



Statistical Analysis Plan

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Sponsor Name: Kangpu Biopharmaceuticals, Ltd

Protocol Number: KPG-818-SLE

Protocol Title: A Phase 1b/2a Multicenter Study to Assess the Safety and Tolerability, Pharmacokinetics, and Preliminary Efficacy of KPG-818 in Patients with Systemic Lupus Erythematosus

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I confirm that I have reviewed this document and agree with the content.

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1. Glossary of Abbreviations

Abbreviation	Description
ACR	American College of Rheumatology
AE	Adverse Event
ADR	Adverse Drug Reaction
ATC	Anatomical Therapeutic Chemical
BLQ	Below the Limit of Quantitation
BMI	Body Mass Index
CI	Confidence Interval
CLASI	Cutaneous Lupus Erythematosus Disease Area and Severity Index
CRF	Case Report Form
CRO	Contract Research Organization
CTCAE	Common Terminology Criteria for Adverse Events
ECG	Electrocardiogram
ET	Early Termination
EULAR	European League against Rheumatism
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IDMC	Independent Data Monitoring Committee
IMP	Investigational Medicinal Product
IRB	Institutional Review Board
MAD	Multiple-Ascending Dose
Max	Maximum
MedDRA	Medical Dictionary for Regulatory Activities
Min	Minimum
MRT	Mean Retention Time
MTD	Maximum Tolerated Dose

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Abbreviation	Description
N/A	Not Applicable
NA	Not Applicable
NSAID	Non-steroidal Anti-inflammatory Drug
OR	Observational Research
OSC	Oral Corticosteroids
PD	Pharmacodynamics
PGA	Physician Global Assessment
PK	Pharmacokinetics
PT	Preferred Term
QC	Quality Control
QTc	Corrected QT Interval
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SLE	Systemic Lupus Erythematosus
SLEDAI-2K	Systemic Lupus Erythematosus Disease Activity Index 2000
SOC	System Organ Class
SOP	Standard Operating Procedure
SRC	Safety Review Committee
TEAE	Treatment-Emergent Adverse Event
TFL	Table, Figure and Listing
TMF	Trial Master File
ULN	Upper Limit of Distribution
WHO	World Health Organization
WOCBP	Women of Childbearing Potential

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2. Purpose

The purpose of this statistical analysis plan (SAP) is to ensure that the data listings, summary tables and figures which will be produced, and the statistical methodologies which will be used, are complete and appropriate to allow valid conclusions regarding the study objectives. This SAP will be developed and finalized prior to database lock.

2.1. Responsibilities

Syneos Health will perform the statistical analyses and is responsible for the production and quality control of all tables, figures and listings. All PD biomarkers will be provided to sponsor directly. PD analysis will be carried out by sponsor or designee.

2.2. Timings of Analyses

The primary analysis of safety and efficacy is planned after all subjects complete the final study visit or terminate early from the study. Unless otherwise specified, the analysis includes all data collected in the database through the time of the database lock.

No independent data monitoring committee (IDMC) will be established in Phase 1b of the study. However, an Safety Review Committee (SRC) will be established to monitor safety and PK data on an ongoing basis. During scheduled meetings, the SRC will review relevant study data for safety or benefit-risk concern.

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3. Study Objectives

3.1. Phase 1b

Primary Objectives:

- To assess the safety and tolerability of multiple oral doses of KPG-818 in patients with systemic lupus erythematosus (SLE) over a 14-day treatment period.
- To characterize the single and multiple oral dose pharmacokinetics (PK) of KPG-818 and its metabolite, KPG-818H.

Exploratory Objectives:

- To evaluate the pharmacodynamics (PD) markers of KPG-818.

3.2. Phase 2a

Primary Objective:

- To assess the safety and tolerability of multiple oral doses of KPG-818 in patients with SLE over a treatment period of 12 weeks and a follow-up period of 4 weeks.

Secondary Objectives:

- To evaluate the preliminary efficacy of KPG-818 compared with placebo in adult patients with active SLE on limited background standard-of-care treatment over a treatment period of 12 weeks and a follow up period of 4 weeks.
- To characterize the multiple oral dose PK of KPG-818 and its metabolite, KPG-818H, over a 12-week treatment period.
- To select dosing regimens for Phase 2b study

Exploratory Objectives:

- To further explore the efficacy of KPG-818.
- To evaluate the PD markers of KPG-818.

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4. Study Design

4.1. Brief Description

This is a Phase 1b/2a multicenter study to evaluate the safety, PK, PD, and clinical efficacy of KPG-818 in patients with SLE. The trial will consist of 2 parts: Phase 1b, a multiple-ascending dose (MAD) study; and Phase 2a a proof of concept (POC) study.

Eligible patients must have a confirmed diagnosis of SLE according to 2019 European League against Rheumatism (EULAR)/American College of Rheumatology (ACR) Classification criteria for SLE.

Phase 1b

The Phase 1b part of the study is an open-label, multicenter, and multiple-dose escalation cohort study. A total of approximately 24 patients will be enrolled into 4 dosing cohorts and receive KPG-818 in an open-label fashion. KPG-818 will be taken orally in the morning approximately every 24 hours for 14 days (up to 14 doses). The total duration of the study is approximately 10 weeks, consisting of 3 periods:

- Screening period: up to 42 days (6 weeks)
- Treatment period: up to 14 days (2 weeks)
- Safety follow-up period: up to 14 days (2 weeks) after the last dose of study treatment

There are 4 dosing cohorts, Cohort A (0.15 mg/day), B (0.6 mg/day), C (2 mg/day), and D (5 mg/day), planned for Phase 1b part of the study. Each cohort will enroll 6 patients to ensure at least 4 evaluable patients to provide an adequate PK profile and safety assessment. The evaluable patient is defined as any patient who completes 14-day treatment and provides blood samples for PK analyses at Day 14.

For Phase 1b part of the study, it is allowed to add additional dose cohorts following review of the safety, tolerability, and PK data by the SRC. The requirement for additional cohorts will be agreed with the Sponsor, documented in the Trial Master File (TMF), and the Institutional Review Board (IRB) will be notified of the changes.

Phase 2a

Phase 2a is planned to be initiated after the completion of Cohort D in Phase 1b, subject to sponsor decision based on the SRC recommendation after a comprehensive review of cumulative safety, PK/PD, and biomarker data.

The Phase 2a part of the study is a randomized, double-blinded, placebo-controlled, and parallel group study in patients with active SLE on limited stable background standard-of-care treatment.

The Phase 2a part of the study consists of 3 periods:

- Screening period: up to 28 days (4 weeks)
- Treatment period: up to 12 weeks
- Safety follow-up period: up to 4 weeks post last dose of study drug

A total of approximately 32 to 48 patients will be randomized (in 1:1:1:1 ratio) to 4 treatment arms. There will be 8 to 12 patients in each arm, with each receiving one of three treatments or placebo: KPG-818 0.15 mg (Treatment Arm E), 0.6 mg (Treatment Arm F), 2 mg (Treatment Arm G), or placebo (Treatment Arm H). KPG-818 or placebo will be taken orally in the morning approximately every 24 hours for 12 weeks.

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The study design for Phase 2a, including the number of treatment arms and dosing regimen, is subject to the SRC's evaluation of the PK, safety, and tolerability data from the Phase 1b part of the study. The total daily dose administered of each Phase 2a arm will not exceed the highest total daily dose shown to be safe and well tolerated in Phase 1b.

The start of the study is defined as the date the first patient signs the informed consent form (ICF). The end of the study is defined as the date of the last patient's last assessment (scheduled or unscheduled).

4.2. Subject Selection

Male and female patients with a diagnosis of SLE will be included in this study.

4.2.1. Inclusion Criteria

Patients for Phase 1b and Phase 2a must satisfy all of the following criteria:

1. Male or female of 18 years of age or older at the time of signing the ICF.
2. Body mass index (BMI) between 18 and 40 kg/m².
3. Able and willing to adhere to the visit schedule and other protocol requirements.
4. Diagnosed with SLE according to the 2019 EULAR/ACR criteria for SLE (See Appendix 1 in protocol).
5. Meeting SLE activity requirements as described below:
 - For the Phase 1b part of the study, patients with or without active SLE may be enrolled if, in the opinion of the Investigator, the disease activity is stable and there will be no need for change or increase in SLE therapy anticipated for the study duration. If patients are on stable standard care of SLE treatment, this should comply with inclusion criteria No.11.
 - For the Phase 2a part of the study, patients must have a Systemic Lupus Erythematosus Disease Activity Index (SLEDAI-2K) score of ≥ 6 points at Screening visit with a SLEDAI-2K clinical score ≥ 4 points at Baseline visit. The "clinical" score is the SLEDAI-2K assessment score without the inclusion of points attributable to any urine or blood laboratory results including immunologic measures. Neurologic descriptors of the SLEDAI-2K are not counted towards the SLEDAI study entry criteria. In addition, the patient must be on stable standard care of SLE treatment with at least one of the followings: OCS, anti-malarial, or immunosuppressant (see inclusion criteria No. 11 for allowed medications and doses).
6. Documented history or presence at Screening of positive autoantibodies associated with SLE, which must include at least 1 of the following:
 - Positive antinuclear antibody (ANA) test with a titer of 1:80 or greater.
 - Anti-dsDNA antibodies elevated to above normal.
 - Anti-Smith antibody elevated to above normal.
7. Women of childbearing potential (WOCBP) must:
 - Have 2 negative serum pregnancy tests as verified by the Investigator prior to starting study therapy, 1 at Screening and again within 3 days before taking the first dose of KPG-818, then have a negative urine pregnancy test at Baseline before dosing. WOCBP must agree to ongoing pregnancy testing during the course of the study, and after end of study treatment. This applies even if the patient practices true abstinence from heterosexual contact.
 - Either commit to true abstinence from heterosexual contact (which must be reviewed on a monthly basis and source documented) or agree to use 2 forms of reliable contraception simultaneously. One must be a highly effective method and 1 additional effective (barrier) method

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(see Appendix 5 in protocol for more details), and both must be practiced without interruption, at least 28 days before starting investigational medicinal product (IMP), during the study therapy (including dose interruptions), and for 28 days after discontinuation of study therapy.

8. Male patients must: Practice true abstinence or agree to use a barrier contraception (male latex condom or non-latex condom NOT made out of natural [animal] membrane [for example, polyurethane]) during sexual contact with a WOCBP while participating in the study, and for at least 90 days following IMP discontinuation, even if he has undergone a successful vasectomy. Male patients must agree not to donate semen or sperm during the treatment period and for at least 90 days following the discontinuation of KPG-818.

9. Female patients who are postmenopausal must demonstrate a follicle stimulating hormone (FSH) blood levels of equal to or greater than 40 mIU/mL at the Screening visit. Women aged > 60 years old whose FSH values are not equal to or greater than 40 mIU/mL may be included at the discretion of the Investigator and in consultation with the Sponsor (see Appendix 5 in protocol for more details).

10. All patients must:

- Understand that KPG-818 could have potential teratogenic risk.
- Agree not to share KPG-818 with another person.
- Be counseled about pregnancy precautions and risks of fetal exposure as described in the Pregnancy Prevention Plan.

11. In Phase 2a part of the study, the patient must be on stable standard care of SLE treatment with at least one of the followings: oral corticosteroid, anti-malarial, or immunosuppressant:

- a. If taking OCS, must be on-treatment for ≥ 4 weeks before the Screening visit, and maintained on a stable dose of ≤ 20 mg/day of prednisone or equivalent for at least 4 weeks before the Baseline visit.
- b. If taking an anti-malarial agent (hydroxychloroquine, chloroquine, or quinacrine), must be on-treatment for ≥ 8 weeks before the Screening visit and be on a stable dose for ≥ 4 weeks before the Screening visit. Anti-malarials at the following doses are allowed:
 - Hydroxychloroquine (≤ 400 mg/day)
 - Chloroquine (≤ 500 mg/day)
 - Quinacrine (≤ 200 mg/day)
- c. If taking allowed immunosuppressants, must be on-treatment for ≥ 8 weeks prior to the Screening visit and be on a stable dose for ≥ 4 weeks before the Screening visit. Only 1 of the immunosuppressants below is allowed at the indicated doses:
 - Micophenolate mofetil (≤ 2 g/day) or mycophenolic acid (≤ 1.44 g/day)
 - Azathioprine (≤ 200 mg/day)
 - Methotrexate (≤ 20 mg/week)
 - Leflunomide (≤ 20 mg/day)
- d. If taking NSAIDs or other regularly administered analgesics, these will be allowed if treatment started ≥ 4 weeks before the Baseline visit and dosing has not been changed within the last 2 weeks before the Baseline visit.
- e. If immunosuppressants, anti-malarial, or OCS is discontinued, the last dose must be more than 4 weeks prior to Screening visit.

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12. Patients must agree not to donate blood (or any component of blood) from 3 months before Screening until 3 months after the last dose of KPG-818.

13. Patients must be willing to comply with precautions to reduce the risk of COVID-19 infection in accordance with recommendations from the applicable medical associations and the investigator for the duration of the study and to undergo COVID-19 polymerase chain reaction (PCR) test as required based on the Investigator judgment and/or local requirements.

4.2.2. Exclusion Criteria

Patients will be excluded from the study if they satisfy any of the following criteria:

1. Use of any prohibited medications within the pre-specified time (refer to Appendix 6 in protocol for details on the required washout period for each drug class).
2. Any of the following noted at Screening (within 6 weeks before Week 1 [Day 1] in Phase 1b, within 4 weeks before Week 1 [Day 1] in Phase 2a):
 - Aspartate aminotransferase (AST) $> 2.0 \times$ upper limit of normal (ULN)
 - Alanine aminotransferase (ALT) $> 2.0 \times$ ULN
 - Total bilirubin $> 1.5 \times$ ULN (unless due to Gilbert's syndrome)
 - Serum creatinine > 2.5 mg/dL (or > 221 μ mol/L)
 - Neutrophil count $< 1500/\mu$ L (or $< 1.5 \times 10^9/L$) ($< 1000/\mu$ L [or $< 1.0 \times 10^9/L$] if the neutropenia is related to SLE)
 - Platelet count $< 50\,000/\mu$ L (or $< 50 \times 10^9/L$) ($< 25\,000/\mu$ L [or $< 25 \times 10^9/L$] if the thrombocytopenia is related to SLE)
 - Hemoglobin < 8 g/dL (or < 80 g/L) (< 7 g/dL [or < 70 g/L] if related to SLE)
3. Have an estimated glomerular filtration rate (eGFR) of < 60 mL/min/1.73 m² (CKD-EPI formula) at Screening.
4. Have a spot urine protein to creatinine ratio (sUPCR) > 2000 mg/g (226 mg/mmol, as an estimate of approximate proteinuria > 2 g/day) at Screening.
5. Active and/or unstable neuropsychiatric SLE (e.g., neuropsychiatric SLE including seizures, psychosis, acute confusional state, cerebrovascular accident, aseptic meningitis, or polyneuropathy).
6. Positive serology test for hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficiency virus (HIV-1 and HIV-2) at Screening. In cases of a positive screening test, patient may be enrolled if a confirmatory test is negative (see Appendix 3 in protocol for details). Exception: patient who test positive for HCV antibodies may be enrolled if confirmed with cured HCV infection and documented completion of treatment more than 3 months before screening and HCV must not be detectable at screening.
7. Active or history of severe systemic bacterial, viral, fungal, mycobacterial, or parasitic infections (requires hospitalizations or IV antibiotics) within 6 months prior to Screening.
8. Any current or recent (within 4 weeks of Screening) signs or symptoms of infection, except for fungal infections of the nail beds, oral or vaginal candidiasis that has resolved, or minor infections (e.g., common cold, viral gastroenteritis, urinary tract infection) that have in the Investigator's judgment, completely resolved prior to the Baseline visit.

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9. Any severe, recurrent, disseminated viral infections, particularly herpes viruses such as HSV-1, HSV-2, VZV, CMV (e.g., herpes encephalitis, ophthalmic herpes, disseminated zoster, CMV colitis) per Investigator's judgment. Recurrent is defined as 2 or more episodes in the past 2 years and/or with an episode within 3 months of Screening.
10. Known history of congenital or acquired immunodeficiency, splenectomy, or any underlying condition that predisposes the patient to infection.
11. Active tuberculosis (TB) or a history of incompletely treated TB, or a positive, QuantiFERON®-TB Gold test. If a patient's initial TB test result is indeterminate, the test can be repeated once. If the test result is again indeterminate (or positive), the patient will be excluded from the study. An exception for positive or indeterminate results may be made for patients who have documentation of having completed appropriate standard treatment for latent TB before screening and do not have other risk factors, radiologic findings, or physical evidence supporting latent or active TB.
12. History of malignancy within 5 years of Screening with the exception of basal cell or squamous cell in situ skin carcinomas or carcinoma in situ of the cervix that has been treated with no evidence of recurrence.
13. History of antiphospholipid syndrome with thromboembolic event within 12 months of screening or not on an adequate anticoagulation regimen. However, presence of antiphospholipid antibodies alone (without a history of thromboembolic event) is not exclusionary.
14. Other non-SLE driven inflammatory joint or skin disease, mixed connective tissue disease, scleroderma, and/or overlap syndromes. An exception may be allowed for rheumatoid arthritis overlapping with SLE (i.e., RHUPUS) with no erosive joint disease after a discussion with the medical monitor. Patients with SLE and secondary Sjogren syndrome are not exclusionary.
15. Clinically significant or unstable or uncontrolled acute or chronic disease not related to SLE that in the Investigator's opinion would preclude patient participation.
16. Concomitant condition (such as asthma) that required systemic corticosteroid use within 1 year before Screening. Use of inhaled corticosteroid is not exclusionary.
17. History of alcohol or drug abuse within 1 year before screening based on the Investigator's judgement.
18. Have a positive urine drug test at screening (see Appendix 3 in protocol) except if the patient has a valid prescription for an allowed concomitant medication or substance abuse/dependence has been ruled out in the Investigator's judgment.
19. History of major surgery within 12 weeks prior to Screening or any planned major surgery during the study.
20. Clinically significant ECG abnormalities or have a QTc interval value > 480 ms at Screening, in the Investigator's opinion would preclude patient participation.
21. Pregnant or breast-feeding female.
22. Signs or symptoms that in the opinion of the Investigator may be suggestive of COVID-19 infection. The patient may be allowed to enter the study if a COVID-19 PCR test performed during the Screening results in a negative outcome.
23. Known allergic reaction to any of the ingredients for study drug or placebo.

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4.2.3. Patient Withdrawal and Replacement

A patient is free to withdraw from the study at any time without providing reason (s) for withdrawal and without prejudice to further treatment. In addition, a patient may be withdrawn if any of the following criteria are met:

- AE/SAE
- Protocol deviation
- Lost to follow up
- Pregnancy
- Decision by Investigator
- Decision by Sponsor

If a patient is withdrawn, the Sponsor will be notified and the date and reason (s) for the withdrawal will be documented in the patient's electronic Case Report Form (eCRF). If a patient is withdrawn, efforts will be made to perform all follow-up assessments, if possible. Other procedures may be performed at the Investigator's (or designee's) and/or Sponsor's discretion. The Investigator (or designee) may also request that the patient return for an additional Follow-up visit. All withdrawn patients will be followed until resolution of all their AEs or until the unresolved AEs are judged by the Investigator (or designee) to have stabilized.

Patients who are withdrawn for reasons not related to study treatment may be replaced following discussion between the Investigator and the Sponsor. Replacement for patients withdrawn as a result of AEs thought to be related to the study treatment will be decided by the SRC.

4.3. Determination of Sample Size

Phase 1b: Approximately 24 patients with SLE will be enrolled in 4 cohorts with 4 proposed dose levels of 0.15, 0.6, 2, and 5 mg/day. Each cohort will enroll 6 patients to ensure at least 4 evaluable patients to provide an adequate PK profile and safety assessment.

Phase 2a: Approximately 32 to 48 patients with SLE will be randomized 1:1:1:1 into 3 treatment arms of 3 proposed dose levels (0.15, 0.6, and 2 mg/day) and 1 placebo arm. The dose levels in the 3 KPG-818 treatment groups will be finalized when the last cohort in Phase 1b of the study is completed.

No formal statistical assessment, in terms of sample size, has been conducted. However, the number of patients in each part of the present study is common in early clinical pharmacology studies and is considered sufficient to achieve the objectives of the study.

4.4. Randomization and Blinding Procedures

4.4.1. Randomization

The Phase 1b part of the study is open-label.

Randomization to placebo/KPG-818 will be performed in Phase 2a using an interactive voice/web response system (IXRS) randomization service. Subjects will be randomized (in 1:1:1:1 ratio) in 4 treatment arms with 8 patients each to receive KPG-818 0.15 mg (Treatment Arm E), 0.6 mg (Treatment Arm F), 2 mg (Treatment Arm G), or placebo (Treatment Arm H).

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The automated Interactive Web Response System (IWRS) will provide the site with the specific medication kit number(s) to use for each qualified patient at the baseline/randomization visit. A randomization number will be assigned to each patient corresponding to the cohort they are assigned to. The numbers will be assigned sequentially. The IWRS system will report a medication kit number to use for each patient corresponding to the randomization number. Before the start of the study, the live randomization scheme will be distributed to patients according to the randomization specification form. The detailed information will be described in the randomization materials specifications.

4.4.2. Blinding

The Phase 1b part is open-label therefore no procedures for blinding are applicable.

The following controls will be employed to maintain the double-blind status of the Phase 2a part:

- The placebo capsules will be identical in appearance to the KPG-818 capsules.
- The Investigator and other members of staff involved in the study will remain blinded to the treatment randomization code during the assembly procedure.
- IMP will be packaged in a blinded manner and assigned by an IXRS using a randomization scheme.
- Identical number of capsules will be taken daily for each arm.
- Lab results or other data that could be unblinding will not be able to be viewed or presented to the blinded investigator, CRO or Sponsor teams.
- IMP assigned by the IXRS will be dispensed, logged and accounted for on Day 1, Day 28, and Day 56 of treatment, and final accountability will be completed at end of treatment. Each arm will receive the same number of bottles in each kits when IP is dispensed per assignment by IXRS.

In case of an emergency, in order to manage patient safety, the decision to unblind resides with the Investigator in consultation with the Medical Monitor and Sponsor. Participant safety must always be the first consideration in making such a determination. If the investigator decides that unblinding is warranted, the investigator should make every effort to contact the Medical Monitor and/ or sponsor prior to unblinding a participant's treatment assignment unless this could delay further management of the participant. The Investigator should discuss breaking the blind in IXRS with the Medical Monitor and Sponsor. If it becomes necessary to break the blind in IXRS during the study, the date, time, and reason will be recorded in the patient's source data and completed in IXRS by the PI or Sub investigator.

The master randomization schedule will be saved in an access-controlled location on the Syneos Health server to maintain the study blind until such time as the study is unblinded or after the database lock.

4.5. Administration of Study Medication

Investigational Medicinal Products

Proposed dose levels for Phase 1b: Cohort A (0.15 mg/day), B (0.6 mg/day), C (2 mg/day), and D (5 mg/day).

Proposed dose levels for Phase 2a: Treatment Arm E (0.15 mg/day), F (0.6 mg/day), G (2 mg/day) and H (placebo).

Administration route: KPG-818 capsules will be administered orally approximately every 24 hours with approximately 240 mL of water in the morning at similar time, with or without food.

Study drug administration should occur at the study site on the below dates so that PK samples can be collected:

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Phase 1b: Days 1, 7, 8, and 14.

Phase 2a: Days 1, 2, 12, 13, 14, 15

Study drug administration may be withheld in case of suspicion of current COVID-19 infection based on the Investigator's clinical judgment.

Reference Product

Administration route: Capsules will be administered orally approximately every 24 hours with approximately 240 mL of water in the morning at similar time, with or without food.

4.6. Study Procedures and Flowchart

The Schedule of Assessment tables in the study protocol provide an overview of the protocol visits and procedures. Refer to the Study Assessments and Procedures section of the protocol for detailed information on each procedure and assessment required for compliance with the protocol.

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5. Endpoints

5.1. Phase 1b

Primary Endpoints:

- Incidence and severity of AEs and serious AEs (SAEs), related AEs, AEs leading to study drug discontinuation, AEs by severity and relatedness.
- 12-lead ECGs parameter results at each visit and changes from baseline.
- Vital signs (blood pressure [BP], heart rate, and temperature) parameter results at each visit and changes from baseline.
- Clinical laboratory results and changes from baseline.
- Physical examinations changes from baseline.
- Study drug exposure/compliance.
- The PK endpoints for assessment of KPG-818 and KPG-818H (if applicable).

After the plasma concentration reaches a steady state (most likely Day 5), the PK parameters to be assessed include but are not limited to:

- time of the maximum observed plasma concentration (t_{max})
- apparent plasma terminal elimination half-life ($t_{1/2}$)
- mean retention time (MRT)
- trough concentrations at steady state (C_{ss_min})
- peak concentrations at steady state (C_{ss_max})
- the area under the concentration-time curve at steady state (the area under the plasma concentration-time curve over a dosing interval [AUC_{τ}])
- the area under the plasma concentration time curve from time zero to infinity [$AUC_{0-\infty}$]),
- clearance (CL/F_{ss})
- the apparent volume of distribution (V_z/F_{ss}), and
- accumulation index and/or ratio (AR)

Exploratory Endpoints:

- Mean change from baseline in potential KPG-818 biomarkers (e.g., Aiolos, Ikaros, and CRBN proteins) at Week 2.
- Mean change from baseline in absolute counts of CD19⁺ B cells, CD268⁺ B cells, CD3⁺ T cells, T regulatory cells (Treg), and plasmacytoid dendritic cells (pDC) at Week 2.
- Mean change from baseline in C3/C4, anti-dsDNA, and immunoglobulins.

5.2. Phase 2a

Primary Endpoints:

- Incidence and severity of AEs and SAEs, related AEs, AEs leading to study drug discontinuation, AEs by severity and relatedness.
- 12-lead ECGs parameter results at each visit and changes from baseline.

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- Vital signs (BP, heart rate, and temperature) parameter results at each visit and changes from baseline.
- Clinical laboratory results and changes from baseline.
- Physical examinations changes from baseline.
- Study drug exposure/compliance.

Secondary Endpoints:

- Mean change from baseline in systemic lupus erythematosus disease activity index 2000 (SLEDAI-2K) score at Week 4, 8, 12, and 16.
- The proportion of patients with SLEDAI-2K improvement ≥ 4 points from baseline at Week 4, 8, 12, and 16.
- Mean change from baseline in Physician Global Assessment (PGA) score at Week 4, 8, 12, and 16.
- Mean change in Cutaneous Lupus erythematosus disease Area and Severity Index (CLASI) activity score from baseline.
- The proportion of patients with a $\geq 50\%$ reduction from baseline in CLASI activity score at Week 12, in patients with baseline CLASI activity score ≥ 10 .
- Mean change in tender and swollen joints from baseline.
- The PK endpoints for assessment of KPG-818 and KPG-818H (if applicable).

After the plasma concentration reaches a steady state (most likely Day 5), the PK parameters to be assessed include but are not limited to:

- time of the maximum observed plasma concentration (t_{max})
- apparent plasma terminal elimination half-life ($t_{1/2}$)
- mean retention time (MRT)
- trough concentrations at steady state (C_{ss_min})
- peak concentrations at steady state (C_{ss_max})
- the area under the concentration-time curve at steady state (the area under the plasma concentration-time curve over a dosing interval [AUC_{τ}])
- the area under the plasma concentration time curve from time zero to infinity [$AUC_{0-\infty}$]),
- clearance (CL/F,ss)
- the apparent volume of distribution ($V_z/F,ss$), and
- accumulation index and/or ratio (AR)

Exploratory Endpoints:

- Mean change in oral corticosteroids (OCS) dose from baseline.
- Mean change from baseline in potential biomarkers (e.g., Aiolos, Ikaros, and CRBN proteins) of KPG-818.
- Mean change from baseline in absolute counts of CD19⁺ B cells, CD268⁺ B cells, CD3⁺ T cells, Treg, and pDC.
- Mean change from baseline in C3, C4, anti-dsDNA, anti-SSA, anti-SSB, anti-Smith, antiphospholipid antibodies (APL), and immunoglobulins.

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6. Analysis Sets

6.1. Efficacy Population

The Efficacy Set (EFS) will include all patients who received at least 1 dose of KPG-818 and have baseline and at least 1 post-baseline efficacy data in Phase 2a part of the study. The efficacy set will be used for the efficacy analyses.

6.2. Safety Population

The Safety Set (SS) will include all patients who received at least 1 dose of study treatment (KPG-818 or placebo). This population will be used for safety analyses.

6.3. Pharmacokinetic Set

The Pharmacokinetic Set (PKS) will include all patients in Phase 1b and Phase 2a who received at least 1 dose of KPG-818 and have evaluable PK data. This population will be used for PK analyses.

6.4. Pharmacodynamic Set

The Pharmacodynamic Set (PDS) will include all patients in Phase 1b and Phase 2a who received at least 1 dose of study treatment (KPG-818 or placebo) and for whom PD markers can be evaluated. This population will be used for PD analyses.

6.5. Treatment Misallocations

If a subject takes a treatment that is not consistent with the treatment they are randomized to, subjects will be reported under the treatment that they actually received for all safety, PK and PD analyses, where applicable.

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7. General Aspects for Statistical Analysis

7.1. General Methods

- Statistical analyses will be carried out by using SAS Version 9.4 or higher. Any deviations from the planned analysis as described in the SAP will be justified and recorded in the clinical study report.
- Unless otherwise specified, summaries will be presented for each dose level and overall.
- Continuous variables will be summarized using the number of observations (n), mean, standard deviation (SD), median, minimum, and maximum. Categorical variables will be summarized using number of observations (n), frequency and percentages of subjects. The denominator for all percentages will be the number of subjects for whom there are data in the dose level within the analysis set of interest, unless otherwise specified. Counts of subjects with missing data will be presented if applicable.
- All data collected in the clinical database will be included in the data listings, as appropriate. Subjects who were randomized and never treated will be accounted for in the data listings.

7.2. Key Definitions

The first dose date (Baseline visit) is counted as Day 1/Week 1, the day immediately after the first dose date will be counted as Day 2 and the date immediately before will be counted as Day -1 (skipped Day 0). Last dose date is defined as the last dose of study medication. For subjects ongoing at time of analysis, last dose date will be considered the date of the most recent study visit in the database for that subject.

Baseline is defined as the last available, valid, non-missing assessment prior to the first dose of study treatment. Measurements that are obtained after the first dose of study drug will be considered post-baseline values. Change from baseline is defined as post-baseline assessment minus baseline assessment.

Study day = start/end date – date of first dosing + 1 when start/end date is on or after the first dosing, otherwise, study day= start/end date – date of first dosing.

7.3. Missing Data

In general, missing data will remain missing and will not be included in analyses.

For PK analysis, only observed concentration data will be used in the data analysis except for concentration values BLQ as described in [Section 10.3](#). No attempt will be made to extrapolate or interpolate estimates for missing data.

7.4. Visit Windows

All data will be displayed and analyzed according to the actual visit data as recorded on the eCRF, even if the assessment is out of the visit window. Unless indicated otherwise, unscheduled visits will be included in data listings only.

7.5. Subgroups

NA

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8. Demographic, Other Baseline Characteristics and Medication

8.1. Subject Disposition and Withdrawals

Disposition data will be summarized descriptively for all screened subjects, overall and by dose level. The number of subjects screened and randomized will be provided. The number and percentage of subjects in each analysis set, subjects completed and discontinued the study, completed and discontinued the study treatment, together with the reason for discontinuation will be provided. All percentages will be based on the number of subjects randomized in each of the treatment group.

Subject completion/withdrawal status will be listed for all subjects. A disposition listing, sorted by dose level, site and subject identifier, will be provided showing for all subjects the assigned dose level, site number, study completion (yes/no), the reason(s) for withdrawal (where applicable), and the dates of:

- Signed informed consent
- Randomization (Visit 2)
- Completion or Discontinuation

8.2. Demographic and Baseline Characteristics

Demographic (Age [years], Sex, Race, Ethnicity, Height [cm], Weight [kg], BMI [kg/m²]) and baseline characteristics (Number and percentage of subjects with prior or concomitant SLE therapy) will be summarized descriptively by dose level on the SS. For categorical parameters, the percentages will be calculated based on the number of subjects in each dose level of SS.

Demographic and other baseline characteristics will be listed for all subjects in SS.

Height (in cm) = height (in inches) * 2.54

Weight (in kg) = weight (in lbs) * 0.4536

BMI (kg/m²) = Weight(kg)/[Height(m)²]

8.3. Medical History and Concomitant Diseases

Medical and Surgical History will be coded using the MedDRA Version 24.0 or later and will be statistically summarized by system organ class (SOC) and preferred term (PT) for all dose levels and overall on Safety population.

A data listing will be presented by dose level and subject.

8.4. Other Baseline Characteristics

Systemic lupus erythematosus (SLE) history will be listed for subjects in the SS including the date of first diagnosis, as well as the clinical domains and criteria if antinuclear bodies are presented. In specific, the number of subjects who ever experienced an SLE sign or symptom will be tabulated in the table of demographic and baseline characteristics.

8.5. Prior and Concomitant Medication and Therapy

Prior and concomitant medications and therapies will be coded using the most updated version of WHO Drug Dictionary (WHODD), and subject incidence will be tabulated by Anatomic Therapeutic Class (ATC) 2nd level and preferred term (PT), overall and by dose level for Phase 1b and Phase 2a combined

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considering the Safety Set. Subjects will be counted only once for each ATC or PT in case of multiple records of the same ATC or PT in the database. Prior and concomitant medications will be summarized separately. No inferential statistics will be performed.

8.5.1. Prior Medication

Prior medication (prescription medications and over-the-counter preparations within the last 3 months) will be defined as any medication which stopped before first administration of study treatment.

8.5.2. Concomitant Medication

Concomitant medications include all medications started on or after first dosing.

Any medication missing both start and stop dates, or having a start date prior to the first dose of study treatment and missing the stop date, or having a stop date on or after the first dose of study treatment and missing start date will be counted as concomitant.

For partial dates, the following approach will be taken:

- If the start day is missing but the start month and year are complete, a medication will be excluded as being concomitant only if the start month/year is before the month/year of study product administration and if the stop date (either full date, month and year if missing day, or year if missing month and day) is before study product administration.
- If the start day and month are missing but the start year is complete, a medication will be excluded as concomitant only if the start year is before the year of study product administration and if the stop date (either: full date, month and year if missing day, or year if missing month and day) is before study product administration.

If using Oral Corticosteroids (OCS) for SLE treatment, patients must be receiving this medication for at least 4 weeks before the Screening visit and on a stable dose equivalent to an average dose of ≤ 20 mg/day of prednisone for at least 4 weeks before the Baseline visit. The mean change from baseline will be descriptively summarized by visit, dose level and overall.

Specifically, the number of subjects taking corticosteroid, immunosuppressant, antimalarial agent, NSAIDs, Biologic or other therapy will be tabulated in the baseline characteristics table. All prior and concomitant medications will be listed by dose level and subject.

8.6. Extent of Exposure

Subject will receive study drug orally once a day through the treatment period: Day 1 to 14 for Phase 1b and Day 1 to 84 for Phase 2a. Study drug exposure will be presented cumulatively. The total cumulative dose received will be the total number of administered dose taken by subject. The number of subjects had dose interruption/delay or treatment discontinuation along with the reason(s) will be summarized by dose level and overall for Safety population. In addition, the treatment duration will be calculated as the sum of days that an enrolled subject received study treatment.

All dose information that recorded on the eCRF will be listed.

8.7. Treatment Compliance

Study drug accountability will be assessed per protocol (Phase 1b: Visit 4 and Visit 5/ET; Phase 2a: Visit 2 to Visit 9, and Visit 11/ET). The final compliance (%), total number of pills dispensed at Day 1, and the number of pills returned will all be summarized descriptively for Safety population. Final compliance (%)

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will be recorded on eCRF. For Phase 2a, the treatment compliance (%) calculation is based on formula below.

Treatment Compliance (%) = (# capsules actually taken / # capsules expected to be taken) * 100

capsules actually taken = [360 capsules dispensed – # capsules lost] – number of pills returned.

capsules expected to be taken = 336

8.8. Protocol Deviation

Deviations from the protocol will be documented on an ongoing basis on the protocol deviations eCRF throughout the study. Major protocol deviations will be determined prior to the database lock. The number and percentage of subjects within each major deviation category will be summarized by treatment group on the SS. The percentages will be calculated based on the number of subjects in each treatment group of the SS. The deviations collected on the eCRF will be listed.

Inclusion and exclusion criteria data will be listed for all subjects.

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9. Efficacy

In Phase 2a, efficacy analyses include assessing improvement in disease activity using SLEDAI-2K, PGA, CLASI activity score and tender and swollen joints count. Each assessment will be listed and summarized descriptively by treatment group on the Efficacy population for all study visits at which the data were collected. No statistical testing will be performed, unless otherwise specified. All data will be listed.

9.1. Preliminary Efficacy Endpoints and Analyses

The preliminary efficacy endpoints are including the following:

- Mean change from baseline in systemic lupus erythematosus disease activity index 2000 (SLEDAI-2K) score at Week 4, 8, 12, and 16.
- The proportion of patients with SLEDAI-2K improvement ≥ 4 points from baseline at Week 4, 8, 12, and 16.
- Mean change from baseline in Physician Global Assessment (PGA) score at Week 4, 8, 12, and 16.
- Mean change in Cutaneous Lupus erythematosus disease Area and Severity Index (CLASI) activity score from baseline.
- The proportion of patients with a $\geq 50\%$ reduction from baseline in CLASI activity score at Week 12, in patients with baseline CLASI activity score ≥ 10 .
- Mean change in tender and swollen joints from baseline.

9.1.1. SLEDAI-2K

The SLEDAI-2K is a global index and includes 24 clinical and laboratory variables that are weighted by the type of manifestation, but not by severity. The SLEDAI-2K activities will be performed for each subject at scheduled visits. The total score falls between 0 and 105, with higher scores representing increased disease activity.

For each planned timepoint, observed values and change from baseline values within each treatment group will be summarized descriptively. The mean change from baseline at Week 4, 8, 12 and 16 will be analyzed using one-sample t-test and corresponding confidence intervals will be presented. The 95% confidence interval of difference between different dose levels will be calculated by two-sample t-test. A mean($\pm$ SE) plot will be generated, plotting mean change from baseline at each planned Visit. There will be separate lines for each treatment group against Visit.

In addition, the proportion of patients with SLEDAI-2K improvement ≥ 4 points from baseline at Week 4, 8, 12, and 16 will be evaluated by Clopper-Pearson exact method and exact confident intervals. A plot for proportion of patients achieving ≥ 4 points improvement from baseline will be generated by treatment group. The difference between active groups and placebo, will be tested using Fisher's exact test, and the two-sided 95% confidence interval of the difference will be estimated by exact method of Chan and Zhang (1999) and presented at each individual visit.

9.1.2. PGA

Physician's Global Assessment of Disease Activity (PGA) will be recorded on a visual analogue scale (VAS; 0 to 10 cm or 0 to 100 mm). The scale for the assessment ranges from 0 representing "no Lupus activity", 1 representing mild disease activity, 2 representing moderate disease activity, to 3 representing

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‘extremely active Lupus’. PGA will be performed for each subject at scheduled visits to determine the SLE disease activity for each subject at the visit.

For each planned timepoint, observed values and change from baseline values within each treatment group will be summarized descriptively. The mean change from baseline at Week 4, 8, 12 and 16 will be analyzed using one-sample t-test and corresponding confidence intervals will be presented. The 95% confidence interval of difference between different dose levels will be calculated by two-sample t-test. Similar mean plot will be generated for PGA score over time.

9.1.3. CLASI

The CLASI is an instrument the Investigator will use to assess the disease activity and damage caused to the skin for SLE patients with or without systemic involvement. The CLASI consists of 2 scores; the first summarizes the activity of the disease, while the second is a measure of the damage done by the disease (see Appendix 13 in protocol). Higher scores indicate worsening disease activity and greater damages. CLASI activity assessment will be performed for each subject at scheduled visits to determine the SLE disease activity for each subject at the visit.

For each planned timepoint, observed values and change from baseline values within each treatment group will be summarized descriptively. The mean change from baseline at Week 4, 8, 12 and 16 will be analyzed using one-sample t-test and corresponding confidence intervals will be presented. The 95% confidence interval of difference between different dose levels will be calculated by two-sample t-test. Similar mean plot will be generated for CLASI activity score over time.

In addition, the number and proportion of patients with a $\geq 50\%$ reduction from baseline in CLASI activity score at Week 12, in patients with baseline CLASI activity score ≥ 10 will be evaluated by Clopper-Pearson exact method and summarized. A plot for proportion of patients achieving ≥ 4 points improvement from baseline will be generated by treatment group. The difference between active groups and placebo will be tested using Fisher’s exact test, and the two-sided 95% confidence interval of the difference will be estimated by exact method of Chan and Zhang (1999) and presented at each individual visit.

9.1.4. Tender and Swollen joints assessment

The joint assessment for tenderness and swelling will be carried out on 28 joints (see Appendix 14 in protocol). Artificial and ankylosed joints will be excluded from tenderness and swelling assessments. Tender and swollen joints assessment will be performed for each subject at scheduled visits to determine the SLE disease activity for each subject at the visit. Lower joint count represents less disease activity.

For each planned timepoint, observed values and change from baseline values within each treatment group will be summarized descriptively. The mean change from baseline at Week 4, 8, 12 and 16 will be analyzed using one-sample t-tests and corresponding confidence intervals will be presented. The 95% confidence interval of difference between different dose levels will be calculated by two-sample t-test. Similar mean plot will be generated for tender and swollen joints over time.

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10. Pharmacokinetics

One of the objectives of this study is to evaluate the PK profile of KPG-818 and its metabolites KPG-818H, after single and multiple oral doses. These analyses will be performed in the PK population and presented for Phase 1b and Phase 2a.

The PK Population will be used for the PK parameter calculations, graphical displays of individual data and the listings of PK parameters, and for all other PK listings and summarization of PK parameters. Subjects with missing PK parameters due to unreliable or missing data will be flagged and excluded from summarization. Samples taken from patients who received placebo will not be analyzed.

PK parameters for KPG-818 and KPG-818H will be derived using the non-compartmental analysis (NCA) applying appropriate software, i.e. Phoenix™ WinNonlin® (Version 8.0 or higher, Certara Corporation). All other analyses and summaries will be produced using SAS® (Version 9.4 or higher, SAS Institute Inc.).

10.1. PK Sampling Schedule

The PK parameters on scheduled time points (see [Table 10-1](#) and [10-2](#)) of KPG-818 and KPG-818H dose proportionality will be examined across dose groups. Refer to [section 11](#) for more information on dose proportionality.

Table 10-1 Phase 1b blood collection time points for pharmacokinetic assessment

Dosing Day (Acceptable Limit)	Blood Collection Point (Acceptable Limit)	Blood Volume (4 mL/Sample)
Day 1 (± 0 days)	within 30 minutes pre-dose	4 mL
Day 7 (± 0 days)	within 30 minutes pre-dose	20 mL
	1 hour (± 15 minutes) post-dose	
	2 hours (± 15 minutes) post-dose	
	6 hours (± 20 minutes) post-dose	
	10 hours (± 40 minutes) post-dose	
Day 8 (± 0 days)	within 30 minutes pre-dose ^a	4 mL
Day 14 (± 1 days)	within 30 minutes pre-dose	4 mL
Day 15 (± 0 days)	within 30 minutes pre-dose ^b	4 mL

Notes:

a. Pre-dose on Day 8 (i.e., 24 hours after the pre-dose on Day 7).

b. Pre-dose on Day 15 (i.e., 24 hours after the pre-dose on Day 14).

Table 10-2 Phase 2a blood collection time points for pharmacokinetic assessment

Dosing Day (Acceptable Limit)	Blood Collection Point (Acceptable Limit)	Blood Volume (4 mL/Sample)
Day 1 (± 0 days)	within 30 minutes pre-dose	4 mL
Day 2 (± 0 days)	within 30 minutes pre-dose	4 mL
Day 12 (± 0 days)	within 30 minutes pre-dose	4 mL
Day 13 (± 0 days)	within 30 minutes pre-dose	4 mL
Day 14 (± 0 days)	within 30 minutes pre-dose	4 mL
	1 hour (± 15 minutes) post-dose	
	2 hours (± 15 minutes) post-dose	
	6 hours (± 20 minutes) post-dose	
	10 hours (± 40 minutes) post-dose	
Day 15 (± 0 days)	24 hours after Day 14 dose	4 mL
Day 85 (± 0 days)	24 hours after dose taken on Day 84	4 mL

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10.2. Calculation of PK Parameters

The following PK parameters will be derived (if possible) from the obtained plasma samples of KPG-818 and its metabolite KPG-818H on Day 7 (for Phase 1b) and on Day 14 (for Phase 2a).

In final analysis, actual PK sampling times will be used in the derivation of PK parameters.

Parameter	Definition	Method of Determination
AUC_{last}	Area under the plasma concentration-time curve, from time 0 to the last measurable concentration.	Linear trapezoidal method
$AUC_{0-\infty}$	Area under the plasma concentration-time curve, from time 0 extrapolated to infinity.	$AUC_{last} + C_{last} / \lambda_z$, where C_{last} is the last measurable concentration
AUC_{τ}	Area under the concentration-time curve at steady state (the area under the plasma concentration-time curve over a dosing interval)	Linear trapezoidal method Computed from dose time to dose time + tau using the estimated concentration at τ (tau = 24 hours)
C_{av}	Average drug concentration at steady-state	Calculated as AUC_{τ} / τ
C_{ss_min}	Trough concentrations at steady state	Observed directly from data (equivalent to C_{tau})
C_{ss_max}	Peak concentrations at steady state	Observed directly from data
t_{max}	Time to reach C_{max} . If the maximum value occurs at more than 1 timepoint, T_{max} is defined as the first timepoint with this value.	Observed directly from data
$t_{1/2}$	Terminal elimination half-life	Calculated as $\ln(2) / \lambda_z$
MRT	Mean Retention Time	$AUMC_{\tau} + \tau (AUC_{0-\infty} - AUC_{\tau}) / AUC_{\tau}$
$CL/F,ss$	Apparent total body clearance at steady-state	Calculated as $Dose / AUC_{0-\tau}$
$V_z/F,ss$	Apparent volume of distribution at steady-state	Calculated as $Dose / (\lambda_z \times AUC_{0-\tau})$
AR	Accumulation index and/or ratio (AR)	

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Note: λ_z will be the negative of the estimated slope of the linear regression of the ln-transformed concentration versus time profile in the terminal elimination phase. The Best-fit method, in Phoenix WinNonlin, will be used to calculate the λ_z from at least 3 concentration data points excluding the C_{max} . Rsq adjusted, the goodness of fit statistic for the terminal elimination phase, adjusted for the number of points used in the estimation of λ_z must be ≥ 0.8 . If the λ_z cannot be measured (e.g.: fewer than 3 non-zero concentrations in the terminal elimination phase or Rsq adjusted < 0.8), the PK parameters derived from λ_z ($AUC_{0-\infty}$, $t_{1/2}$, MRT and V_z/F , ss) will be presented in the listing with a flag and excluded from descriptive statistics. The timepoint where ln-linear λ_z calculation begins (λ_z Lower) and the actual sampling time of the last measurable concentration used to estimate the λ_z (λ_z Upper), as well as the Rsq adjusted for the ln-linear regression for the calculation of the elimination rate constant will be reported.

Some PK parameters may not be calculated for all or some subjects, at the discretion of the Syneos Pharmacokineticist if the concentration data is not deemed to be amenable to evaluation. Explanations for PK parameters that could not be estimated will be provided in the report.

No statistical analysis is planned on samples obtained from subjects who received the placebo, but any cases of detectable and quantifiable levels observed in these subjects (for those who were analyzed) will be addressed descriptively in the report.

10.3. Attainment of Steady-State

Achievement of steady state may be determined using appropriate statistical methods using the trough levels collected during the multiple dosing. Repeated measures analysis will be carried out on ln-transformed pre-dose concentrations to determine attainment of steady-state. The approach is based on the comparison of ln-transformed trough concentration values.

For Phase 2a, repeated measures analysis will be carried out on ln-transformed C_{trough} (pre-dose concentrations) for Days 12, 13, and 14 to explore the attainment of steady-state concentrations for KPG-818 and KPG-818H.

The example SAS code will be:

```
proc mixed data= dataset;
class dose time patient_id;
model logpk = dose dose*time / ddfm=KR;
repeated / type=un subject= patient_id (dose);
lsmeans dose*time;
run;
```

The DDFM = KR (Kenward Roger) option performs the degrees-of-freedom calculations detailed by Kenward and Roger (1997). It is highly recommended by the SAS manual to estimate the denominator degrees of freedom for the fixed effects as the most appropriate method in the mixed-model analysis.

Contrasts will be tested between a time point and the pooled mean over all remaining time points.

- Day 12 pre-dose value vs. the average pre-dose of Day 13 and Day 14
- Day 13 pre-dose value vs. the pre-dose of Day 14

The first non-significant comparison will be concluded to be the dose number at which steady state concentrations are attained. The p-value for difference of Least Square Means (LSM), LSM Ratio, and the 90% CI for the contrasts will be provided.

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10.4. Assessment of Dose Proportionality

The PK parameters will be analyzed for dose proportionality using a power model approach or analysis of variance (ANOVA) model as appropriate.

For the SAD (Part A) portion only, an exploratory assessment of dose proportionality will be undertaken for the PK parameters AUC_{0-t} , $AUC_{0-\infty}$, and C_{max} . The power model will be used, and will include the PK parameter as the response variable and dose (mg) as the explanatory variable. For this model, the variable dose will be treated as a continuous variable. Cohorts that will be considered for the analysis include KPG-818 dose levels (where a minimum of three different dose levels are required in order to conduct the analysis). The form of the model is as follows:

PK Parameter = $e^{\alpha} \times \text{Dose}^{\beta} \times e^{\epsilon}$, where $\text{Dose} \geq 0$, and e^{ϵ} represents the associated error.

Thus, perfect dose proportionality is met when $\beta=1$ (ignoring error). This becomes a linear relationship following a natural-log transformation, to which a linear regression will be fit by ordinary least squares (OLS):

$\ln(\text{PK Parameter}) = \alpha + \beta \times \ln(\text{Dose}) + \epsilon$ where $\text{Dose} > 0$, and ϵ represents the associated error.

The estimate of β together with a 90% confidence interval (CI) will be provided (for each PK parameter model), and this will be used to quantify dose proportionality. According to Hummel et al. (2009), the following criterion may be used for exploratory dose proportionality evaluations: If the (two-sided) 90% CI for β is wholly contained within the interval, $[1+\ln(0.5)/\ln(p), 1+\ln(2)/\ln(p)]$, then dose proportionality is suggested across the investigated dose range. Here, p is defined as the ratio of the highest to lowest dose. This interval criterion will be reported along with the corresponding 90% CI estimate for β (presented to three decimal places).

The PK parameter values estimated from the power model will be plotted against dose.

The SAS code for the analysis model will follow the format given below (using the Mixed procedure to fit the linear regression). The input variables (or datasets) are depicted in slanted red text and have been given generic names.

```
proc mixed data=dataset order=data;  
model ln_pk_parameter = ln_dose / solution;  
estimate 'Beta Estimate' ln_dose 1 / cl alpha=0.1;  
ods output estimates = estimates;  
run;
```

10.5. Presentation of Concentration Data

10.5.1. Handling of Dropouts, Missing Data or Data Below Lower Limit of Quantification

Missing concentration data for all patients who are administered study drug will be considered as non-informative missing and will not be imputed. No concentration estimates will be provided for missing sample values.

For the derivation of AUC and for the individual plasma concentration vs. time curves, the following rules will apply:

- Concentration values below the assay's lower limit of quantification (BLQ) in predose samples and in samples taken before the time of the first quantifiable concentration will be treated as zero; post-dose BLQ values after the first quantifiable time point will be set to missing.
- The sampling time of predose samples relative to dosing will also be treated as zero; if the actual time of sampling is missing, the planned time can be used.

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For plasma concentration summarizing, BLQ in predose samples and in post-dose samples will be treated as zero.

10.5.2. Listing and Presentation of Individual PK Data

- The sampling time of predose samples relative to dosing will be treated as zero for all sampling periods separately;
- For linear plots, zero concentration value(s) before the first quantifiable concentration will be included in the plot. For log-linear plots, zero concentration value(s) before the first measurable concentration will be assigned a missing value.

Following presentations of individual PK concentrations will be produced:

- Listing of PK sampling times including nominal and actual time elapsed from dose with the deviation from the nominal time and measured concentrations of the drug.
- Individual PK profiles in linear and log-linear scale for all patients by dose level combined on one graph and plotted vs. actual time of the samples elapsed from the start of dose.

10.5.3. Data summarization

The mean/median value at a time point where 1 or more samples have BLQ values will be reported (in tabular or graphical fashion) even if the mean/median value is BLQ.

- Zero mean or median values will be included in summary tables.
- SD will not be displayed if more than 30% of values are missing or BLQ.
- Tables of summary statistics for concentration-time data/PK parameters will be reported as per [Table 10-3](#).

Following presentations of mean PK concentrations will be produced:

- Table of PK concentrations summarized by nominal time for each dose level separately.
- Mean PK profiles in linear and log-linear scale for all dose levels plotted vs. nominal time relative to the start of dose separately for each intense sampling period.

Pharmacokinetic parameters and plasma concentration data will be summarized by each dose level using the following descriptive statistics:

Table 10-3: PK Summary Statistics

Variable	Summarized with:
PK concentration at each time point	n, number and % BLQ, arithmetic mean, SD, coefficient of variance (CV) %, minimum, median and maximum
C_{max} , AUC_{τ} , AUC_{last} , MRT	n, arithmetic mean, SD, CV%, minimum, median, maximum, geometric mean and geometric CV%
Categorical PK parameters (t_{max})	n, minimum, Q1, median, Q3 and maximum
Semi-continuous PK parameters ($t_{1/2}$, CL/F, ss)	n, arithmetic mean, SD, CV%, minimum, median, maximum
CV% = SD/mean in %.	
%BLQ = 100 * (total number of patients who have BLQ values/total number of patients within each dose level at each time point)	

Table 10-4: Precision of PK Parameters Reporting

Statistics	Degree of Precision
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Minimum, Maximum	3 significant digits or as needed based on actual measured values (for example PK concentrations)
Mean (arithmetic and geometric), Median, Q1, Q3	4 significant digits or as needed based on actual measured values (for example PK concentrations)
SD	5 significant digits or as needed based on actual measured values (for example PK concentrations)
CV% and Geometric CV%	1 decimal place or as needed based on actual measured values (for example PK concentrations)
AUC _{last} , C _{ss_max} , CL/F _{ss} , etc.	4 significant digits
t _{max} , Rsq adjusted	2 decimal places
t _{1/2}	1 decimal places

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11. Pharmacodynamics and Biomarkers

The selected biomarkers are listed in [Table 11-1](#). Blood samples from each of the 24 patients in Phase 1b will be collected at 3 time points: pre-dose on Day 1, pre-dose on Day 7, and pre-dose on Day 15 (i.e., 24 hours after the pre-dose on Day 14).

Biomarkers in Phase 2a, will be collected from each of the 32-48 patients at 3 time points: pre-dose on Day 1, 24 hours post-dose Day 14 (drawn on Day 15), and 24 hours after the last dose on Day 84 (drawn on Day 85).

Table 11-1 Biomarkers for testing in Phase 1b and Phase 2a

Leukocytes	Total B cells (CD19 ⁺)
	Activated B cells (CD268 ⁺)
	Total T cells (CD3 ⁺)
	T regulatory cells (Treg)
	Plasmacytoid dendritic cells (pDC)
PD markers	Aiolos (intracellular protein)
	Ikaros (intracellular protein)
	CRBN (intracellular protein)
	IFN- α , IFN- β , and IL-2

Abbreviations: IFN = interferon, PD = pharmacodynamics

11.1. Pharmacodynamic Biomarkers

Blood samples will be collected for the following biomarkers assessments according to [Table 11-2](#) and [Table 11-3](#).

- Potential biomarkers (e.g., Aiolos, Ikaros, and CRBN proteins) of KGP-818
- CD19⁺ B cells, CD268⁺ B cells, CD3⁺ T cells, Treg, and pDC.

Table 11-2 Phase 1b blood collection time points for pharmacodynamic assessment

Dosing Day (Acceptable Limit)	Blood Collection Point
Day 1 ($\pm$ 0 days)	within 30 minutes pre-dose
Day 7 ($\pm$ 0 days)	within 30 minutes pre-dose
Day 15 ($\pm$ 0 days)	within 30 minutes pre-dose ^a

a. Pre-dose on Day 15 (i.e., 24 hours after the pre-dose on Day 14).

Table 11-3 Phase 2a blood collection time points for pharmacodynamic assessment

Dosing Day (Acceptable Limit)	Blood Collection Point
Day 1 ($\pm$ 0 days)	within 30 minutes pre-dose
Day 15 ($\pm$ 0 days)	24 hours after Day 14 dose
Day 85 ($\pm$ 0 days)	24 hours after Day 84 dose

Biomarkers from prematurely discontinued patients will be collected at Early Termination visit.

11.2. Serologic Markers

Sample for autoantibodies (including ANA, anti-dsDNA, anti-Smith, anti-SSA, anti-SSB, and APL), complement C3, C4, and immunoglobulins will be collected at Screening and Day 14/ET for phase 1b; Screening, Day 1, Day 28, Day 56 and Day 85/ET for phase 2a.

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The biomarkers will be analyzed to assess the pharmacological activity and mechanism of action of KPG-818.

Data will be summarized by absolute values of the biomarker, as well as the mean changes from baseline for serologic markers (e.g., but not limited to C3, C4, ANA). All serologic biomarkers will be listed by subject, visit and analyte.

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12. Gene Expression Test

Efficacy of KPG-818 may closely correlate with the 5 gene expression levels. The examination data of the genes will help with the efficacy analysis and stratification and selection of the patients in the future.

For Phase 2a, mRNA assay for Aiolos and Type I IFNGS (whole blood sample) targeting the five genes (IKZF3, IFI44, IFI44L, IFI27, RSAD2) will be collected once, on Day 1 (pre-dose).

Table 12-1 Phase 2a blood collection time point for gene expression test

Dosing Day (Acceptable Limit)	Blood Collection Point	Blood Volume (2 mL/sample)
Day 1 ($\pm$ 0 days) mRNA sample	within 30 minutes pre-dose	2 mL

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13. COVID-19

Given the current COVID-19 pandemic, per regulatory guidance, a listing of all patients either experiencing COVID-19 or at least possibly affected by COVID-19 related measures will be produced where applicable. Every effort will be taken to document where clinical trial conduct is affected by COVID-19 infection or related measures.

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14. Safety

The population used for safety analyses will be the Safety Set (SS). Safety will be assessed based on adverse event (AE) or adverse drug reactions (ADR) reports, clinical laboratory data, ECG parameters, physical examinations, and vital signs.

14.1. Adverse Events / Adverse Drug Reactions

Adverse events (AEs) will be coded by the Medical Dictionary for Regulatory Activities (MedDRA version 24.0 or later) and graded for severity according to CTCAE version 5.0.

Treatment emergent AE is defined as an AE with onset date on or after the start of treatment or start date prior to start of treatment but a worsening in severity during treatment.

If the start date of an AE is partially or completely missing, the date will be compared as far as possible with the date of the start of administration of study treatment. The AE will be assumed to be treatment-emergent if it cannot be definitively shown that the AE did not occur or worsen during the treatment-emergent period (worst case approach). The following general rules will be used:

- If the start day is missing but the start month and year are complete, an AE will be excluded as being treatment-emergent only if the start month/year is before the month/year of study drug administration or if the stop date is before study drug administration.
- If the start day and month are missing but the start year is complete, an AE will be excluded as being treatment-emergent only if the start year is before the year of study drug administration or if the stop date is before study drug administration.
- If the start date is completely missing, an AE will be considered treatment-emergent unless the stop date is before study drug administration.

A dose-limiting toxicity (DLT) is defined as any Grade 3 or higher study drug-related adverse event (AE), according to Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.

An AE is considered study drug-related, if the relationship to study treatment is documented as 'possibly related' and 'related'.

Summary analyses of AEs will be performed only for those events that are considered treatment-emergent, but all AEs will be included in the listings.

Adverse events are summarized by subject incidence rates; therefore, in any tabulation, a subject contributes only once to the count for a given SOC or PT (i.e., the most related occurrence or the highest severity level occurrence). Missing relationship will be considered related to study treatment. Missing severity will be considered as severe.

The following summarizes will be tabulated with number and advantage of subjects as well as number of events provided. These will be presented by SOC and PT, sorted by decreasing frequency.

- An overall summary of TEAEs, serious TEAEs, treatment related TEAEs, DLTs, TEAEs leading to study drug withdrawn, TEAEs leading to study drug interruption and TEAEs leading to death
- TEAEs overall and by system organ class and preferred term
- Treatment-related TEAEs, overall and by system organ class and preferred term
- TEAEs by maximum severity, overall and by system organ class and preferred term

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- Serious TEAEs, overall and by system organ class and preferred term
- TEAEs by relationship to study treatment, overall and by system organ class and preferred term
- TEAEs leading to study drug withdrawn, overall and by system organ class and preferred term
- TEAEs leading to study drug interruption, overall and by system organ class and preferred term
- TEAEs leading to death, overall and by system organ class and preferred term

14.2. Laboratory Evaluations

Clinical laboratory values for each laboratory parameter and Urine Pregnancy test will be evaluated as appropriate (Phase 1b: Screening, Day 1, Day 8, Day 14/ET and Follow-up (D28); Phase 2a: Screening, Day 1, Day 14, Day 28, Day56, Day 85/ET and Follow-up (D112)). Clinical laboratory evaluations include hematology, clinical chemistry and urinalysis etc. For all female patients, two serum pregnancy tests will be performed, one is at Screening and again within 3 days before taking the first dose of KPG-818. QuantiFERON®-TB Gold test and urine drug screening will be conducted on Screening only. The clinical laboratory evaluations are specified in [Table 13-1](#).

Hematology, clinical chemistry, coagulation and urinalysis will be tabulated and listed separately. Absolute laboratory data at each visit and changes from baseline will be summarized descriptively for continuous variables. For categorical data, the frequency and percentage regarding the visits and cohort will be calculated.

In addition, shift tables from baseline to each visit will be descriptively summarized with values of 'normal' (within normal limits), 'high', 'low' for clinical chemistry, hematology and serology parameters. Abnormal laboratory values will be flagged and identified as those outside (above or below) the normal ranges.

All laboratory results will be listed with flags that indicate abnormality. Pregnancy tests and QuantiFERON®-TB Gold test will be listed separately.

Table13-1 Clinical Laboratory Evaluations

Clinical Chemistry	Hematology	Serology	Urinalysis
Alanine aminotransferase	Hematocrit	Anti-hepatitis B core antibody	Bilirubin
Albumin	Hemoglobin	Hepatitis B surface antigen (HBsAg)	Blood
Alkaline phosphatase	Mean cell hemoglobin	Hepatitis B virus DNA ^b	Color and appearance
Aspartate aminotransferase	Mean cell hemoglobin concentration	Hepatitis C antibody	Glucose
Bicarbonate	Mean cell volume	Hepatitis C virus RNA ^c	Ketones
Blood urea nitrogen	Platelet count	Human immunodeficiency (HIV-1 and HIV-2) antibodies and p24 antigen	Leukocyte esterase
Calcium	Red blood cell (RBC) count	ANA	Nitrite
Chloride	RBC distribution width	Anti-dsDNA	pH
Cholesterol	White blood cell (WBC) count	Anti-Smith antibody	Protein

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Creatinine	WBC differential: Basophils Eosinophils Lymphocytes Monocytes Neutrophils	Anti-SSA	Specific gravity
Creatine kinase		Anti-SSB	Urobilinogen
Gamma-glutamyl transferase		Antiphospholipid antibodies (APL)	Microscopic examination (if protein, leukocyte esterase, nitrite, or blood is positive)
eGFR		C3 and C4 Complement	Microscopic examination
Glucose		Ig isotype profile (IgG and IgM)	spot urine protein to creatinine ratio (sUPCR)
Lipase			
Potassium			
Serum creatinine			
Sodium			
Total bilirubin ^a			
Total protein			
Coagulation	Drug Screen	Hormone panel – females only^d	QuantiFERON®-TB Gold test
Activated partial thromboplastin time	Including but not limited to: Amphetamines/methamphetamine	Follicle-stimulating hormone (postmenopausal females only)	
International Normalized Ratio	Barbiturates	Serum pregnancy test (human chorionic gonadotropin) (women of childbearing potential)	
Prothrombin time	Benzodiazepines	Urine pregnancy test (women of childbearing potential)	mRNA
	Cocaine (metabolite)		
	Methadone		
	Phencyclidine		
	Opiates		
	Tetrahydrocannabinol/cannabinoids		
	Cotinine test		

Notes:

- Direct and indirect bilirubin will be analyzed if total bilirubin is elevated.
- Patients who test negative to hepatitis B surface antigen (HBsAg) and positive to Hepatitis B core (HBc) antibody should further undergo hepatitis B virus DNA titer detection to exclude active hepatitis B virus infection. If patients are negative to viral DNA, they can be enrolled. If patients are positive to HBsAg, they are excluded.
- Patient with hepatitis C virus antibody positive test results must be further tested for hepatitis C virus RNA to exclude active hepatitis C virus infection.
- Pregnancy tests are only required for women with childbearing potential.

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14.3. Vital Signs

Vital signs will be taken at Screening, Day 1, Day 7, Day 8, Day 14/ET Day 15 and Follow-up (D28) for Phase 1b; Screening, Day 1, Day 14, Day 28, Day56, Day 85/ET and Follow-up (D112) for Phase 2a. Height will be measured at screening only. Body weight will be measured at Screening, Day 1 and Day 14/ET for Phase 1b or Screening, Day 1 and Day 85 for Phase 2a.

Vital signs will include oral body temperature (°C), systolic and diastolic blood pressures (mmHg), pulse rate (beats/minute), respiratory rate (breaths/min), height (cm), body weight (kg) and BMI (kg/m²).

All vital signs will be performed singularly and repeated once if outside the relevant clinical reference ranges. The median value measured at Day 1 (Visit 2) will be used as the baseline.

The absolute values and change from baseline will be descriptively summarized by visit/assessment (multiple assessments per visit will be summarized by nominal time) for vital signs by dose level and overall.

All vital sign data will be reported in a by-subject listing.

The conversion for temperature: Temperature (in °C) = 5/9 (Temperature [in °F]-32)

14.4. Electrocardiogram

12-lead electrocardiograms (ECGs) will be collected at Screening, Day 1, Day 14/ET and Follow-up (Day 28) for Phase 1b; Screening, Day 1, Day 85/ET and Follow-up (D112) for Phase 2a. ECG parameters will include PR interval (msec), QRS interval (msec), QT interval (msec), QTcB interval (msec), QTcF interval (msec) and overall interpretation.

All 12-lead ECGs will be performed singularly and repeated once if outside the relevant clinical reference ranges. The mean value measured at Day 1 (Visit 2) will be used as the baseline.

The 12-lead ECGs will be repeated twice, and an average of the 3 readings will be taken, only if either of the following criteria apply:

- QTc interval value > 500 ms
- QTc change from baseline (pre-dose) is > 60 ms.

The absolute values and change from baseline to each visit will be descriptively summarized by visit/assessment, dose level and overall. The frequency distribution of ECG overall interpretation result at baseline and the changes from baseline will be presented for each visit by dose level and overall. Electrocardiogram data will be listed by subject and visit.

14.5. Physical Examination

A full physical examination (including a questionnaire for COVID-19) will be performed at Screening, Day 1, Day 7, Day 8, Day 14/ET and Follow-up (Day 28) for Phase 1b; Screening, Day 1, Day 14, Day 28, Day56, Day 85/ET and Follow-up (D112) for Phase 2a. The date and result will be reported in a by-subject listing.

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15. Interim Analyses

No formal interim analyses are planned for this study.

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16. Safety Review Committee

The specific requirements for the content, task, processes and responsibilities in the collection, presentation, and assessment of clinical data required for the SRC meetings are documented in a separate Safety Review Committee and Cohort Management Plan/Charter.

During the Phase 1b part of the study, the SRC may provide the following recommendations to the Sponsor:

- Expanding a cohort at a specific dosing level, or repeating a lower dose in a subsequent cohort.
- Continuing a dose level for a given cohort.
- Escalating a dose level for a subsequent cohort.
- Termination of current or previous cohort (s).

During the Phase 2a part of the study, the SRC may continue to review the safety data.

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17. Changes from Analysis Planned in Protocol

Not Applicable.

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18. Reference List

Aringer M, et al. 2019 European League Against Rheumatism/American College of Rheumatology Classification Criteria for Systemic Lupus Erythematosus. Arthritis Rheumatol. 2019; 71(9): 1400-12.

Chan ISF, Zhang Z. Test based exact confidence intervals for the difference of two binomial proportions. Biometrics, 1999; 55:1201-1209.

Hummel J, McKendrick S, Brindley C and French, R. Exploratory assessment of dose proportionality: review of current approaches and proposal for a practical criterion. Pharmaceut. Statist. 2009; 8: 38-49.

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19. Programming Considerations

All TFLs, and statistical analyses will be generated using SAS for Windows, Release 9.4 or higher (SAS Institute Inc., Cary, NC, USA). Computer-generated TFL output will adhere to the following specifications.

PK analysis will be performed using non-compartmental analysis in professional PK software Phoenix WinNonLin 8 or higher (Certara, Princeton, NJ, USA).

19.1. General Considerations

- One SAS program can create several outputs, or a separate SAS program will be created for each output
- One output file can contain several outputs, or each output will be stored in a separate file
- Output files will be delivered in Word format or portable document format pdf
- Numbering of TFLs will follow ICH E3 guidance

19.2. Table, Figure, and Listing Format

19.2.1. General

- All TFLs will be produced in landscape format on American letter size, unless otherwise specified.
- All TFLs will be produced using the Courier New font, size 8 which is the smallest acceptable point size for the Regulatory Authorities
- The data displays for TFLs will have a minimum blank 1-inch margin on all 4 sides
- Headers and footers for figures will be in Courier New font, size 8 which is the smallest acceptable point size for the Regulatory Authorities
- Legends will be used for all figures with more than one variable, group, or item displayed
- TFLs will be in black and white (no color), unless otherwise specified
- Specialized text styles, such as bolding, italics, borders, shading, and superscripted and subscripted text, will not be used in the TFLs, unless otherwise specified. On some occasions, superscripts 1, 2, or 3 may be used (see below)
- Only standard keyboard characters will be used in the TFLs. Special characters, such as non-printable control characters, printer-specific, or font-specific characters, will not be used. Hexadecimal-derived characters will be used, where possible, if they are appropriate to help display math symbols (e.g., μ). Certain subscripts and superscripts (e.g., cm^2) will be employed on a case-by-case basis
- Mixed case will be used for all titles, footnotes, column headers, and programmer-supplied formats, as appropriate

19.2.2. Headers

- All output will have the following header at the top left of each page:

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- Kangpu Biopharmaceuticals, Ltd
- Protocol KPG-818-SLE
- Version x.x
- Draft/Final Run
- All output will have Page n of N at the top or bottom right corner of each page. TFLs are internally paginated in relation to the total length (i.e., the page number will appear sequentially as page n of N, where N is the total number of pages in the table)
- The date the output was generated will appear along with the program name as a footer on each page

19.2.3. Display Titles

- Each TFL will be identified by the designation and a numeral. (i.e., Table 14.1.1). A decimal system (x.y and x.y.z) are used to identify TFLs with related contents. The title will be centered. The analysis set will be identified on the line immediately following the title and will be enclosed in parenthesis. The title and table designation will be single spaced. A solid line spanning the margins will separate the display titles from the Column headers. There will be one blank line between the last title and the solid line.

Table x.y.z
First Line of Title
Second Line of Title if Needed
(Safety Analysis Set)

19.2.4. Column Headers

- Column headings will be displayed immediately below the solid line described above in initial upper-case characters.
- In the case of efficacy tables, the variable (or characteristic) column is on the far left followed by the treatment group columns and total column (if applicable). P-values may be presented under the total column or in separate p-value column (if applicable). Within-treatment comparisons may have p-values presented in a row beneath the summary statistics for that treatment
- For numeric variables, include 'unit' in column or row heading when appropriate
- Analysis set sizes will be presented for each treatment group in the column heading as (N=xx) (or in the row headings, if applicable). This is distinct from the 'n' used for the descriptive statistics representing the number of subjects in the analysis set
- The order of treatments in the tables and listings will be Placebo first in the case of placebo controlled studies and Active comparators first in the case of active comparator trials, followed by a total column (if applicable)

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19.2.5. Body of the Data Display

19.2.5.1. General Conventions

Data in columns of a table or listing are formatted as follows:

- Alphanumeric values will be left-justified;
- Whole numbers (e.g., counts) will be right-justified; and
- Numbers containing fractional portions will be decimal aligned.

19.2.5.2. Table Conventions

- Units will be included where available
- For categorical parameters, all categories will be presented in the table, even if n=0 for all treatment groups in a given category. For example, the frequency distribution for symptom severity would appear as:

Severity Rating	N
severe	0
moderate	8
mild	3

Where percentages are presented in these tables, zero percentages will not be presented and so counts of 0 will be presented as 0 and not as 0 (0%).

- An Unknown or Missing category will be added to each parameter for which information is not available for 1 or more subjects
- Unless otherwise specified, the estimated mean and median for a set of values will be printed out to 1 more significant digit than the original values, and standard deviations will be printed out to 2 more significant digits than the original values. The minimum and maximum will report the same significant digits as the original values. For example, systolic blood pressure will be presented as follows:

N	XX
Mean	XXX.X
Std Dev	X.XX
Median	XXX.X
Minimum	XXX
Maximum	XXX

- P-values will be output in the format: '0.xxx', where xxx is the value rounded to 3 decimal places. Every p-value less than 0.001 will be presented as <0.001. If the p-value are less than 0.0001, then present as <0.0001. If the p-value is returned as >0.999, then present as >0.999

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- Percentage values will be printed to one decimal place, in parentheses with no spaces, one space after the count (e.g., 7 (12.8%), 13 (5.4%)). Pre-determine how to display values that round down to 0.0. A common convention is to display as '<0.1', or as appropriate with additional decimal places. Unless otherwise noted, for all percentages, the number of subjects in the analysis set for the treatment group who have an observation will be the denominator. Percentages after zero counts will not be displayed and percentages equating to 100% will be presented as 100%, without decimal places
- Tabular display of data for medical history, prior/concomitant medications, and all tabular displays of adverse event data will be presented by the body system, treatment class, or SOC with the highest occurrence in the active treatment group in decreasing order, assuming all terms are coded. Within the body system, drug class and SOC, medical history (by preferred term), drugs (by ATC1 code), and adverse events (by preferred term) will be displayed in decreasing order. If incidence for more than 1 term is identical, they will then be sorted alphabetically. Missing descriptive statistics or p-values which cannot be estimated will be reported as '-'
- The percentage of subjects will normally be calculated as a proportion of the number of subjects assessed in the relevant treatment group (or overall) for the analysis set presented. However, careful consideration is required in many instances due to the complicated nature of selecting the denominator, usually the appropriate number of subjects exposed. Details will be described in footnotes or programming notes, as necessary
- For categorical summaries (number and percentage of subjects) where a subject can be included in more than one category, a footnote or programming note will be added describing whether the subject is included in the summary statistics for all relevant categories or just 1 category as well as the selection criteria
- Where a category with a subheading (such as system organ class) has to be split over more than one page, output the subheading followed by '(cont)' at the top of each subsequent page. The overall summary statistics for the subheading should only be output on the first relevant page

19.2.5.3. Listing Conventions

- Listings will be sorted for presentation in order of treatment groups as above, subject number, visit/collection day, and visit/collection time
- Missing data will be represented on subject listings as either a hyphen ('-') with a corresponding footnote ('- = unknown or not evaluated'), or as 'N/A', with the footnote 'N/A = not applicable', whichever is appropriate
- Dates will be printed in SAS DATE9.format ('DD_MMM_YYYY': 01JUL2000). Missing portions of dates will be represented on subject listings as dashes (--JUL2000). Dates that are missing because they are not applicable for the subject will be output as 'N/A', unless otherwise specified
- All observed time values will be presented using a 24-hour clock HH:MM or HH:MM:SS format (e.g., 11:26:45, or 11:26). Time will only be reported if it was measured as part of the study
- Units will be included where available

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19.2.5.4. Figure Conventions

- Unless otherwise specified, for all figures, study visits will be displayed on the X-axis and endpoint (e.g., treatment mean change from Baseline) values will be displayed on the Y-axis

19.2.6. Footnotes

- A solid line spanning the margins will separate the body of the data display from the footnotes.
- All footnotes will be left justified with single-line spacing immediately below the solid line underneath the data display
- Footnotes will always begin with 'Note:' if an informational footnote, or 1, 2, 3, etc. if a reference footnote. Each new footnote will start on a new line, where possible
- Subject specific footnotes are avoided, where possible
- Footnotes will be used sparingly and add value to the TFL. If more than six lines of footnotes are planned, then a cover page is strongly recommended to be used to display footnotes, and only those essential to comprehension of the data will be repeated on each page
- The last line of the footnote section will be a standard source line that indicates the name of the program used to produce the data display, the date the program was run, and the listing source (i.e., 'Program : myprogram.sas Listing source: 16.x.y.z')
- Sources and/or cross-references in footnotes will use the keyword prefix (in singular form) for each reference and will be separated by a comma when multiple cross-references are displayed

Example

Listing source: Listing 16.2.4.1.1, Listing 16.2.4.1.2, Listing 16.2.4.2.1

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20. Quality Control

SAS programs are developed to produce output such as analysis data sets, summary tables, data listings, figures or statistical analyses. An overview of the development of programs is detailed in Syneos Health Developing Statistical Programs SOP (3907).

Syneos Health Developing Statistical Programs SOP (3907), Conducting the Transfer of Biostatistical Deliverables SOP (3908) and the SAS Programming and Validation Plan describes the quality control procedures that are performed for all SAS programs and output. Quality control is defined here as the operational techniques and activities undertaken to verify that the SAS programs produce the output by checking for their logic, efficiency and commenting and by review of the produced output.

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