient was enrolled in the study, provided that it did not deteriorate in an unexpected manner during the study (e.g. surgery performed earlier than planned).
- Results in persistent or significant disability/incapacity or substantial disruption of
- the ability to conduct normal life functions.
- Results in a congenital anomaly/birth defect

Any other AE/ADR which is not included in the above definitions will be considered as non-serious. The Investigator should also promptly report all the SAEs to the Sponsor's Drug Safety Manager.

Algorithm for Causality Assessment of Adverse Events

The causality (causal relationship to the study drug) of AEs will be assessed based on the following algorithm:

1. **Definitely related**: An AE, including a laboratory test abnormality assessed as clinically significant (CS), is considered certainly related to a drug when it occurs in a plausible time relation to the administration of the drug, and which cannot be explained by concurrent disease or other drugs or chemicals. The response to withdrawal of the drug (de-challenge) should be clinically plausible. The event must be definitely related, pharmacologically or phenomenological, using a satisfactory re-challenge procedure if necessary.
2. **Probably related**: An AE, including a laboratory test abnormality assessed as CS, is considered probably related to a drug when it occurs in a reasonable time relation to the administration of the drug, is unlikely to be attributed to concurrent disease or other drugs or chemicals, and which follows a clinically reasonable response on withdrawal (de-challenge). Re-challenge information (AE reappearance after drug reintroduction) is not required to fulfil this definition.
3. **Possibly related**: An AE, including a laboratory test abnormality assessed as CS, is considered possibly related to a drug when it occurs in a reasonable time relation to the administration of the drug, or it could also be explained by concurrent disease or other drugs or chemicals. Information on drug withdrawal (de-challenge) may be lacking or unclear.

4. **Unlikely related**: An AE, including a laboratory test abnormality assessed as CS, is considered unlikely related to a drug when other drugs, chemicals or underlying disease provide plausible explanations and/or the temporal relation to the administration of the drug makes a causal relation improbable.
5. **Unrelated**: An AE, including a laboratory test abnormality assessed as CS, is considered not related to the use of a drug in case of existence of a clear alternative explanation and/or unreasonable temporal relationship, and/or non plausibility.

An AE in which the relationship is ranked 1, 2, 3 is defined as an ADR. AEs ranked 4 or 5 are not considered as ADRs.

7.3. Analysis populations

The following analysis populations will be considered in the statistical analysis:

- DLT population: All patients receiving the complete run-in dose and at least 75% of the planned SL-901 doses in Cycle 1 and completing study assessments through C2D1, or patients discontinuing Cycle 1 due to DLT irrespective of the SL-901 dose actually received.
- Safety population: all patients enrolled into the study and who received any amount of SL-901.
- Efficacy population: all patients enrolled into the study and who received any amount of SL-901 (it corresponds to the safety population).
- Per Protocol (PP) population: all patients who received at least 1 cycle of treatment, have at least 1 post-baseline efficacy assessment, and have no major protocol violations.
- PK population: all patients who receive at least one dose of SL-901 and have at least one PK sample collected and the corresponding PK concentration. .

7.4. On study and pre-study closure activities

7.4.1. Data monitoring

This study will be monitored in accordance with the ICH Guidelines for GCP.
In conjunction with the investigators, the Sponsor will constantly monitor the incoming safety data, especially TEAEs, SAEs and SUSARs to continuously assess the overall risk/benefit of the patients enrolled in this study and to take appropriate actions.
The DM review is also intended as data quality check in order to verify the consistency of the data entered and identify any possible misconduct from the site.
All monitoring activities will be described in detail in the study-specific monitoring plan.

Data Safety Review Committee

Weekly cohort review meetings and dose escalation meetings were regularly conducted during Part 1 to closely monitor the patients' safety.

7.4.2. Protocol Deviations and Data Review Meeting

Critical, Major or minor protocol deviations are defined based on the impact on the efficacy or safety of study treatments.
Before database lock, a data review meeting (DRM) will take place to identify protocol deviations. Major protocol violations will be discussed, and on a case-by-case basis it will be determined whether or not to exclude the patients from the Per Protocol population. The final decisions on which patients to include or exclude from the Per Protocol population will be finalized prior to database lock.
Categories of protocol violations will be defined and will be integrated in the statistical analysis.
Significant protocol violations that potentially compromise the data integrity and patients' safety will be summarized on the Safety Population as follows:

- The number and percentage of patients with a critical protocol deviation by cohort and overall and by type of deviation
- The number and percentage of patients with a major protocol deviation by cohort and overall and by type of deviation
- The number and percentage of patients with a minor protocol deviation by cohort and overall and by type of deviation
- A by-patient listing of all critical protocol deviations.
- A by-patient listing of all major protocol deviations.
- A by-patient listing of all minor protocol deviations.

8. Determination of sample size

No formal sample size calculation is required in this Phase 1 dose-escalation and dose expansion study. For each dosing schedule, 3 to 6 patients are to be enrolled in each dose escalation cohort in Part 1a. Up to 60 patients in total are to be enrolled in the dose escalation cohorts.

The total number of patients to be enrolled is dependent upon the observed safety profile, which will determine the number of patients per dose cohort, as well as the number of dose-escalations required to achieve the MTD.

A sample size of at least 3 patients in each cohort, expanding to 6 patients in the event of a marginal DLT rate (33%), is a conventional approach in dose-escalation studies of investigational oncologic agents.

Six to 12 patients in each expansion cohort (up to 4 cohorts) are to be enrolled in Part 1b.

9. Randomization Methodology

Not applicable.

10. Stopping Rules and Blinding

10.1. Stopping Rules

Not applicable.

10.2. Blinding

This is an open-label study; thus, study subjects and investigators will not be blinded to treatment assignment.

Unblinded safety data will be reviewed at all dose-escalation steps by the DSRC.

11. Statistical analysis and methods

11.1. Multiplicity adjustment

Not applicable.

11.2. Descriptive statistics

All study variables (with the exception of PK variables) will be presented by cohort and overall separately for each study part, using the appropriate descriptive statistics according to the variable nature, unless otherwise specified:

- **Continuous variables**: number of non-missing observations, arithmetic mean, standard deviation (SD), minimum, median, maximum;
- **Categorical variables**: number of non-missing observations and column percentages (n, %), where percentage is calculated over the relative population; when tabulating categorical data, “missing” will be included as a category and the number of subjects with missing data will be presented.
- **Time to event variables**: number of non-missing observations, number and percentage of events, number and percentage of censored observations, 1st quartile (Q1), median and its 95% Confidence Interval (CI), 3rd quartile (Q3), Kaplan-Meier survival curves.

The behaviour over time of study variables will be summarised by cohort and overall as follows:

- **Continuous variables**: descriptive statistics for each assessment time point;
- **Categorical variables**: descriptive statistics for each assessment time point.

11.3. Data imputation

Adverse Events

Completely missing AE dates (i.e., missing day, missing month and missing year) will not be imputed. Partial AE start and stop dates will be imputed according to the rules as follows in a sequential fashion.

In the imputation of missing or partial dates, if the imputed date is after min (death date, cut-off date), min (death date, cut-off date) will be used as the imputed date.

AE Stop Date

- If month and year are present, then impute as the last day of that month
- If only the year is present, impute as December 31 of that year
- If the stop date is entirely missing, assume the event is ongoing

AE Start Date

- If month and year are present, and are not equal to the month and year of the first dose, then imputed as the first day of the month
- If month and year are present, and are equal to the month and year of first dose
    - If stop date is complete and earlier than the date of first dose, then impute as the first day of the month
    - Else impute as the date of first dose
- If only the year is present, and the year is not equal to the year of the first dose, then impute as January 1 of the year
- If only the year is present, and the year is equal to the year of the first dose
    - If stop date is complete and earlier than the date of first dose, then impute as January 1 of the year
    - If stop date is partially missing and the month and year of stop date are earlier than the month and year of first dose, then impute as January 1 of the year
    - Else impute as the date of first dose
- If the start date is entirely missing
    - If the stop date is complete and earlier than the date of first dose, then impute as January 1 of the stop year
    - If the day of stop date is missing, and the month and year are earlier than the month and year of first dose, then impute as January 1 of the stop year
    - If the day and month of stop date are missing, and the year is earlier than the year of first dose, then impute as January 1 of the stop year
    - Else impute as the date of first dose

Prior and Concomitant Medications

The same imputation rules as outlined for the Adverse Events will be used for Prior and Concomitant Medications.

Post-treatment systemic anti-cancer therapy

- In case of partial start date of post-treatment systemic anti-cancer therapy, the date will be imputed as the first day of the month but not earlier than the last dose date.
- In case of completely missing start date, it will be imputed as:
  min [max(PD date + 1, last SL-901 dose date + 1), end date of new anti-cancer therapy].

Last study drug administration

The following rules should be used for the imputation of date of last SL-901 administration:

- If the date of last administration is completely missing and there is no EOT eCRF and no death date, the subject is considered as ongoing and the cut-off date should be used as the last dosing date.
- If the date of last administration is completely or partially missing and the EOT eCRF is available (prior to any death date or withdrawal of consent date, if available):
  - Case 1: The date of last administration is completely missing, and the EOT visit date is complete, then this latter date should be used.
  - Case 2: Only Year(yyyy) of the dose end date is available and yyyy < the year of EOT date: Use Dec31yyyy
  - Case 3: Only Year(yyyy) of the dose end date is available and yyyy = the year of EOT date: Use EOT date
  - Case 4: Both Year(yyyy) and Month (mm) are available for the date of last administration, and yyyy = the year of EOT date and mm < the month of EOT visit: Use the last day of the Month (mm).
  - Use min (EOT date, death date) for all other cases.

After imputation, compare the imputed date with the start date of that specific record, if the imputed date is < start date of that record: Use the start date of that record.

Tumor Assessment

Completely or partially missing Tumor Assessment (TA) dates will not be imputed.

- In case date of last TA is missing and there are no previous TA dates, then the date of first study drug admin will be used for censoring

- In case date of last TA is missing and there are previous TA dates, then the previous TA date will be used for censoring
- If there are multiple scan dates associated with an evaluation, the earliest of the scan dates associated with the evaluation will be used as the date of assessment.

Handling of PK concentrations Below the Lower Limit of Quantification and missing sampling timepoints

In all data presentations (except listings), plasma concentration values below the lower limit of quantification (BLQ) will be set to zero before the t_{max} and to "missing" after the t_{max}. Data-replacements will be implemented by the PK analyst from Clinical Pharmacology and Pharmacometrics department.
In listings, BLQ values will be reported as "BLQ".
A footnote will be added to the listing, tables, and figures, to indicate the lower limit of quantification (LOQ) value.
If more than half of the subjects in a given analyte/time point combination have values <BLQ, then the descriptive statistics will not be presented and instead displayed as BLQ for the mean and missing for all other statistics.
If actual sampling time is missing, the nominal time will be used and flagged in the listings.

11.4. Patient disposition and Baseline tables

Patient Disposition

Patient disposition will be tabulated by cohort and overall, separately for each study part, including the following:

- Number of patients screened
- Number (%) of screening failures, with reason for screening failure
- Number (%) of patients treated (i.e. who received at least one SL-901 dose)
- Number (%) of patients who are still on-treatment (based on the absence of the 'Disposition Status - Treatment Discontinuation' eCRF)
- Number (%) of patients who discontinued study treatment (based on the presence of the 'Disposition Status - Treatment Discontinuation' eCRF)
- Reason for study treatment discontinuation (based on 'Disposition Status - Treatment Discontinuation eCRF)
- Number (%) of patients in each analysis population
- Number (%) of patients who terminated the study with reason for termination (based on the 'Disposition Status - End of Study' eCRF)

Demographic and Baseline Characteristics

Demographic and baseline characteristics will be summarized by cohort and overall, separately for each study part, on the Efficacy Population using descriptive statistics; the following variables will be displayed:

- Age, sex, race, ethnicity
- ECOG PS
- Location of primary tumor, disease stage at screening, years from diagnosis (calculated as year of screening visit – year of diagnosis), disease stage at diagnosis, number and setting of previous lines of cancer treatment, best response to previous cancer treatment.
- Tumor mutation status (Part 1a and Part 1b

By-patient listings will be produced for demography, tumor history, ECOG PS and tumor mutation status.

Medical History, Procedures and Prior Radiotherapy

Medical history will be presented by cohort and overall, separately for each study part, using frequency counts and percentages on the Efficacy Population.

Medical/Procedure History are those conditions which started and ended before the date and time of first SL-901 intake; concomitant medical conditions/procedures are the ones with an end date on or after the date and time of first SL-901 intake, or still ongoing).

The following summaries will be produced by MedDRA system organ class (SOC) and preferred term (PT):

- Medical History
- Procedure History
- Concomitant Medical Conditions
- Concomitant Procedures

Summary of prior radiotherapy will include time from last therapy to first dose of study drug, site of radiotherapy, response to treatment.

Medical/Procedure history, concomitant medical conditions/procedures and prior radiotherapy will also be reported in by-patient listings.

Prior and Concomitant Medications

Prior and Concomitant Medications will be presented by cohort and overall, separately for each study part, using frequency counts and percentages on the Efficacy Population.

Prior medications are those with start and end dates prior to the date and time of first SL-901 intake; concomitant medications are those with start date on or after the date and time of first SL-901 administration; prior and concomitant medications are those with start date prior to the date and time of first SL-901 intake and end date on or after the date and time of first SL-901 intake or still ongoing.

The following summaries will be produced by WHO Drug Global Dictionary PT and Anatomical Therapeutic Chemical (ATC) code level 4:

- Prior Medications
- Prior and Concomitant Medications
- Concomitant Medications

Prior, concomitant and prior and concomitant medications will be reported in by-patient listings.

11.5. Safety analysis

Safety and toxicity will be evaluated on the Safety population by means of descriptive statistics during each study part. Safety evaluations will be based on the incidence, relationship, severity grade, and seriousness of treatment emergent adverse events (TEAEs), ECOG performance status, vital signs, ECGs, physical examination, and laboratory tests of chemistry, hematology, and coagulation parameters, as well as dose modifications (interruptions/reductions) due to TEAEs, and treatment discontinuations due to TEAEs. In addition, study drug exposure and compliance will be summarized.

11.5.1. Safety assessments

Safety and tolerability endpoints will be derived from the following measurements/evaluations:

- Incidence, grade, seriousness, and causality of TEAEs;
- Physical examination;
- Vital signs;
- Safety laboratory tests (Haematology, Serum Chemistry and Coagulation);
- 12-lead-ECG.
- ECOG PS

and will be presented by cohort and overall, separately for each study part, on the Safety population, with the exception of DLTs which will be presented on the DLT population.

11.5.2. Adverse Events

All identified AEs are recorded and described on the appropriate AE page of the eCRF, except for those events occurring prior to the start of the screening period, which are recorded on the Medical History eCRF page. All Adverse Events (including non-TEAEs or AEs happening after End of Study Visit of the patient) recorded in the eCRF will be listed.

The following definitions apply:

- An AE is considered as treatment-related if has been reported as Definitely Related, Probably Related, Possibly Related or if the relationship is missing.
- An AE is leading to drug interruption if action taken with study drug is “Drug interrupted”
- An AE is leading to drug withdrawal if action taken with study drug is “Drug withdrawn”
- An AE is leading to dose reduction if action taken with study drug is “Dose reduced”
- An AE is leading to death if the outcome of the event is “Fatal”

In all summaries, patients with more than one AE under the same SOC or PT are counted only once for that SOC or PT.
For summaries by maximum CTCAE grade, patients with multiple events under the same SOC or PT will be counted only under the category of their most severe event within that SOC or PT.
For summaries by relationship to study drug, events judged to be Definitely Related, Probably Related, Possibly Related will be considered as Treatment-related.

Excluding the general summaries of TEAEs, all other tables will report both the number of patients experiencing events and the number of events.

An overall summary of TEAEs will include the number of patients in the following categories:

- Any TEAE
- Any serious TEAE
- Any related TEAE
- Any serious related TEAE
- Any TEAE by Relationship with study drug
- Any TEAE by Outcome,
- Any TEAE by CTCAE Grade
- Any TEAE by Action Taken
- Any TEAE by Pattern

TEAEs will also be summarized by SOC and PT for the following categories:

- DLTs
- All TEAEs
- TEAEs by Maximum Grade
- TEAEs leading to drug interruption
- TEAEs leading to drug withdrawal
- TEAEs leading to dose reduction
- TEAEs leading to death
- Serious TEAEs (SAEs)
- SAEs by Maximum Grade
- Treatment-related TEAEs
- Treatment-related TEAEs by Maximum Grade
- Treatment-related TEAEs leading to drug interruption
- Treatment-related TEAEs leading to drug withdrawal
- Treatment-related TEAEs leading to dose reduction
- Treatment-related TEAEs leading to death
- Serious Treatment-related TEAEs
- Serious Treatment-related TEAEs by Maximum Grade
-

All adverse events will be listed. At minimum the following information will be reported for all AEs listings: date of onset and resolution, study cycle of occurrence, duration in days, grade and seriousness of the event, relationship to study drug, action taken with study drug.
Listings will be produced for all AEs, all TEAEs, DLTs, SAEs, Treatment-related TEAEs, Serious Treatment-related TEAEs.

11.5.3. Vital Signs

Vital signs will only be listed:

- Height (cm)
- Weight (kg)
- Body Mass Index (BMI, kg/m^2), calculated as Weight (kg) / Height (m)^2
- Heart Rate (bpm)
- Systolic Blood Pressure (mmHg)
- Diastolic Blood Pressure (mmHg)
- Respiratory Rate (breaths/min)

- Temperature (°C)

11.5.4. Physical Examination

A listing of Physical Examination results will be provided.

11.5.5. 12-lead ECG

ECG parameters will be summarized using descriptive statistics both in terms of absolute values and change from baseline at each visit and time point.
The following parameters will be presented in the summary tables:

- Heart Rate (bpm)
- PR Interval (msec)
- QRS Duration (msec)
- QT Interval (msec)
- QTcF Interval (msec)

In addition, the following categorical analysis on QTcF interval prolongation will be presented according to the ICH E14 guideline:

- Number (%) of subjects with QTcF > 450 msec and ≤480 msec
- Number (%) of subjects with QTcF > 480 msec and ≤500 msec
- Number (%) of subjects with QTcF > 500 msec
- Number (%) of subjects with QTcF change from baseline > 30 msec and ≤60 msec
- Number (%) of subjects with QTcF change from baseline > 60 msec

Overall ECG Interpretation (Normal, Abnormal NCS, Abnormal CS) will only be listed.
All ECG parameters will be listed.
Results from unscheduled visits will not be included in the summary tables but will only be listed.

11.5.6. Echocardiogram

Echocardiogram results (ejection fraction (%) and interpretation) obtained at Screening will be presented by cohort and overall, separately for each study part, using summary statistics on the Safety Population.

11.5.7. Safety laboratory tests

Laboratory parameters, including haematology, chemistry and coagulation, will be summarized using descriptive statistics both in terms of absolute values and change from baseline at each visit.

Laboratory values will be reported in SI units and will be compared to the relevant reference range in SI units and categorized as follows:

- Low: < lower limit of the reference range
- Normal: ≥ lower limit of the reference range and ≤ upper limit of the reference range
- High: > upper limit of the reference range.

Shift tables of laboratory parameters from baseline to the worst post-baseline low/normal/high categorization will be performed; in the shift tables, percentages will be calculated based on the number of subjects that have valid data for both baseline and at least 1 post-baseline assessment.

For analysis purposes, values preceded by a “<” or “>” sign will be considered equal to the lower or upper limit of quantification, respectively.
All laboratory parameters, including low/normal/high categorization, will be listed.
Results from unscheduled visits will not be included in the summary tables but will only be listed.

11.5.8. ECOG Performance Status

ECOG PS will be summarized using frequency counts and percentages at each visit.
In addition, shift tables of ECOG PS values from screening to End of Treatment visit will be presented.
All ECOG PS values will also be listed.
Results from unscheduled visits will not be included in the summary tables but will only be listed.

11.5.9. Reproductive System Findings and Pregnancy Test

Reproductive system findings (child-bearing potential, postmenopausal status, surgical sterilization) as well as pregnancy test results (positive/negative) at each study visit will only be listed.

11.5.10. Treatment exposure and compliance

The following parameters will be summarized using descriptive statistics:

- Cumulative dose (mg) is the sum of the number of capsules taken at each occasion multiplied by the strength of each capsule.
- Treatment duration from first intake (days) is calculated as (Last dose date – First dose date in run-in period + 1).
- Treatment duration from Cycle 1 Day 1 (days) is calculated as (Last dose date – First dose date in Cycle 1 Day 1 + 1).
- Actual Dose Intensity (mg/day) = [cumulative dose (mg)] / [treatment duration from first intake (days)]
- Planned Dose Intensity (mg/day) = Total daily dose for the cohort (see Table 1).
- Relative Dose Intensity (%) = [actual dose intensity (mg/day)] / [planned dose intensity (mg/day)]

Study treatment administration at the site and study drug accountability as collected in the eCRF, as well as the daily records from the patient diary will be listed.

12. Efficacy evaluations

Efficacy evaluations are based upon the Investigator's assessment.
Tumor assessment will occur at Screening (for identification of baseline disease) and after every 2 cycles of treatment thereafter. Response will be evaluated using Response Evaluation Criteria in Solid Tumors (RECIST) v1.1.
After completion of the EOT visit, patients will then be followed every 90 days for survival status for 12 months. The survival follow-up may be by telephone contact. If the patient discontinued study drug for reasons other than progressive disease, disease assessments should continue to be performed on an every 8-week basis (±1 week) through 6 months after the first study drug dose and then on an every 90-day basis or until, in the judgment of the Investigator, there is evidence of relapsed or progressive disease.

12.1. Efficacy analysis

12.1.1. Best Overall Response and Objective Response

Best overall response (BOR) will be assessed based on reported overall lesion responses at different evaluation time points from the first dose of SL-901 until the first documentation of PD, according to the following hierarchical rules.

- CR = at least two determinations of CR at least 4 weeks apart and before first documentation of PD
- PR = at least two determinations of PR or better (PR followed by PR or PR followed by CR) at least 4 weeks apart and before first documentation of PD (and not qualifying for a CR)
- SD (applicable only to patients with measurable disease at baseline) or Non-CR/non-PD (applicable only to patients with non-measurable disease at baseline) = at least one SD (or non-CR/non-PD) assessment (or better) ≥ 6 weeks after the first dose of SL-901 and before first documentation of PD (and not qualifying for CR or PR).
- SD = unconfirmed CR/PR (i.e. one determination of CR or PR followed by PD or NE) occurring at least 6 weeks after the first dose of SL-901
- PD = at least one documentation of PD (and not qualifying for CR, PR, SD or non-CR/non-PD).
- NE = all other cases.

Objective Response (OR) is defined as confirmed BOR of CR or PR according to RECIST v1.1.
Each patient will have an objective response status (0: no OR; 1: OR).
OR rate (ORR) is the proportion of patients with OR in the relevant analysis set.
Disease Control (DC) is defined as BOR of CR, PR, non-CR/non-PD or SD.
DC rate (DCR) is the proportion of patients with DC in the relevant analysis set.
CR rate (CRR) is the proportion of patients with a confirmed BOR of CR in the relevant analysis set.

ORR, DCR and CRR by cohort and overall will be calculated along with the 2-sided 95% CI using the Clopper-Pearson method (exact CI for a binomial proportion as computed by default by the FREQ procedure using the EXACT option).
In addition, the number and percentage of patients with BOR of CR, PR, SD, non-CR/non-PD (applicable only to patients with non-measurable disease at baseline), PD, and NE will be tabulated.
These analyses will be presented by cohort both in the Efficacy and in the Per Protocol populations.

All data related to target lesions, non-target lesions, new lesions and response assessment will be listed.

12.1.2. Duration of Response

Duration of response (DOR) is defined, for patients with OR, as the time (in months) from the first documentation of objective response (CR or PR) to the date of first documentation of PD.
Duration of Complete Response (DOCR) is defined, for patients with a confirmed BOR of CR, as the time from the first documentation of CR to the date of first documentation of PD.

DOR and DOCR will be calculated as follows:

DOR (months) = [date of event or censoring– first date of OR +1]/30.4375
DOCR (months) = [date of event or censoring– first date of CR +1]/30.4375

DOR and DOCR will be censored at the last tumor assessment if the patient did not have disease progression. If a patient receives a new systemic anti-cancer therapy before disease progression, DOR and DOCR will be censored at the last tumor assessment before the date of initiation of new systemic anti-cancer therapy. In addition, patients who experience PD after ≥2 missing tumor assessments will be censored at the last tumor assessments prior to the missed visits.

DOR and DOCR will be analyzed by cohort using the Kaplan-Meier method, with the median, 25th and 75th percentiles as well as DOR and DOCR rates at 3, 6 and 12 months (and every 6 months thereafter until the end of follow-up or no more subjects are at risk) reported along with the 2-sided 95% CIs calculated according to Brookmeyer and Crowley using a linear transformation (CONFTYPE=LINEAR in SAS Proc LIFETEST). Number and percentage of patients with event (PD) and censoring reasons will be presented by cohort.
DOR and DOCR will be displayed graphically using Kaplan-Meier curves.
These analyses will be presented by cohort both in the Efficacy and in the Per Protocol populations.

12.1.3. Progression-free survival

Progression-free survival (PFS) is defined as the time (in months) from the date of first intake of SL-901 to the date of the first documentation of PD (per RECIST v1.1) or death due to any cause, whichever occurs first, regardless of whether the patients withdraws from study treatment.

[redacted]

PFS will be analyzed by cohort and overall using the Kaplan-Meier method, with the median, 25th and 75th percentiles as well as PFS rates at 3, 6 and 12 months (and every 6 months thereafter until the end of follow-up or no more subjects are at risk) reported along with the 2-sided 95% CIs calculated according to Brookmeyer and Crowley using a linear transformation (CONFTYPE=LINEAR in SAS Proc LIFETEST). Number and percentage of patients with each event type (PD or death) and censoring reasons will be presented by cohort.
PFS will be displayed graphically using Kaplan-Meier curves.
These analyses will be presented by cohort both in the Efficacy and in the Per Protocol populations.

12.1.4. Overall Survival

Overall survival (OS) is defined as the time from the date of first SL-901 intake to the date of death due to any cause, regardless of whether the patient withdraws from study treatment or receives another anticancer therapy.

OS (months) = [date of death or censoring– date of first SL-901 intake +1]/30.4375

Patients not known to have died at the time of analysis will be censored at the last recorded date on which the subject was known to be alive, based on the data collected in the “Long Term Follow-up” eCRF.

OS will be analyzed by cohort and overall using the Kaplan-Meier method, with the median, 25th and 75th percentiles as well as OS rates at 12, 18 and 24 months (and every 6 months thereafter until the end of follow-up or no more subjects are at risk) reported along with the 2-sided 95% CIs calculated according to Brookmeyer and Crowley using a linear transformation (CONFTYPE=LINEAR in SAS Proc LIFETEST). Number and percentage of patients with event (death) and censored will be presented by cohort and overall.

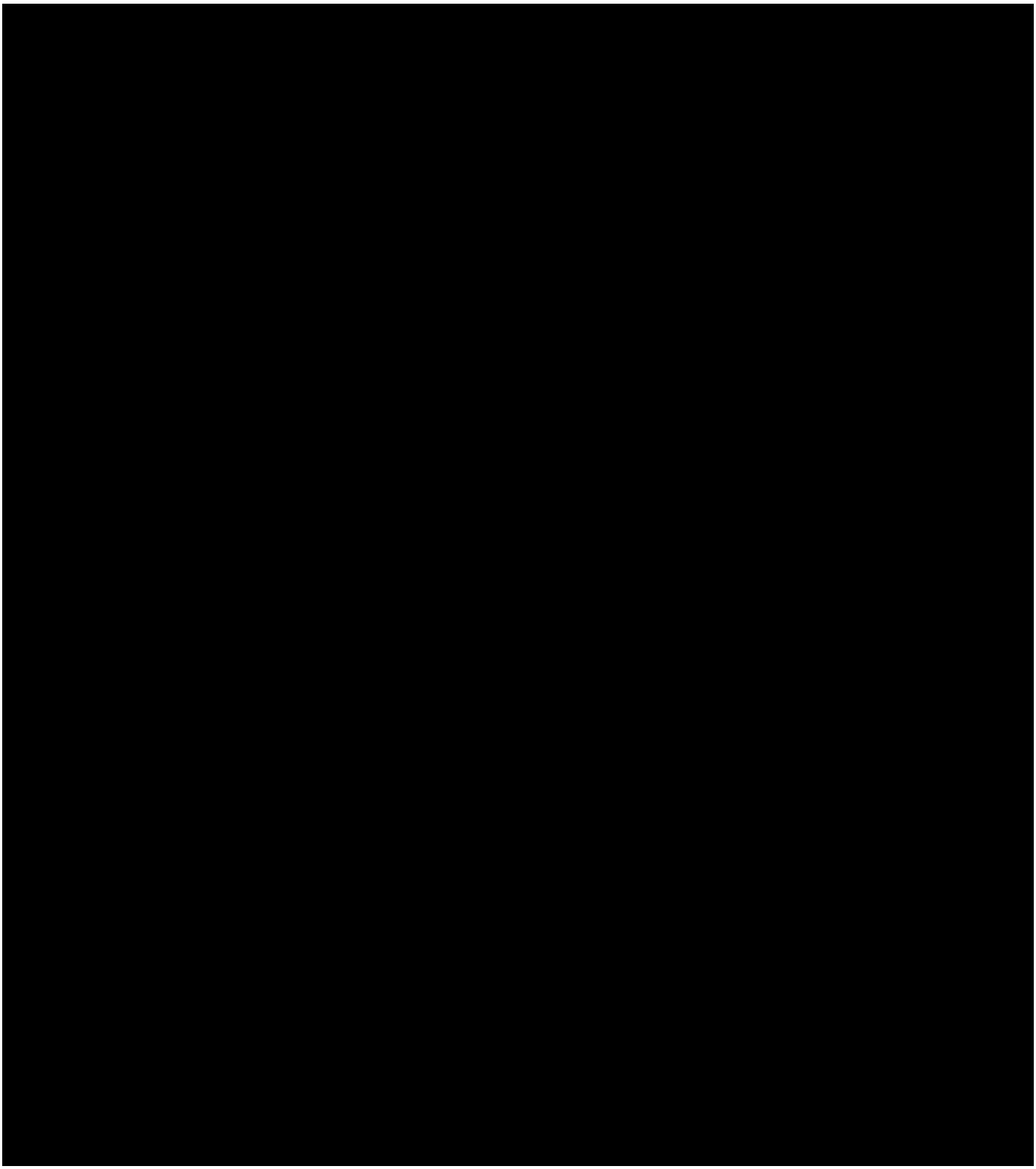
OS will be displayed graphically using Kaplan-Meier curves.

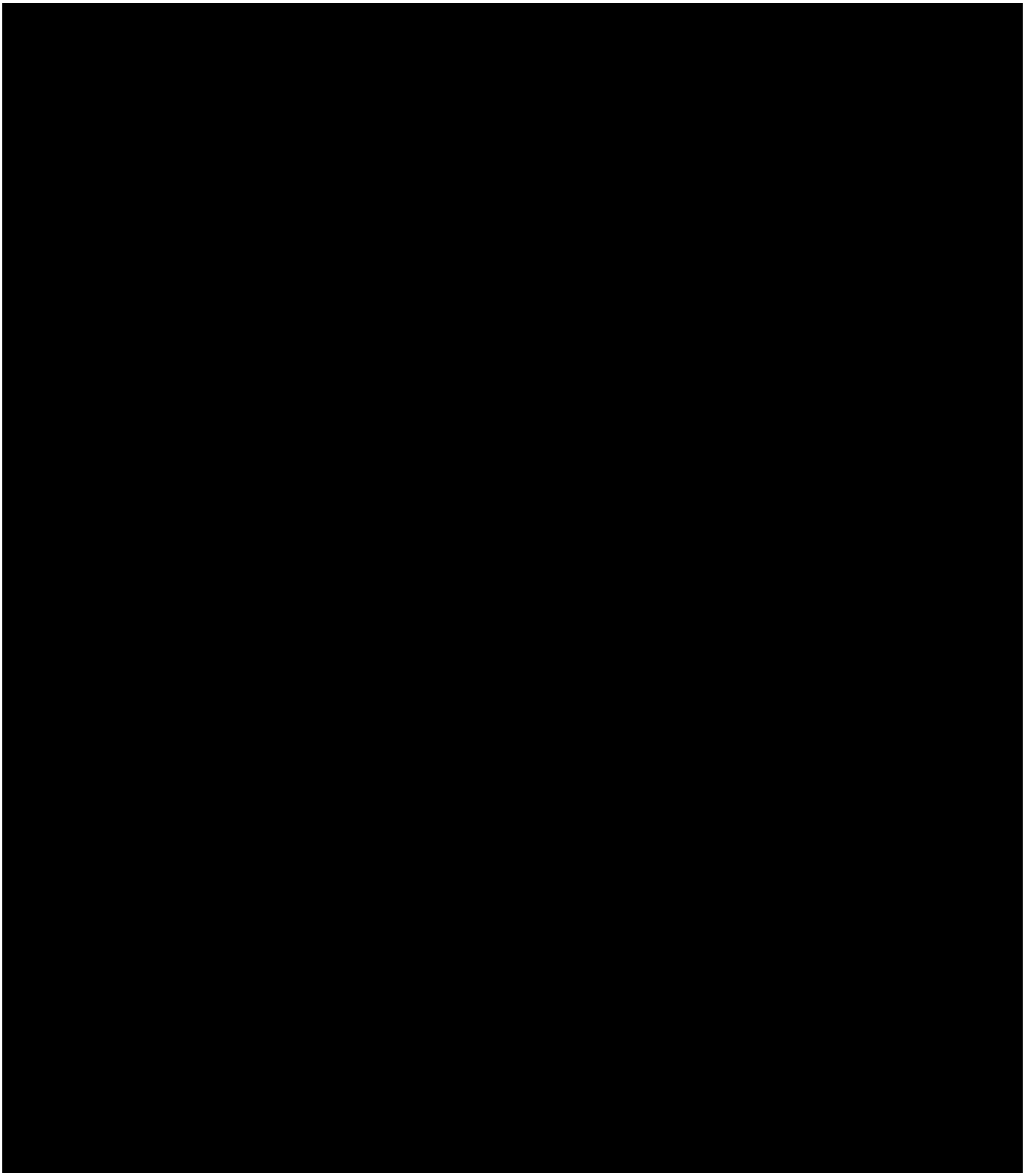
These analyses will be presented by cohort both in the Efficacy and in the Per Protocol populations.

12.2. Subgroup analyses

Not Applicable.

12.3. Pharmacokinetic analysis





13. Tables, listings and figures

13.1. Statistical Analysis Report

The TLF (Tables, Listings and Figures) will follow the list of tables, plots, and listings agreed with the Study Team.

13.2. Index of TLFs

13.2.1. Tables

13.2.2. Listings

Listing 16.2.9.3: PD Sampling

13.2.3. Figures

Figure 14.2.3: Kaplan-Meier Plot of Duration of Response – Investigator's assessment (RECIST v1.1)
Figure 14.2.5: Kaplan-Meier Plot of Duration of Complete Response – Investigator's assessment (RECIST v1.1)
Figure 14.2.7: Kaplan-Meier Plot of Progression-free Survival – Investigator's assessment (RECIST v1.1)
Figure 14.2.9: Kaplan-Meier Plot of Overall Survival – Investigator's assessment (RECIST v1.1)
Figure 14.4.2: SL-901 Individual Steady-State Plasma Concentration-time Curves – Linear Scale
Figure 14.4.3: SL-901 Individual Steady-State Plasma Concentration-time Curves – Semi-Log Scale
Figure 14.4.4: SL-901 Mean (±SD) Plasma Concentration-time Curves – Run-In – Linear Scale
Figure 14.4.5: SL-901 Mean (±SD) Plasma Concentration-time Curves – Cycle 1 Day 15 – Linear Scale
Figure 14.4.6: SL-901 Mean (±SD) Plasma Concentration-time Curves – Run-In - Semi-Log Scale
Figure 14.4.7: SL-901 Mean (±SD) Plasma Concentration-time Curves – Cycle 1 Day 15 - Semi-Log Scale