April 18th 2023

The Novatech logo was removed from the first page of the *STATISTICAL ANALYSIS PLAN: A PHASE 1 RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, DOSEESCALATION, SAFETY AND PHARMACOKINETIC STUDY OF LMN-101 INHEALTHY VOLUNTEERS* in order to submit it in the correct PDF/A file format to clintrials.gov.

STATISTICAL ANALYSIS PLAN
A PHASE 1 RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, DOSE-ESCALATION, SAFETY AND PHARMACOKINETIC STUDY OF LMN-101 IN HEALTHY VOLUNTEERS

Protocol No.: CAM01

Product Code: LMN-101

PREPARED FOR: Lumen Bioscience, Inc.
1441 N. 34th Street, Suite 300
Seattle, WA 98103, USA
+01 (206) 899-1904

PREPARED BY: Novotech (Australia) Pty Ltd
Level 3, 235 Pyrmont Street
Pyrmont, NSW, 2009
Australia

DATE OF ISSUE: 18 March 2020 (Final Version 2.0)

VERSION/STATUS: Final Version 2.0

VERSION DATE: 18 March 2020

AUTHOR: Lucas Thornton

SAP APPROVAL

By my signature, I confirm thatthis SAP has been reviewed by Lumen Bioscience, Inc., and has been approved for use on the CAM01 study:

Name	Title / Company	Signature	Date
Jan Agosti, MD	Chief Medical Officer, Lumen Bioscience, Inc.	rT D	-3 / t 6/?J)2.0
Mastan Shaik	Pharmacometrician, Novotech and CNS	Signature: [signature] Electronically signed by: Mastan Shaik Reason: I have reviewed Date: 2020-03-23 10:04:49+10:00 Email: Mastan.Shaik@clinical.net.au	
Lucas Thomton	Senior Biostatistician, Novotech and CNS	Signature: L Thornton Electronically signed by: Lucas Thomton Reason: I am the Author Date: 2020-03-23 11:49:53+11:00 Email: Lucas.Thomton@novotech-cro.com	

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1. INTRODUCTION

The following Statistical Analysis Plan (SAP) provides the outline for the statistical analysis of the data from the CAM01study.

The planned analyses identified in this SAP may be included in clinical study reports (CSRs), regulatory submissions, or future manuscripts. Also, post hoc exploratory analyses not necessarily identified in this SAP may be performed to further examine study data. Any post hoc, or unplanned, exploratory analyses performed will be clearly identified as such in the final CSR.

2. PROJECT OVERVIEW

2.1 Study Design

The study will consist of two-parts: Part A, an open-label administration of a single dose of LMN-101 and Part B, a randomized, double-blind, placebo-controlled, dose-escalation study of 3 dose levels of LMN-101.

In Part B, healthy volunteers will take LMN-101 or placebo orally at one of three dose levels three times daily over 28 days. Study observation will continue until 4 weeks after the last dose of study drug. Healthy volunteers will be recruited from the community by media and from the existing clinical research center population of healthy volunteers. Individuals meeting all inclusion and exclusion criteria will be sequentially assigned to Part A and then Part B. In Part A, participants will be assigned to a single dose of 3000 mg PO given as six 500-mg capsules of LMN-101 (2 participants).

In Part B, participants will be sequentially assigned to escalating dose regimens and will be randomized within each dose regimen to active or placebo treatment:

- 300 mg PO three times daily (TID) given as a single 300-mg capsule of LMN-101 orally for 28 days (4 participants) or identical-appearing placebo capsule (2 participants).
- 1000 mg PO TID given as two 500-mg capsules of LMN-101 orally three times daily for 28 days (4 participants) or identical-appearing placebo capsules (2 participants).
- 3000 mg PO TID given as six 500-mg capsules of LMN-101 orally three times daily for 28 days (4 participants) or identical-appearing placebo capsules (2 participants).

For both study parts, protocol-specified evaluations and procedures will be performed on days 1-2 and at one- to two-week intervals during dosing. Study observation will continue until 4 weeks after the last dose of study drug. For Part A, the follow up visit occurs on Day 29, while for Part B the follow up visit occurs on Day 56.

Enrolment is planned for 20 participants: Part A, 2 participants, and Part B 18 participants (LMN-101: 12 participants; placebo: 6 participants), 6 per dose cohort (LMN-101: 4 participants per dose cohort; placebo: 2 participants per dose cohort).

Study Days are defined as consecutive calendar days beginning from the start time of the first study drug administration for each participant (Day 1). Protocol-specified evaluations and procedures will be performed on Days 1, 2, 8, 15, 28 (Part B only), and 29, with an additional evaluation 4 weeks after the final dose at Day 56 for Part B. There will be an interim safety review between each dose cohort. Study observations will continue until 4 weeks (± 1 week) after the last dose of study drug.

2.2 Objectives

2.2.1 Primary Objective

The primary objective of this study is to determine the safety and tolerability of LMN-101.

2.2.2 Secondary Objectives

The secondary objectives of this study are to determine:

- Serum pharmacokinetics (PK) of LMN-101; and
- Formation of anti-drug antibodies.

2.3 Endpoints

2.3.1 Primary Endpoint

The primary endpoint will be safety and tolerability of LMN-101.

2.3.2 Secondary Endpoints

The secondary endpoints for this study are:

- Peak serum VHH concentration following administration of the initial dose and peak serum VHH concentration following a course of treatment (if systemic absorption is observed).
- Area under the serum VHH concentration versus time curve (AUC) following administration of the initial dose and following a course of treatment (if systemic absorption is observed).
- Induction of serum anti-VHH IgG antibodies (if systemic absorption is observed).

2.4 Sample Size

A maximum of 20 healthy volunteers will be enrolled in this study, consisting of 2 in Part A and 18 in Part B: cohorts 1 to 3. If a participant was enrolled and discontinued before starting study drug, they will be replaced in the study. A participant who withdraws after dosing but before completing the full study will be replaced if they have not completed at least three weeks of study drug (apart from Part B, Cohort 3 where there will be no replacements).

The sample size is not based on formal power calculations as this study is designed only to provide an initial assessment of the safety and PK of LMN-101 in healthy participants.

2.5 Randomization

This will be a two-part study: Part A, an open-label administration of a single dose of LMN-101 and Part B, a randomized, double-blind, placebo-controlled, dose-escalation study of 3 dose levels of LMN-101.

Two participants in Part A will be allocated to a single dose of 3000 mg PO (orally) treatment of LMN-101. Participants in Part B will be allocated to treatment, according to the master randomization schedule produced by Novotech (Australia) Pty Ltd, manually by the study site.

As Part B participants are enrolled into the study, participants will be assigned to a unique randomization number.

If a participant was enrolled and discontinued before starting study drug, they will be replaced in the study. A participant who withdraws after dosing but before completing the full study will be replaced if they have not completed at least three weeks of study drug. There will be a single set of replacement participants.

Randomization numbers are randomly assigned to treatment according to the specified randomization scheme. In each of Part B cohorts 1 to 3, four randomization numbers will be randomly assigned to LMN-101 and 2 will be randomly assigned to placebo. A maximum of 2 healthy volunteers will be enrolled in Part A and 18 healthy volunteers in Part B: Cohorts 1 to 3.

3. STATISTICAL CONSIDERATIONS

This study is a dose-escalation study with the goal of assessing the safety and tolerability of LMN-101. The general analytical approach for all endpoints will be descriptive in nature. No formal statistical hypothesis testing will be conducted. No p-value will be presented due to the small sample size of this study. Data will be handled and processed according to the sponsor's representative (Novotech (Australia) Pty Ltd) Standard Operating Procedures (SOPs), which are written based on the principles of GCP (Good Clinical Practice.)

3.1 General Considerations

All data collected on the eCRFs will be presented in the data listings and will be listed and sorted by study part, cohort, treatment, subject ID number and visit (timepoint), where applicable. All summaries will present the data by study part and treatment group, as applicable.

Unless otherwise stated, the following statistical approaches will be taken:

- Continuous variables: Descriptive statistics will include the number of non-missing values (N), mean, standard deviation (SD), median, minimum, maximum.

  The appropriate precision for derived variables will be determined based on the precision of the data on which the derivations are based, and statistics will be presented in accordance with the abovementioned rules.

  When reporting descriptive statistics, the following rules will apply in general:

  - n will be an integer.
  - Arithmetic mean, SD and median will use 1 decimal place more than the original data to a maximum of 3 decimal places.
  - Minimum and maximum will be reported using the same number of decimal places as the original value.
  - Geometric mean, geometric SD, and geometric CV% will be employed for PK parameter summaries.

- Categorical variables: Descriptive statistics will include frequency counts and percentages per category. Percentages will be rounded to one decimal place, with the denominator being the number of participants in the relevant population with non-missing data, unless otherwise specified.

  Percentages displayed based on continuous data (e.g., percentage changes from Baseline) will be displayed to 1 decimal place. Unless otherwise stated, the denominator for the percentages will be based on the number of study participants in the respective analysis set and treatment arm.

- Baseline: Baseline values will be defined as the last valid, non-missing observation for each participant prior to dosing of study drug on Day 1.

- Follow-up: For Part A, the follow up visit occurs on Day 29, while for Part B the follow up visit occurs on Day 56. Follow-up data is defined as the last valid, non-missing observation for each participant after the final day 1 dosing event for Part A and final day 28 dosing event for Part B. For Part B participants follow up data will be collected on day 56 and will be required for comparison to in study data for hematology, chemistry and coagulation results. For participants where no follow up data is available, there will be no comparison between follow up data and in study data.

- Repeat/Unscheduled assessments (Safety): No repeat/unscheduled assessments will be included in summary presentations (Tables, Figures). All repeat/unscheduled

assessments captured in the Electronic Data Capture (EDC) system will be presented in the data listings.

- Assessment windows: All assessments will be included in the data listings and no visit windows will be applied to exclude assessments that were performed outside of the protocol specified procedure windows.
- Date and time display conventions: The following display conventions will be applied in all outputs where dates and/or times are displayed:
    - Date only: YYYY-MM-DD
    - Date and time: YYYY-MM-DD/HH:MM

  If only partial information is available, unknown components of the date or time will be presented as 'NK' (not known), i.e., '2016-NK-NK'. Times will be reported in military time.

3.2 Key Definitions

- Baseline: The baseline value is defined as the last available valid (quantifiable continuous or categorical value), non-missing observation for each participant prior to first study drug administration. Repeat and unscheduled assessments will be included in the derivation of the baseline values.
- Change from Baseline: The change from baseline value is defined as the difference between the result collected/derived at a post-baseline visit/time point and the baseline value.

  The change from baseline value at each post-baseline visit/time point will be calculated for all continuous parameters using the following formula:

    - Change from Baseline Value = Result at Visit/Time Point – Baseline Value

  The change from baseline value will only be calculated if the specific post-baseline visit/time point result and the baseline value for the parameter are both available and will be treated as missing otherwise.
- Percent Change from Baseline

  Percent Change from Baseline at each post-baseline visit/time point will be calculated for all continuous parameters using following formula

    - % Change from Baseline =100 x [(Post-Dose Visit Value – Baseline) / Baseline]
- Study day: The study day of an event is defined as the relative day of the event starting with the date of the first study drug administration (reference date) as Day 1 (there will be no Day 0).

  Relative days for an event or measurement occurring before the date of first dose will be calculated as follows:

    - Relative Day =Event Date – Date of First Dose

  The relative day for an event or measurement occurring on or after the reference date to the date of the last dose will be calculated as follows:

    - Relative Day =Event Date – Date of First Dose+1

  There is no relative Day 0. Relative day will not be calculated for partial dates in cases where relative day is shown in a data listing.

3.3 Hypothesis Testing

No inferential analysis will be included.

3.4 Multiple Comparisons and Multiplicity Adjustments.

Not applicable.

3.5 Handling of Dropouts or Missing Data

Missing, unused, or spurious data will be handling in the following manner:

- There will be no imputations or substitution made for missing safety data points.
- For the PK analyses, imputations will be made for missing data points as noted in section 9.

For TEAEs and concomitant medications determination, the following rules will be followed:

a. If the date/time is present, the full date/time will be compared to the date/time of first study drug administration.

b. If time is missing (start and/or end time), the event/medication dates will be used for TEAE/concomitant medication determination. I.e. if the event/medication have the same start/stop date as the Adverse Event (AE)/medications, the event/medication will automatically be classified as a TEAE/concomitant medication (unless a partial time confirms the event/medication to have started/been given pre or post treatment).

c. If dates are completely missing (start and end dates), the event/medication will automatically be classified as a TEAE/concomitant medication.

d. For TEAEs, if the event end date (time) is prior to first study drug administration, the event will not be classified as a TEAE. For concomitant medications, if the medication start date (time) is post the first study drug administration, the medication given will be classified as a Concomitant medication.

e. If only the AE start year/concomitant medication end year is present and is the same or is after the first study drug administration year unit, the event/medication will be classified as a TEAE/Concomitant medication.

f. If the TEAE start month and year/concomitant medication end month and year are present and are the same or after the first study drug administration month and year combination, the event/medication will be classified as a TEAE/Concomitant medication.

Conversion of categorical values

In some instances, continuous variables are expressed as a range (i.e. < 10). In such cases these values may be converted to a continuous value. The rule for expression such values are as follows:

- Value = the categorical boundary
- As an example, a value of <10 may be converted to 10
- Such substitutions will be clearly documented in the footnotes of relevant outputs.

All other data will be analysed as collected and missing values will not be imputed nor replaced.

End of Study (EOS) vs. Early Termination (ET)

For any analyses based on safety data, data for participants that terminates the study early (ET assessments) will be summarised with the EOS assessments of participants that complete the study as planned.

3.6 Coding of Events and Medications

Adverse event verbatim terms will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) Version 23.0 or the latest version in use. Terms will be coded to the full MedDRA hierarchy, but the System Organ Class (SOC) and Preferred Terms (PT) will be of primary interest for the analysis.

Prior and concomitant medications will be coded using the World Health Organization Drug Dictionary (WHO-DD, Sep-2019) or the latest version in use. Medications will be mapped to the full WHO-DD Anatomical Therapeutic Chemical (ATC) class hierarchy, but PTs will be of primary interest in this analysis.

3.7 Treatment assignment and treatment groups

TFLs will be presented by treatment groups, and for all study participants in the given analysis set, where applicable.

The following order will be used in the TFLs (with the treatment arm displayed, as applicable to the output):

- Part A: 3000 mg LMN-101
- Part B: 300 mg LMN-101 PO TID
- Part B: 1000 mg LMN-101 PO TID
- Part B: 3000 mg LMN-101 PO TID
- Part B: LMN-101 Overall
- Part B: Placebo
- Overall

4. ANALYSIS SETS

In this study, two analysis sets are defined: The Safety and PK Analysis Sets.

Any additional exploratory analysis not specified in the SAP will be identified in the final CSR as exploratory post hoc analyses. This may include the addition of additional study populations or subgroups of interest.

The number and percentage of participants in each analysis set will be summarized.

4.1 Analysis Sets Descriptions

4.1.1 Safety Analysis Set

The safety analysis set will be defined as a modified Intention-to-treat (mITT) analysis set which will include all randomized participants meeting inclusion criteria who receive at least one dose of study drug. The safety analysis set will be based on actual treatment received if different from randomized treatment.

4.1.2 Pharmacokinetic (PK) Analysis Set

The PK analysis set will be defined as a per Protocol population which consists of all randomized subjects who complete the full course of study drug and who have an adequate quantifiable and interpretable serum concentrations of VHH. Subjects with protocol violations to be assessed on a subject-by-subject basis for inclusion in the PK Population. The sponsor will confirm the eligibility of subjects after a review of the serum concentrations data of VHH. Patients who receive only placebo will be excluded from the PK set. PK parameters will be excluded from the analysis and summary statistics where there are inadequate serum concentrations of VHH. PK analysis of serum VHH will be conducted using the Pharmacokinetic analysis set.

5. PARTICIPANT DISPOSITION AND ANALYSIS POPULATIONS

Outcomes will be summarized as noted in section 3.1 by treatment group and will be based on the safety analysis set. All data will be listed by treatment group.

5.1.1 Participant Disposition

A detailed description of participant accountability will be generated by treatment group including count of:

- Number of participants screened.
- Number of participants randomized.
- Number (%) of participants who terminated the study early and the primary reason for early termination.
- Number (%) of participants included in each analysis set.

A listing of participant disposition with study discontinuation will be presented. Reason for consent withdrawal, date of death, primary reason for death and whether an autopsy was performed will also be listed.

Screening failures and reason for screening failure, will be noted in the listing of eligibility criteria. All withdrawals from the study, taking place on or after study drug administration, will be fully documented in the body of the clinical study report (CSR).

6. PROTOCOL DEVIATIONS

Protocol deviations will be presented for each participant in the by-participant data listings for the enrolled set. All data will be listed (by-participant listings) by treatment group.

Prior to database lock, all protocol deviations will be reviewed by medical monitors and assigned a status of important protocol deviation/or not.

Protocol deviations may include, but are not limited to the following:

- Violation of inclusion/exclusion criteria
- Missed or out of window assessments
- Non-compliance to study treatment
- Use of prohibited concomitant medications, treatments or procedures
- Deviation from study specific instructions.

7. DEMOGRAPHIC AND BASELINE INFORMATION

Demographic and baseline information will be summarized as noted in section 3.1 by treatment group and will be based on the safety analysis set.

7.1 Demographics

7.1.1 Endpoints

- Age (years)
- Sex
- Race
- Ethnicity
- Childbearing Potential (as a % of all female participants)
- Height (cm)
- Weight (kg)
- BMI (kg/m^2)

7.2 Medical history

Medical history will be coded using medical dictionary for regulatory activities (MedDRA®) and will be listed.

7.3 Serology (HIV/HBsAg/HCV Ab)

The following viral detection results (serologies) at Screening, will be listed for each participant: HIV 1 Antibody/ HIV 2 Antibody, HBsAg and HCV Antibody.

7.4 Urine Drug Test

Urine drug test screen/results at Screening will be listed for each participant.

7.5 Informed Consent and Eligibility

Informed consent date and inclusion/exclusion eligibility criteria information, including any criteria not met, will be listed for each participant.

8. STUDY DRUG ADMINISTRATION

Study drug administration results and drug accountability will be presented based on the safety analysis set.

Two by-participant data listings will be generated for study drug administration. The first listing will include date and time of administration, participant fasting status 1 hour before and after dosing, dose per administration and whether the dose was given per protocol for Day for Parts A and B.

Drug accountability over the complete course will be listed for Part B and will include date dispensed/returned, missed doses, date of missed dose, dose size missed, reason for missed dose, type of tablet dispensed, and number of tablets dispensed. Study drug compliance will be calculated by participant as follows:

$$Study\ Drug\ Compliance(\%) = (1 - \frac{\#\ Tablets\ returned}{\#\ Tablets\ dispensed}) * 100$$

9. PHARMACOKINETICS (PK)

Pharmacokinetics will be analyzed using the PK analysis set. If VHH concentration determination of serum samples indicates systemic absorption, then PK analysis will be performed on serum VHH concentration data.

The serum levels of VHH will be determined for both Part A (a single dose treatment) and Part B (MAD, thrice daily treatment) groups before the first dose (pre-dose) and at 2 hours (Day 1), and 24 hours (Day 2) after the first post-dose. If serum levels of VHH are quantified, serum pharmacokinetics of VHH will be determined and summarized.

The serum levels of VHH will be determined for Part B (MAD, thrice daily treatment) groups on Day 8, day 28 and day 29. If serum levels of VHH are quantified and systemic absorption is observed serum pharmacokinetics of VHH will be determined and reported.

All PK data collected at scheduled and unscheduled visits will be included in the listings, but only results collected as scheduled visits will be included in the summary tables.

Stool samples will be collected, and supernatant stored for potential future analysis if required. Fecal concentrations of VHH will be considered and analyzed (based on new SAP) if requested or recommended by the Regulatory Authority.

Pharmacokinetic parameter estimation:

Definition and estimation of PK parameters are described below. PK parameters will be determined from the levels of VHH from PK analysis set for both Part A and Part B subjects. PK parameters will be determined for each subject by non-compartmental analysis using PhoeniX WinNonlin software (version 8.1 or higher). The following parameters (but not limited to) will be derived, where appropriate from the individual concentration versus time profiles of VHH.

Parameter	Definition
C_{max}	Maximum observed peak VHH concentration following administration of the initial dose and a course of treatment if systemic absorption is observed
C_{last}	Last observed concentration, obtained directly from concentration data
AUC_{0-t}	The area under the concentration-time curve, from 0 (time of Dosing) to the last time point with measurable analyte concentration following administration of the initial dose and a course of treatment if systemic absorption is observed, calculated by the linear up and the log down trapezoidal method calculated as: $$\mathrm{AUC}(t_1 - t_2) = \sum_{t1}^{t2} \frac{(C(t_1)+C(t_2))}{2} * (t_2 - t_1)$$
AUC_{0-inf}	Area under the concentration-time curve extrapolated to infinite time calculated as $$AUC_{0-inf} = AUC_{0-t} + \frac{C_{last}}{\lambda_z}$$

t_{max} Time to reach C_{max} following administration of the initial dose and a course of treatment if systemic absorption is observed. If the maximum observed concentration value occurs at more than 1 time point, t_{max} is defined as the first time point with this value.

λ_z Apparent first order terminal elimination rate constant, estimated using the negative slope of the least square regression analysis of the log concentration versus time data for the terminal linear portion of the curve.

$t_{½}$ Terminal elimination half-life computed as

$$t_{½} = \frac{\ln(2)}{\lambda_z}$$

Actual sampling times will be used for the PK analysis and if the actual sampling time is not recorded, the nominal sampling time will be used.

All concentration values reported as no results (not collected or not determined) values will be treated as missing. For the calculation of concentration summaries, all concentrations below the quantifiable limit (BLQ) will be treated as 0 except for geometric statistics (geometric mean and geometric CV%). For the purpose of calculating PK parameters and plotting mean and individual concentration-time profiles, BLQ values will be treated as 0 prior to the first quantifiable concentration. After the first measurable concentration, subsequent BLQ values are treated as missing.

Summary statistics (n, nBLQ, mean, standard deviation [SD], coefficient of variation [CV%], median, minimum, maximum, geometric mean, geometric SD, and geometric CV%) will be calculated for each time point. Geometric mean, SD, CV% are only for PK parameter summaries.

Pharmacokinetic parameters for VHH will be listed and summarized descriptively, including n, arithmetic mean, SD, minimum, median, maximum, coefficient of variation [CV(%)], geometric mean (GM), geometric SD, geometric CV%; geometric CV% calculated as the square root of the exponentiated SD of the natural log transformed data (SQRT(exp(sln^2)-1), where appropriate. For t_{max}, only n, minimum, median, and maximum will be reported.

When reporting individual values and descriptive statistics for PK concentrations of VHH, the following rules will apply regarding rounding and precision:

- Individual values for PK concentration data will be reported to the same level of precision as received from the bioanalytical laboratory.
- Descriptive statistics for PK concentration data will be reported to the same level of precision as the individual data for the minimum and maximum, and to 1 additional decimal place or 1 additional significant figure– depending on the reporting format of the original data with a maximum of 4 significant digits - for the mean (arithmetic and geometric), median and SD. The 95% CI for the geometric mean will use 1 decimal place more, or 1 significant figure more – depending on the reporting format of the original data – than the value around which the confidence interval is constructed.
- Geometric CV will be reported as a percentage to 1 decimal place.

When reporting individual values and descriptive statistics for PK parameters the following rules will apply with regard to rounding and precision:

- Individual values for PK parameters will be reported to 3 significant figures.
- Descriptive statistics for PK parameters should be rounded to 4 significant figures for the mean, median and SD and to 3 for the others.
- Data listings containing all documented data and all derived data will be generated.
- Missing data will not be imputed.

9.1 Biostatistical methods

The levels of VHH will be listed for all timepoints collected. Concentrations will be summarized for all scheduled timepoints by study part, per dose cohort and total. Timepoints will be calculated and listed in terms of study days elapsed following initial dose and will be employed for determination of area under the concentration time curve rather than the nominal study timepoint.

The area under the VHH concentration-time curve, from time t_1 to t_2 hours where the values of t_1-t_2 are:

Part A

- Pre-dose to 2 hours after the initial dose.
- Pre-dose to 24 hours post initial dose

Part B

- Pre-dose to 2 hours after the initial dose.
- Pre-dose to day 29 post initial dose.

Figures representing mean ± SE (standard error) will be included for VHH concentrations and percentage change from baseline of Part A, Part B: Cohorts 1, 2, 3 and Part B: Placebo.

10. PHARMACODYNAMICS (PD)

Not applicable

11. EFFICACY

Not applicable

12. SAFETY

Safety endpoints will be analysed using the safety analysis set. TFLs will be presented as specified in section 3.1 by treatment group.

12.1 Adverse Events

12.1.1 Endpoints

- AE
- SAE
- TEAE

AEs and SAEs are defined in the study protocol. TEAEs are defined as adverse events that occurred or worsened following the first administration of study medication.

All AEs will be coded using MedDRA. AE summaries will be restricted to TEAEs only.

Summary tables will include the number of participants (%) experiencing an event and the number of events. Participants will be counted only once at each SOC and PT level of summary.

The TEAE summaries will include:

- Overall Summary of TEAEs
    - Number of TEAEs
    - Number of TEAEs with Toxicity ≥ Grade 3
    - Number of Serious TEAEs
    - Number of Study Drug Related TEAEs (Drug Related: A Possibly or Probably related TEAE)
    - Number of TEAEs leading to study withdrawal
- TEAE and SAE summary by SOC and PT
    - TEAEs
    - Treatment Emergent SAEs
    - TEAE by relationship to Study Drug
    - TEAE summary by Toxicity Grade

All AEs will be listed and will include verbatim term, PT, SOC, treatment group, relationship to study drug, toxicity grade, seriousness, reason for serious event. outcome, and action taken with regards to the study drug and AE. Separate listings will be created for SAEs and events leading to study drug withdrawal.

12.2 Concomitant medication

Prior medication will be defined as any medication stopped prior to the first dose of study drug.

Concomitant medications will be summarized by ATC class Level 3 and PT. Within each category, the number of participants who used the medication (count and percentage) will be presented. Participants who used the same medication on multiple occasions will only be counted once in the specific category (PT). PTs will be sorted alphabetically. In addition to the summaries by the coded terms, the number of participants who used at least one concomitant medication during the study will be presented.

All information that was collected on the Concomitant Medication eCRF as well as the coded WHO-DD terms will be included in the listings.

Prior medications will be listed only.

12.3 Safety Laboratory

Blood samples will be collected at the time points specified in the schedule of events (refer to the Protocol) to conduct haematology, serum chemistry, and coagulation analyses.

12.3.1 Endpoints

Hematology:

- Hemoglobin
- Leukocytes
- Neutrophils
- Eosinophils
- Monocytes
- Lymphocytes
- Basophils
- Platelets
- Other

Serum Chemistry:

- Sodium
- Potassium
- Calcium
- Magnesium
- Phosphate
- Creatinine
- Albumin
- AST
- ALT
- Alkaline phosphatase
- Total bilirubin
- eGFR
- Other

Coagulation:

- aPTT
- INR

All laboratory data collected at scheduled and unscheduled visits will be included in the listings, but only results collected as scheduled visits will be included in the summary tables excepts for baseline assessment where unscheduled visit prior to first study medication could be considered for baseline summary.

Results for individual parameters may be reported in different units depending on the analysing laboratory. If required, the results (and the corresponding normal range cut-off values) for

individual parameters may be converted to International System of Units (S.I.) units to summarize the data.

For all the parameters where a unit value has been reported, the parameter names that will be used in the outputs will comprise of the test name and the unit of measure, for example, 'Albumin (g/L)'. For the urinalysis parameters, the parameter name will be the reported test name only. Parameters will be sorted alphabetically within tables and listings.

For all parameters where a normal range limit value was reported, the normal range will be derived based on the available lower and upper limit values and any reported mathematical symbols. If both a lower and upper limit value is available, the normal range will be presented as '(Lower, Upper)'.

The reported results for each parameter with a defined normal range will be classified ('Low', 'Normal', 'High') in relation to the defined normal range limits. If a result is equal to the normal range cut-off value, the result will be considered 'Normal'.

The decimal precision to which the summaries for each parameter will be based on the maximum number of decimals to which the reported result or the normal range limits are presented to in the raw data. The results and normal ranges will be displayed to the same decimal precision in the listings.

If a result for a parameter that is normally considered continuous is reported as a range (i.e., the result for basophils is reported as '<0.01' for a single time point), the result may be converted to a numeric as noted in section 3.5 to contribute to the derivations and the summary statistics. Any conversion rules that are applied will be highlighted in the footnotes of the affected tables and listings. The original reported result value will however be included in the listing.

The haematology, coagulation and serum chemistry results tables will present summary statistics for each laboratory parameter within the specific test panel. For each parameter, summaries will be presented for the baseline and each scheduled post-baseline visit. In addition, summaries will be presented for the change from baseline values at each scheduled post-baseline visit.

Additionally, counts (%) of number participants with values out of normal range at each scheduled time point will also be presented along with shift tables that will represent the changes in normal range categories across post-baseline time points. Clinical significance for out of range values will be listed only.

12.4 Vital Signs

The following vital signs measurements will be taken at the time points specified in the Schedule of Events (refer to the Protocol).

12.4.1 Definition of variables

- Heart Rate (beats/min),
- Systolic blood pressure (SBP) (mmHg),
- Diastolic blood pressure (DBP) (mmHg),
- Respiratory rate (breaths/min),
- Temperature (ºC).

All vital signs data collected at scheduled and unscheduled visits will be included in the listings, but only results collected as scheduled visits will be included in the summary tables.

The parameter names that will be used in the outputs will comprise of the test name and the unit of measure, for example, 'Systolic Blood Pressure (mmHg)'. Parameters will be sorted in

the order that the measurements were collected in on the Vital Signs eCRF page within the tables and listings.

The change from baseline to the pre-dose assessment at each post-baseline visit will be calculated for all parameters. An assessment of clinical significance for each result will be reported.

The decimal precision to which the summaries for each parameter will presented will be based on the maximum number of decimals to which the results were reported on the eCRF.

Vital signs measurements will present summary statistics for the results at the baseline and each scheduled post-baseline visit for each of the parameters. In addition, summaries will be presented for the change from baseline values and interpretation of each result at each scheduled post-baseline visit.

The listings of vital signs measurements will include all the information collected. In addition, the observations that are used as the baseline record (value) for each parameter will be flagged, and the change from baseline values at each post-baseline visit will be presented.

12.5 Physical Examination

Full physical examination and targeted physical assessments will be listed for all time points.

12.6 Pregnancy Test Results

All information related to pregnancy testing (urine and serum based) will be listed. This listing will include all pregnancy test results collected during the study.

13. IMMUNOGENICITY

Immunogenicity endpoints will be analysed using the PK analysis set if systemic absorption of LMN-101 is observed. Listings will be presented as specified in section 3.1 by treatment group.

13.1 Serum anti-VHH IgG antibodies

Serum samples will be collected at baseline, Day 28 (Part B only), and end of study for measuring for antidrug antibodies if systemic absorption of LMN-101 is observed. If anti-drug antibodies are observed, additional determinations will be performed for antibodies. If antibodies are observed on confirmatory assays, additional testing will be done to measure antibody titers.

Immunogenicity assessments will be listed for all time points.

14. CHANGES TO THE PLANNED ANALYSIS

No changes to the biostatistical methods planned in the protocol were made.

15. INTERIM AND FINAL ANALYSIS

15.1 Interim Analyses

An interim dataset of serum VHH concentration data will produced by an unblinded biostatistician in the form of an Excel® spreadsheet and provided to Lumen Biosciences. The dataset, blinded to subject and treatment data, will determine if PK analysis and Anti-VHH antibody testing is required.

15.2 Final Analysis (End of Study)

The final analysis will be conducted after all participants have completed the study, the clinical database has been locked, the analysis sets have been approved and the study has been unblinded.

The final analysis will be based on the final version of the SAP. Any deviations from the planned analysis will be documented in the CSR.

16. SOFTWARE

The following software will be used to perform the statistical analyses:

- SAS® Version 9.2 or higher (SAS Institute, Cary, North Carolina, USA.)
- PhoeniX WinNonlin version 8.1 or higher (Certara USA, Inc., Princeton, NJ, USA.)

17. TABLES

No.	Title	Analysis Set
	PARTICIPANT DISPOSITION AND ANALYSIS SETS	
14.1.1	Summary of Participant Enrollment and Disposition	Safety
	DEMOGRAPHIC AND BASELINE INFORMATION	
14.1.2	Summary of Demographics and Baseline Characteristics	Safety
14.1.3	Summary of Medical History, by SOC and PT	Safety
14.1.4	Summary of Study Drug Compliance for Part B	Safety
	PHARMACOKINETIC ANALYSIS	
14.2.1.1	Summary of Serum Concentrations of VHH by Timepoint	PK
14.2.1.2	Summary of Serum PK Parameters of VHH	PK
	SAFETY	
14.3.1.1	Summary of Concomitant Medication	Safety
14.3.3.1	Overall Summary of Treatment-Emergent Adverse Events	Safety
14.3.3.2	Summary of Treatment-Emergent Adverse Events, by SOC and PT	Safety
14.3.3.3	Summary of Serious Treatment-Emergent Adverse Events, by SOC and PT	Safety
14.3.3.4	Summary of Treatment-Emergent Adverse Events by Toxicity, by SOC and PT	Safety
14.3.3.5	Summary of Treatment-Emergent Adverse Events by Relationship, by SOC and PT	Safety
14.3.4.1.1	Summary of Hematology & Coagulation by Timepoint	Safety
14.3.4.1.2	Summary of Hematology & Coagulation Shifts from Baseline (Low, Normal, High)	Safety
14.3.4.1.3	Summary of Hematology & Coagulation Shifts from Follow-up (Low, Normal, High)	Safety
14.3.4.2.1	Summary of Serum Chemistry by Timepoint	Safety
14.3.4.2.2	Summary of Serum Chemistry Shifts from Baseline (Low, Normal, High)	Safety

14.3.4.2.3	Summary of Serum Chemistry Shifts from Follow-up (Low, Normal, High)	Safety
14.3.4.4.1	Summary of Vital Signs by Timepoint	Safety
14.3.4.4.2	Summary of Vital Signs Shifts from Baseline (Low, Normal, High)	Safety
	IMMUNOGENICITY	
14.4.1	Summary of Immunology by Timepoint	Safety
14.4.2	Summary of Immunology Shifts from Baseline (Low, Normal, High)	Safety

18. LISTINGS

No.	Title	Analysis Set
	PARTICIPANT DISPOSITION AND ANALYSIS POPULATIONS	
16.2.1.1	Analysis Populations	Safety
16.2.1.2	Participant Disposition	Safety
	PROTOCOL DEVIATIONS	
16.2.2.1	Protocol Deviations	Safety
	DEMOGRAPHIC AND BASELINE INFORMATION	
16.2.4.1	Demographics and Baseline Characteristics at Screening	Safety
16.2.4.2	Serology	Safety
16.2.4.3	Medical History	Safety
16.2.4.4	Urine Drug Screen/Test	Safety
16.2.4.5	Eligibility Criteria	Safety
16.2.4.6	Prior Medication	Safety
16.2.5.1	Randomization	Safety
16.2.5.2	Study Drug Administration	Safety
16.2.5.3	Study Drug Accountability	Safety

No.	Title	Analysis Set
16.2.5.4	Missed Doses	Safety
16.2.5.5	Pregnancy Test	Safety
	PHARMACOKINETIC	
16.2.6.1	PK Serum Sample Collection Times	PK
16.2.6.2	Individual Serum Concentrations of VHH	PK
16.2.6.3	Individual Serum PK Parameters of VHH	PK
16.2.6.4	Stool Collection	PK
	SAFETY	
16.2.7.1	Adverse Events	Safety
16.2.7.2	Serious Adverse Events	Safety
16.2.7.3	Adverse Events leading to Study Drug Withdrawal	Safety
16.2.8.1.1	Hematology & Coagulation	Safety
16.2.8.1.2	Abnormal Hematology & Coagulation	Safety
16.2.8.2.1	Serum Chemistry	Safety
16.2.8.2.2	Abnormal Serum Chemistry	Safety
16.2.9.1	Vital Signs	Safety
16.2.9.3	Physical Examination	Safety
16.2.10.1	Concomitant Medication	Safety
	IMMUNOGENICITY	
16.2.11.1	Immunology – Anti-VHH Antibodies	Safety
16.2.11.2	Abnormal Immunology – Anti-VHH Antibodies	Safety

19. FIGURES

No.	Title	Analysis Set
14.2.1.1	Mean (+/-SE) Serum Concentrations of VHH by Day – Baseline to Day 2 (24hrs)	PK
14.2.1.2	Log10Mean (+/-SE) Serum Concentrations of VHH by Day – Baseline to Day 2 (24hrs)	PK
14.2.1.3	Mean (+/-SE) Serum Concentrations of VHH by Days – All Timepoints	PK
14.2.1.4	Log10 Mean (+/-SE) Serum Concentrations of VHH by Days – All Timepoints	PK
14.2.2.1	Individual Serum Concentrations of VHH by Day – Baseline to Day 2 (24hrs)	PK
14.2.2.2	Log10 Individual Serum Concentrations of VHH by Day – Baseline to Day 2 (24hrs)	PK
14.2.2.3	Individual Serum Concentrations of VHH by Days – All Timepoints	PK
14.2.2.4	Log10 Individual Serum Concentrations of VHH by Days – All Timepoints	PK

20. REFERENCES

1) Clinical Study Protocol Version 1.1 dated 15 October 2019.
2) Protocol Clarification Letter, dated 30th January 2020.

CAM01: Mock Tables: Table of Contents

Tables

GENERAL COMMENTS

- Where a count is 0, the percentage will not be shown (e.g. 0(0.0%) will be displayed as 0)
- Unless otherwise stated, parameters will be listed in alphabetical order
- The minimum and maximum values will be presented to the same number of decimal places as recorded in the electronic Case Report Form (eCRF)
- Mean (95%CI), SD, and Median will be presented to one more decimal place than the raw data
- CV% will be presented to one decimal place; p-values will be presented to 4 decimal places
- Percentages will be rounded to one decimal place, with the denominator being the number of subjects in the relevant population with non-missing data, unless otherwise specified
- Change from Baseline (calculated as):

$$Change\ from\ baseline = new\ value - baseline\ value$$

- Change from Follow-up (calculated as):

$$Change\ from\ follow\ up = new\ value - follow\ up\ value$$

- Unscheduled visits will be excluded from summary tables
- Names and order of Treatment Groups:
  - Part A: LMN-101 3000mg
  - Part B: LMN-101 300mg
  - Part B: LMN-101 1000mg
  - Part B: LMN-101 3000mg
  - LMN-101 Overall
  - Placebo
  - Overall

- Names of visits:
  - Screening
  - Day 1: Pre-dose
  - Day 1: 2 hours
  - Day 2: 24 hours
  - Day 8
  - Day 15
  - Day 28
  - Day 29: Follow-up (Part A only)
  - Day 29 (Part B only)
  - Day 56: Follow-up (Part B only)
  - Early Termination

    - Unscheduled

- Column widths and text-wrapping may be altered in final output in order to best present the data
- Footnotes may be added/amended if required

Sponsor: Lumen Bioscience, Inc.
Protocol: CAM01

Database Lock: yyyy-mm-dd

Table 14.1.1 Summary of Subject Enrollment and Disposition (All Randomized)

	Part A		Part B				
	LMN-101 3000 mg (N=xx)	LMN-101 300 mg (N=xx)	LMN-101 1000 mg (N=xx)	LMN-101 3000 mg (N=xx)	LMN-101 Overall (N=xx)	Placebo (N=xx)	Overall (N=xx)
Number of Subjects Screened							xx
Number of Subjects Randomized	xx	xx	xx	xx	xx	xx	xx
Number of Subjects who Completed the Study as Planned	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Withdrawn	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Primary Reason for Non-Completion of Study							
Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Death	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Failure to Meet Randomisation Criteria	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost to Follow-up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Non-compliance with Study Drug	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Physician Decision	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pregnancy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Protocol Deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Screen Failure	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Site Terminated by Sponsor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Study Terminated by Sponsor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Technical Problems	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrawal by Subject	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects included in							
Safety Analysis Set	x (xx.x%)	x (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PK Analysis Set	x (xx.x%)	x (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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Sponsor: Lumen Bioscience, Inc.
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Database Lock: yyyy-mm-dd

Table 14.1.2 Summary of Demographics and Baseline Characteristics (Safety Analysis Set)

		Part A	Part B					
		LMN-101 3000 mg (N=xx)	LMN-101 300 mg (N=xx)	LMN-101 1000 mg (N=xx)	LMN-101 3000 mg (N=xx)	LMN-101 Overall (N=xx)	Placebo (N=xx)	Overall (N=xx)
Age (years) at Screening	n	xx	xx	xx	xx	xx	xx	xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Minimum	xx	xx	xx	xx	xx	xx	xx
	Maximum	xx	xx	xx	xx	xx	xx	xx
Sex n(%)	Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Race n(%)	Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Black or African	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Aboriginal or Torres Strait Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ethnicity n(%)	Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Unknown	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

SD: Standard Deviation

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Table 14.1.2 Summary of Demographics and Baseline Characteristics (Safety Analysis Set) – Continued

		Part A LMN-101 3000 mg (N=xx)	Part B LMN-101 300 mg (N=xx)	Part A LMN-101 3000 mg (N=xx)	Part B LMN-101 300 mg (N=xx)	LMN-101 Overall (N=xx)	Placebo (N=xx)	Overall (N=xx)
Height (cm)	n	xx	xx	xx	xx	xx	xx	xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Minimum	xx	xx	xx	xx	xx	xx	xx
	Maximum	xx	xx	xx	xx	xx	xx	xx
Weight (kg)	n	xx	xx	xx	xx	xx	xx	xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Minimum	xx	xx	xx	xx	xx	xx	xx
	Maximum	xx	xx	xx	xx	xx	xx	xx
BMI (kg/m^2)	n	xx	xx	xx	xx	xx	xx	xx
	Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
	Minimum	xx	xx	xx	xx	xx	xx	xx
	Maximum	xx	xx	xx	xx	xx	xx	xx

SD: Standard Deviation

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Table 14.1.3 Summary of Medical History, by SOC and PT (Safety Analysis Set)

System Organ Class (SOC) Preferred Term (PT)	Part A LMN-101 3000 mg (N=xx)	Part B LMN-101 300 mg (N=xx)	Part A LMN-101 3000 mg (N=xx)	Part B LMN-101 300 mg (N=xx)	LMN-101 Overall (N=xx) n (%) m	Placebo (N=xx) n (%) m	Overall (N=xx) n (%) m
Subjects with at least one medical history event	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT4	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT4	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT5	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Etc.							

Note: If a subject has multiple occurrences of a medical history event, the subject is presented only once in the Subject count (n) column for a given System Organ Class and Preferred Term. Occurrences are counted each time in the mentions/Occurrence (m) column.

MedDRA Version xx.x

Programming Note:
- Include all SOCs and all PTERMs.

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Table 14.1.4 Summary of Study Drug Compliance for Part B (Safety Analysis Set)

Part Treatment Group	Timepoint Interval Dispense Study Day	 Return Study Day	Study Drug Compliance (%) n	 Mean	 SD	 Median	 Minimum	 Maximum	 CV%
Part B									
LMN-101 300 mg (N=xx)	Day 1	Day 2	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
	Day 2	Day 8	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
	Day 8	Day 28	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
	Day 28	Day 29	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
LMN-101 1000 mg (N=xx)	Day 1	Day 2	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
	Day 2	Day 8	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
	Day 8	Day 28	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
	Day 28	Day 29	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx

etc.

SD: Standard Deviation; CV: Coefficient of Variation
[1]Baseline is defined as the last valid, non-missing assessment prior to study drug administration on Day 1.

Programming Note:
- Include all treatment groups: Part B: LMN-101 300 mg, Part B: LMN-101 1000 mg, Part B: LMN-101 3000 mg, Placebo.

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Protocol: CAM01

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Table 14.2.1.1 Summary of Serum Concentrations of VHH by Timepoint (PK Analysis Set)

Treatment Group Timepoint	Actual Value (unit)							
	n	n BLQ	Mean	SD	Median	Minimum	Maximum	CV%
Part A: LMN-101 3000 mg (N=xx)								
Day 1 Pre-dose[1]	xx	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
Day 1 2h Post-dose	xx	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
Day 2	xx	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
Part B: LMN-101 300 mg (N=xx)								
Day 1 Pre-dose[1]	xx	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
Day 1 2h Post-dose	xx	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
Day 2	xx	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
Day 8	xx	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
Day 28	xx	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
Day 29	xx	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
Part B: LMN-101 1000 mg (N=xx)								
Day 1 Pre-dose[1]	xx	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
Day 1 2h Post-dose	xx	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
Day 2	xx	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
Day 8	xx	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
Day 28	xx	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx
Day 29	xx	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx.xx

etc.

SD: Standard Deviation; CV: Coefficient of Variation
[1]Baseline is defined as the last valid, non-missing assessment prior to study drug administration on Day 1.
nBLQ: number of datapoints below the quantifiable limit

Programming Note:
- Include all treatment groups: Part A: LMN-101 3000 mg, Part B: LMN-101 300 mg, Part B: LMN-101 1000 mg, Part B: LMN-101 3000 mg.
- Include all scheduled visits/time points.

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Table 14.2.1.2 Summary of PK Parameters (PK Analysis Set)

Parameter: C_{max} at Day 1: 2h post dose

Treatment Group Visit	n	Mean	SD	Median	Minimum	Maximum	%CV	GM	GSD	%GCV	Geometric 95% CI Mean
Part A: LMN-101 3000 mg (N=xx)	xx	xx.x	xx.x	xx.x	xx	xx	xx.x	xx.x	xx.x	xx.x	xx.x, xx.x
Part B: LMN-101 300 mg (N=xx)	xx	xx.x	xx.x	xx.x	xx	xx	xx.x	xx.x	xx.x	xx.x	xx.x, xx.x
Part B: LMN-101 1000 mg (N=xx)	xx	xx.x	xx.x	xx.x	xx	xx	xx.x	xx.x	xx.x	xx.x	xx.x, xx.x
Part B: LMN-101 3000 mg (N=xx)	xx	xx.x	xx.x	xx.x	xx	xx	xx.x	xx.x	xx.x	xx.x	xx.x, xx.x
etc.											

SD: Standard Deviation; CV: Coefficient of Variation; Cmax: Peak VHH Concentration

Programming Note:

- Include all PK Parameters: Cmax at Day 1: 2h post dose, Cmax after Day 1, Tmax , λ_z, $t_{½}$, AUC_{0-2hr}, $AUC_{0-course}$, AUC_{0-inf}
- For all parameters other than tmax; n, mean, SD, median, minimum, maximum, %CV, Geometric mean, geometric SD, geometric CV% and geometric 95% CI.
- For t_{max}, only n, minimum, median, and maximum will be reported.

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Table 14.3.1.1 Summary of Concomitant Medication (Safety Analysis Set)

	Part A:		Part B:				
Anatomic Therapeutic Classification (ATC) Preferred Term (PT)	LMN-101 3000 mg (N=xx) n (%) m	LMN-101 300 mg (N=xx) n (%) m	LMN-101 1000 mg (N=xx) n (%) m	LMN-101 3000 mg (N=xx) n (%) m	LMN-101 Overall (N=xx) n (%) m	Placebo (N=xx) n (%) m	Overall (N=xx) n (%) m
Subjects with at least one Concomitant Medication	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
ATC1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
ATC2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
ATC3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Etc.							

Concomitant medications are medications taken at least once after study drug administration on Day 1. If a subject has multiple occurrences of a medication, the subject is presented only once in the Subject count (n). Occurrences are counted each time in the mentions/Occurrence (m) column.

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Programming Note:
- Include all ATCs and all PTERMs.

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Table 14.3.3.1 Overall Summary of Treatment-Emergent Adverse Events (Safety Analysis Set)

	Part A:		Part B:				
	LMN-101 3000 mg (N=xx) n (%) m	LMN-101 300 mg (N=xx) n (%) m	LMN-101 100 mg (N=xx) n (%) m	LMN-101 3000 mg (N=xx) n (%) m	LMN-101 Overall (N=xx) n (%) m	Placebo (N=xx) n (%) m	Overall (N=xx) n (%) m
Number of subjects reporting at least:							
One TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
One Grade 3 or Higher TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
One Serious TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
One Drug Related TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
One TEAEs Leading to Drug Withdrawal	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Note: A treatment-emergent adverse event (TEAE) is defined as an adverse event that occurred or worsened following the first administration of study drug. If a subject has multiple occurrences of a TEAE, the subject is presented only once in the Subject count (n) column. Occurrences are counted each time in the mentions/Occurrence (m) column.

Related TEAE = A Possibly Related or Related TEAE.
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Table 14.3.3.2 Summary of Treatment-Emergent Adverse Events, by SOC and PT (Safety Analysis Set)

	Part A:		Part B:				
System Organ Class (SOC) Preferred Term (PT)	LMN-101 3000 mg (N=xx) n (%) m	LMN-101 300 mg (N=xx) n (%) m	LMN-101 1000 mg (N=xx) n (%) m	LMN-101 3000 mg (N=xx) n (%) m	LMN-101 Overall (N=xx) n (%) m	Placebo (N=xx) n (%) m	Overall (N=xx) n (%) m
Subjects with at least one TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT4	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT4	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT5	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Etc.							

Note: A treatment-emergent adverse event (TEAE) is defined as an adverse event that occurred or worsened following the first administration of study drug. If a subject has multiple occurrences of a TEAE, the subject is presented only once in the Subject count (n) column for a given System Organ Class and Preferred Term. Occurrences are counted each time in the mentions/Occurrence (m) column.

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Programming Note:
- Include all SOCs and all PTERMs.

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Table 14.3.3.3 Summary of Serious Treatment-Emergent Adverse Events, by SOC and PT (Safety Analysis Set)

	Part A:		Part B:				
System Organ Class (SOC) Preferred Term (PT)	LMN-101 3000 mg (N=xx) n (%) m	LMN-101 300 mg (N=xx) n (%) m	LMN-101 13000 mg (N=xx) n (%) m	LMN-101 3000 mg (N=xx) n (%) m	LMN-101 Overall (N=xx) n (%) m	Placebo (N=xx) n (%) m	Overall (N=xx) n (%) m
Subjects with at least one Serious TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT4	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT3	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT4	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT5	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Etc.							

Note: A treatment-emergent adverse event (TEAE) is defined as an adverse event that occurred or worsened following the first administration of study drug. If a subject has multiple occurrences of a TEAE, the subject is presented only once in the Subject count (n) column for a given System Organ Class and Preferred Term. Occurrences are counted each time in the mentions/Occurrence (m) column.

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Programming Note:
- Include all SOCs and all PTERMs.

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Table 14.3.3.4 Summary of Treatment-Emergent Adverse Events by Toxicity, by SOC and PT (Safety Analysis Set)

	Part A:		Part B:				
System Organ Class (SOC) Preferred Term (PT) Severity	LMN-101 3000 mg (N=xx) n (%) m	LMN-101 300 mg (N=xx) n (%) m	LMN-101 1000 mg (N=xx) n (%) m	LMN-101 3000 mg (N=xx) n (%) m	LMN-101 Overall (N=xx) n (%) m	Placebo (N=xx) n (%) m	Overall (N=xx) n (%) m
Subjects with at least one TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Mild	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Moderate	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Severe	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Life-threatening	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Death	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Mild	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Moderate	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Severe	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Life-threatening	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Death	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Mild	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Moderate	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Severe	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Life-threatening	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Death	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx

Etc.

Note: A treatment-emergent adverse event (TEAE) is defined as an adverse event that occurred or worsened following the first administration of study drug. If a subject has multiple occurrences of a TEAE, the subject is presented only once in the Subject count (n) column for a given System Organ Class and Preferred Term. Occurrences are counted each time in the mentions/Occurrence (m) column.

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Programming Note:
- Include all SOCs and all PTERMs.

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Table 14.3.3.5 Summary of Treatment-Emergent Adverse Events by Relationship, by SOC and PT (Safety Analysis Set)

	Part A:		Part B:				
System Organ Class (SOC) Preferred Term (PT) Causality	LMN-101 3000 mg (N=xx) n (%) m	LMN-101 300 mg (N=xx) n (%) m	LMN-101 1000 mg (N=xx) n (%) m	LMN-101 3000 mg (N=xx) n (%) m	LMN-101 Overall (N=xx) n (%) m	Placebo (N=xx) n (%) m	Overall (N=xx) n (%) m
Subjects with at least one TEAE	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Mild	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Moderate	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Severe	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Life-threatening	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Death	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Unrelated	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Possibly Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Probably Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
SOC2	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
PT1	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Unrelated	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Possibly Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Probably Related	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx	xx (xx.x%) xx
Etc.							

Note: A treatment-emergent adverse event (TEAE) is defined as an adverse event that occurred or worsened following the first administration of study drug. If a subject has multiple occurrences of a TEAE, the subject is presented only once in the Subject count (n) column for a given System Organ Class and Preferred Term. Occurrences are counted each time in the mentions/Occurrence (m) column.

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Programming Note:
- Include all SOCs and all PTERMs.

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Table 14.3.4.1.1 Summary of Hematology & Coagulation by Timepoint (Safety Analysis Set)

Parameter: Hemoglobin (g/L)

Treatment Group Visit	Actual Value						Change from Baseline[1]					
	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
Part A: LMN-101 3000 mg (N=xx)												
Baseline[1]	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	-	-	-	-	-	-
Day 8	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 15	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 29	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Part B: LMN-101 300 mg (N=xx)												
Baseline[1]	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	-	-	-	-	-	-
Day 8	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 15	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 28	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 56	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x

etc.

SD: Standard Deviation
[1]Baseline is defined as the last valid, non-missing assessment prior to study drug administration on Day 1.

Programming Note:
- Include all treatment groups: Part A: LMN-101 3000 mg, Part B: LMN-101 300 mg, Part B: LMN-101 1000 mg, Part B: LMN-101 3000 mg, LMN-101 Overall, Placebo and Overall.
- Include all scheduled visits/time points and all Hematology and Coagulation parameters.
- Produce change from baseline and change from follow up tables.

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Table 14.3.4.1.1 Summary of Hematology & Coagulation by Timepoint (Safety Analysis Set) – Continued

Parameter: Hemoglobin (g/L)

Treatment Group / Visit	Actual Value						Change from Follow-up[1]					
	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
Part A: LMN-101 3000 mg (N=xx)												
Screening	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 1 Pre dose	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 8	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 15	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Follow-up	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	-	-	-	-	-	-
Part B: LMN-101 300 mg (N=xx)												
Screening	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 1 Pre dose	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 8	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 15	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 28	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Follow-up	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	-	-	-	-	-	-

etc.

SD: Standard Deviation
[1] Follow up result is defined as the Day 29 result for Part A and Day 56 result for Part B.

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Sponsor: Lumen Bioscience, Inc. Database Lock: yyyy-mm-dd
Protocol: CAM01

Table 14.3.4.1.2 Summary of Hematology & Coagulation Shifts from Baseline (Low, Normal, High) (Safety Analysis Set)

Parameter: Hemoglobin (g/L)

Treatment Visit Baseline Result Classification	Baseline[1] n(%)	Post-dose Result Classification Low	 Normal	 High
Part A: LMN-101 3000 mg (N=xx)				
Day 8				
n	xx	xx	xx	xx
Low	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 15				
n	xx	xx	xx	xx
Low	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 29				
n	xx	xx	xx	xx
Low	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
etc.				

[1]Baseline is defined as the last valid, non-missing assessment prior to study drug administration on Day 1.
Percentages are based on the number of subjects with data at the specific visit.

Programming Note:
- Include all treatment groups: Part A: LMN-101 3000 mg, Part B: LMN-101 300 mg, Part B: LMN-101

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Sponsor: Lumen Bioscience, Inc. Database Lock: yyyy-mm-dd
Protocol: CAM01

Table 14.3.4.1.3 Summary of Hematology & Coagulation Shifts from Follow-up (Low, Normal, High) (Safety Analysis Set)

Parameter: Hemoglobin (g/L)

Treatment Visit Follow-up Result Classification	Follow-up[1] n(%)	Result Classification Low	 Normal	 High
Part A: LMN-101 3000 mg (N=xx)				
Screening				
n	xx	xx	xx	xx
Low	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 1 Pre dose				
n	xx	xx	xx	xx
Low	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 8				
n	xx	xx	xx	xx
Low	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
etc.				

[1] Follow up result is defined as the Day 29 result for Part A and Day 56 result for Part B.
Percentages are based on the number of subjects with data at the specific visit.

Programming Note:
- Include all treatment groups: Part A: LMN-101 3000 mg, Part B: LMN-101 300 mg, Part B: LMN-101

Sponsor: Lumen Bioscience, Inc. Database Lock: yyyy-mm-dd
Protocol: CAM01

Table 14.3.4.2.1 Summary of Serum Chemistry by Timepoint (Safety Analysis Set)

Parameter: Sodium (g/L)

Treatment Group Visit	Actual Value						Change from Baseline[1]					
	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
Part A: LMN-101 3000 mg (N=xx)												
Baseline[1]	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	-	-	-	-	-	-
Day 8	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 15	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 29	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Part B: LMN-101 300 mg (N=xx)												
Baseline[1]	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	-	-	-	-	-	-
Day 8	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 15	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 28	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 56	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
etc.												

SD: Standard Deviation
[1]Baseline is defined as the last valid, non-missing assessment prior to study drug administration on Day 1.

Programming Note:
- Include all treatment groups: AR882 25mg, AR882 50mg, AR882 75mg, AR882 Overall, Placebo.
- Include all scheduled visits/time points and all Serum Chemistry parameters.
- Serum Creatinine (safety) is also evaluated on: Day 4 and Day 6.

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Protocol: CAM01

Database Lock: yyyy-mm-dd

Table 14.3.4.2.1 Summary of Serum Chemistry by Timepoint (Safety Analysis Set) – Continued

Parameter: Sodium (g/L)

Treatment Group Visit	Actual Value						Change from Follow up[1]					
	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
Part A: LMN-101 3000 mg (N=xx)												
Screening	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 1 Pre dose	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 8	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 15	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Follow-up	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	-	-	-	-	-	-
Part B: LMN-101 300 mg (N=xx)												
Screening	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 1 Pre dose	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 8	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 15	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 28	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Follow-up	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	-	-	-	-	-	-
etc.												

SD: Standard Deviation
[1] Follow up result is defined as the Day 29 result for Part A and Day 56 result for Part B.

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Table 14.3.4.2.2 Summary of Serum Chemistry Shifts from Baseline (Low, Normal, High) (Safety Analysis Set)

Parameter: Sodium (g/L)

Treatment Visit Baseline Result Classification	Baseline[1] n(%)	Post-dose Result Classification Low	 Normal	 High
LMN-101 25 mg (N=xx)				
Day 2				
n	xx	xx	xx	xx
Low	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 5				
N	xx	xx	xx	xx
Low	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 8				
n	xx	xx	xx	xx
Low	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
etc.				

[1]Baseline is defined as the last valid, non-missing assessment prior to study drug administration on Day 1.
Percentages are based on the number of subjects with data at the specific visit.

Programming Note:
- Include all treatment groups: AR882 25mg, AR882 50mg, AR882 75mg, AR882 Overall, Placebo.
- Include all scheduled visits/time points and all Serum Chemistry parameters.
- Serum Creatinine (safety) is also evaluated on: Day 4 and Day 6.

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Table 14.3.4.2.3 Summary of Serum Chemistry Shifts from Follow up (Low, Normal, High) (Safety Analysis Set)

Parameter: Sodium (g/L)

Treatment Visit Follow-up Result Classification	Follow-up[1] n(%)	Result Classification Low	 Normal	 High
Part A: LMN-101 3000 mg (N=xx)				
Screening				
n	xx	xx	xx	xx
Low	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 1 Pre dose				
n	xx	xx	xx	xx
Low	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 8				
n	xx	xx	xx	xx
Low	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
etc.				

[1] Follow up result is defined as the Day 29 result for Part A and Day 56 result for Part B.
Percentages are based on the number of subjects with data at the specific visit.

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Protocol: CAM01

Database Lock: yyyy-mm-dd

Table 14.3.4.4.1 Summary of Vital Signs by Timepoint (Safety Analysis Set)

Parameter: Systolic Blood Pressure (mmHg)

Treatment Group Visit	Actual Value						Change from Baseline[1]					
	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
Part A: LMN-101 3000 mg (N=xx)												
Baseline[1]	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	-	-	-	-	-	-
Day 1: 2 Hour Post-dose	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 8	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 15	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 29	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Part B LMN-101 300 mg (N=xx)												
Baseline[1]	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	-	-	-	-	-	-
Day 1: 2 Hour Post-dose	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 8	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 15	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 28	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 56	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
etc.												

SD: Standard Deviation
[1]Baseline is defined as the last valid, non-missing assessment prior to study drug administration on Day 1.

Programming Note:
- Include all treatment groups: Part A: LMN-101 3000 mg, Part B: LMN-101 300 mg, Part B: LMN-101 1000 mg, Part B: LMN-101 3000 mg, LMN-101 Overall, Placebo.
- Produce separate tables for change from baseline and change from follow-up

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Table 14.3.4.4.1 Summary of Vital Signs by Timepoint (Safety Analysis Set) – Continued

Parameter: Systolic Blood Pressure (mmHg)

Treatment Group Visit	Actual Value						Change from Follow-up[1]					
	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
Part A: LMN-101 3000 mg (N=xx)												
Screening	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 1: Pre-dose	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 1: 2 Hour Post-dose	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 8	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 15	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Follow-up[1]	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	-	-	-	-	-	-
Part B LMN-101 300 mg (N=xx)												
Screening	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 1: Pre-dose	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 1: 2 Hour Post-dose	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 2	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 8	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 15	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 28	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Follow-up[1]	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	-	-	-	-	-	-
etc.												

SD: Standard Deviation
[1] Follow up result is defined as the Day 29 result for Part A and Day 56 result for Part B.

Programming Note:
- Include all treatment groups: Part A: LMN-101 3000 mg, Part B: LMN-101 300 mg, Part B: LMN-101 1000 mg, Part B: LMN-101 3000 mg, LMN-101 Overall, Placebo.
- Produce separate tables for change from baseline and change from follow-up

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Protocol: CAM01

Table 14.3.4.4.2 Summary of Vital Signs Shifts from Baseline (Low, Normal, High) (Safety Analysis Set)

Parameter: Systolic Blood Pressure (mmHg)

Treatment Visit Result Classification	Baseline[1] n(%)	Post-dose Result Classification Low	 Normal	 High
Part A: LMN-101 3000 mg(N=xx)				
Day 1: 2 Hour Post-dose				
n	xx	xx	xx	xx
Low	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 8				
N	xx	xx	xx	xx
Low	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 15				
n	xx	xx	xx	xx
Low	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
etc.				

[1]Baseline is defined as the last valid, non-missing assessment prior to study drug administration on Day 1.
Percentages are based on the number of subjects with data at the specific visit.

Programming Note:
- Include all treatment groups: Part A: LMN-101 3000 mg, Part B: LMN-101 300 mg, Part B: LMN-101 1000 mg, Part B: LMN-101 3000 mg, LMN-101 Overall, Placebo.

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Table 14.3.4.4.3 Summary of Vital Signs Shifts from Follow-up (Low, Normal, High) (Safety Analysis Set)

Parameter: Systolic Blood Pressure (mmHg)

Treatment Visit Follow-up Result Classification	Follow-up[1] n(%)	Result Classification Low	 Normal	 High
Part A: LMN-101 3000 mg (N=xx)				
Screening				
n	xx	xx	xx	xx
Low	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 1: Pre-dose				
N	xx	xx	xx	xx
Low	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 1: 2 Hour post-dose				
n	xx	xx	xx	xx
Low	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
etc.				

[1]Baseline is defined as the last valid, non-missing assessment prior to study drug administration on Day 1.
Percentages are based on the number of subjects with data at the specific visit.

Programming Note:
- Include all treatment groups: Part A: LMN-101 3000 mg, Part B: LMN-101 300 mg, Part B: LMN-101 1000 mg, Part B: LMN-101 3000 mg, LMN-101 Overall, Placebo.

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Sponsor: Lumen Bioscience, Inc.
Protocol: CAM01

Database Lock: yyyy-mm-dd

Table 14.4.1 Summary of Immunology by Timepoint (Safety Analysis Set)

Parameter: Anti-VHH Antibodies (Units)

Treatment Group Visit	Actual Value						Change from Baseline[1]					
	n	Mean	SD	Median	Minimum	Maximum	n	Mean	SD	Median	Minimum	Maximum
Part A: LMN-101 3000 mg (N=xx)												
Baseline[1]	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	-	-	-	-	-	-
Day 29	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Part B: LMN-101 300 mg (N=xx)												
Baseline[1]	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	-	-	-	-	-	-
Day 28	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 56	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Part B: LMN-101 1000 mg (N=xx)												
Baseline[1]	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	-	-	-	-	-	-
Day 28	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 56	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Part B: LMN-101 3000 mg (N=xx)												
Baseline[1]	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	-	-	-	-	-	-
Day 28	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
Day 56	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x	xx	xx.xx	xx.xx	xx.xx	xx.x	xx.x
etc.												

SD: Standard Deviation
[1]Baseline is defined as the last valid, non-missing assessment prior to study drug administration on Day 1.

Programming Note:
- Include all treatment groups: Part A: LMN-101 3000 mg, Part B: LMN-101 300 mg, Part B: LMN-101 1000 mg, Part B: LMN-101 3000 mg, LMN-101 Overall, Placebo.

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Table 14.4.2 Summary of Immunology Shifts from Baseline (Low, Normal, High) (Safety Analysis Set)

Parameter: Anti-VHH Antibodies (Units)

Treatment Visit Baseline Result Classification	Baseline[1] n(%)	Post-dose Result Classification Low	 Normal	 High
LMN-101 25 mg (N=xx)				
Day 2				
N	xx	xx	xx	xx
Low	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 5				
N	xx	xx	xx	xx
Low	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Day 8				
n	xx	xx	xx	xx
Low	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
High	xx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
etc.				

[1]Baseline is defined as the last valid, non-missing assessment prior to study drug administration on Day 1.
Percentages are based on the number of subjects with data at the specific visit.

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Listings

GENERAL COMMENTS

- Unless otherwise stated, parameters will be listed in alphabetical order
- Change from Baseline (calculated as):

$$Change\ from\ baseline = new\ value - baseline\ value$$

- Change from Follow-up (calculated as):

$$Change\ from\ follow\ up = new\ value - follow\ up\ value$$

- Names and order of Treatment Groups:
  - Part A: LMN-101 3000mg
  - Part B: Cohort 1/ LMN-101 300mg
  - Part B: Cohort 1/ Placebo
  - Part B: Cohort 2/ LMN-101 1000mg
  - Part B: Cohort 2/ Placebo
  - Part B: Cohort 3/ LMN-101 3000mg
  - Part B: Cohort 3/ Placebo
- Names of visits:
  - Screening
  - Day 1: Pre-dose
  - Day 1: 2 hours
  - Day 2: 24 hours
  - Day 8
  - Day 15
  - Day 28
  - Day 29: Follow-up (Part A only)
  - Day 29 (Part B only)
  - Day 56: Follow-up (Part B only)
  - Early Termination
  - Unscheduled
- Column widths and text-wrapping may be altered in final output in order to best present the data
- Footnotes may be added/amended if required

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Listing 16.2.1.1 Analysis Populations (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Safety Analysis Set	PK Population
XXX-XXX	Yes	Yes
XXX-XXX	Yes	Yes
XXX-XXX	Yes	Yes
XXX-XXX	Yes	Yes
XXX-XXX	Yes	Yes
XXX-XXX	Yes	Yes

Etc.

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Listing 16.2.1.2 Participant Disposition (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Did the Subject Complete the Study?	Primary Reason for Discontinuation of Study	Date of Completion/ Early Withdrawal (YYYY-MM-DD)
XXX-XXX	Yes		YYYY-MM-DD
XXX-XXX	Yes		YYYY-MM-DD
XXX-XXX	No	Other: XXXXXXXXXXXXX	YYYY-MM-DD

Etc.

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Listing 16.2.2.1 Protocol Deviations (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Category of Deviation	Date of Deviation (YYYY-MM-DD)	Visit	Description of Deviation
XXX-XXX	Other: XXXX	YYYY-MM-DD	Day 1	ABCD
	Study Drug not taken as per protocol	YYYY-MM-DD	Day 28	ABCD
	Etc.			
XXX-XXX	Non-compliance with Assessment schedule	YYYY-MM-DD	Day 2	ABCD
	Inc/Exc criteria not met	YYYY-MM-DD	Day 8	ABCD
	Etc.			
XXX-XXX	Non-compliance with Assessment schedule	YYYY-MM-DD	Day 8	ABCD
XXX-XXX	Inc/Exc criteria not met	YYYY-MM-DD	Day 15	ABCD
XXX-XXX	Other: XXXX	YYYY-MM-DD	Day 15	ABCD
XXX-XXX	Study Drug not taken as per protocol	YYYY-MM-DD	Day 1	ABCD
Etc.				

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Listing 16.2.4.1 Demographics and Baseline Characteristics at Screening (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Date of Informed Consent (YYYY-MM-DD)	Date of Birth (YYYY-MM-DD)	Age at Informed Consent (years)	Gender	Race	Ethnicity	Height (cm)	Weight (kg)	BMI (kg/m^2)
XXX-XXX	YYYY-MM-DD	YYYY-MM-DD	xx	Male	Asian	Not Hispanic or Latino	xxx	xx.x	xx.x
XXX-XXX	YYYY-MM-DD	YYYY-MM-DD	xx	Male	White	Not Hispanic or Latino	xxx	xx.x	xx.x
XXX-XXX	YYYY-MM-DD	YYYY-MM-DD	xx	Female	White	Not Hispanic or Latino	xxx	xx.x	xx.x
XXX-XXX	YYYY-MM-DD	YYYY-MM-DD	xx	Female	Other: XXXXXX	Hispanic or Latino	xxx	xx.x	xx.x
Etc.									

BMI: Body Mass Index.

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Listing 16.2.4.2 Serology (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Visit	Assessment Performed	Collection Date/Time (YYYY-MM-DD/HH:MM)	Test	Result
XXX-XXX	Screening	Yes	YYYY-MM-DD/HH:MM	Anti-HIV Ab	Negative
				HBsAg	Negative
				HCV Ab	Negative
XXX-XXX	Screening	Yes	YYYY-MM-DD/HH:MM	Anti-HIV Ab	Negative
				HBsAg	Negative
				HCV Ab	Negative
Etc.					

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Listing 16.2.4.3 Medical History (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID		Medical Condition/ System Organ Class/ Preferred Term	Start Date/ End Date (YYYY-MM-DD)	Ongoing at Study Start?	Is the condition being treated with a concomitant medication
XXX-XXX	xx	XXXXXXXXXX/ YYYYYYYYY/ ZZZZZZZZZ	YYYY-MM-DD/ YYYY-MM-DD	No	No
	xx	XXXXXXXXXX/ YYYYYYYYY/ ZZZZZZZZZ	YYYY-MM-DD/ YYYY-MM-DD	Yes	Yes
	Etc.				
XXX-XXX	xx	XXXXXXXXXX/ YYYYYYYYY/ ZZZZZZZZZ	YYYY-MM-DD/ YYYY-MM-DD	No	No
XXX-XXX	xx	XXXXXXXXXX/ YYYYYYYYY/ ZZZZZZZZZ	YYYY-MM-DD/ YYYY-MM-DD	No	No
XXX-XXX	xx	XXXXXXXXXX/ YYYYYYYYY/ ZZZZZZZZZ	YYYY-MM-DD/ YYYY-MM-DD	No	No
XXX-XXX	xx	XXXXXXXXXX/ YYYYYYYYY/ ZZZZZZZZZ	YYYY-MM-DD/ YYYY-MM-DD	No	No
Etc.					

MH No: Medical Condition Number.

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Listing 16.2.4.4 Urine Drug Test (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Visit	Was Sample Collected?	Collection Date/ Time (YYYY-MM-DD/ HH:MM)	Result
XXX-XXX	Screening	Yes	YYYY-MM-DD/ HH:MM	Negative
	Day 1	Yes	YYYY-MM-DD/ HH:MM	Negative
XXX-XXX	Screening	No: XXXX	YYYY-MM-DD/ HH:MM	
	Day 1	Yes	YYYY-MM-DD/ HH:MM	Positive
XXX-XXX	Screening	Yes	YYYY-MM-DD/ HH:MM	Negative
	Day 1	Yes	YYYY-MM-DD/ HH:MM	Negative
XXX-XXX	Screening	Yes	YYYY-MM-DD/ HH:MM	Negative
	Day 1	Yes	YYYY-MM-DD/ HH:MM	Negative

Etc.

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Listing 16.2.4.5 Eligibility Criteria (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Visit	Eligibility Assessment Date (YYYY-MM-DD)	Has the Subject Met All of the Inclusion and None of the Exclusion Criteria?	Inclusion/ Exclusion Criteria Not Met
XXX-XXX	Screening	YYYY-MM-DD	Yes	
	Day -2	YYYY-MM-DD	Yes	
XXX-XXX	Screening	YYYY-MM-DD	No	Inclusion 6
	Day -2	YYYY-MM-DD	Yes	
XXX-XXX	Screening	YYYY-MM-DD	Yes	
	Day -2	YYYY-MM-DD	Yes	
XXX-XXX	Screening	YYYY-MM-DD	Yes	
	Day -2	YYYY-MM-DD	Yes	

Etc.

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Listing 16.2.5.1 Randomization (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Was the Subject Randomized?	Date and Time of Randomization (YYYY-MM-DD HH:MM)	Randomisation Number	Part/Cohort	Treatment Received	Date and Time of Unblinding[1] (YYYY-MM-DD HH:MM)	Reason for Unblinding[1]
XXX-XXX	Yes	YYYY-MM-DD HH:MM	RXXXX	Part A	LMN-101 3000mg		
XXX-XXX	Yes	YYYY-MM-DD HH:MM	RXXXX	Part A	LMN-101 3000mg		

Etc.

[1]Only applicable in case of medical emergency

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Listing 16.2.5.2 Study Drug Administration – First Dose (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Visit	Was Study Drug Administered?	Administration Date and Time (YYYY-MM-DD HH:MM)	Actual Dose Administered (mg)	Was Subject Fasting 1 hour prior to dosing?	Was Subject Fasting 1 hour after dosing?	Was study drug given as per protocol?
XXX-XXX	Day 1	Yes	YYYY-MM-DD HH:MM	xx	xxx	xxx	xxx
XXX-XXX	Day 1	Yes	YYYY-MM-DD HH:MM	xx	xxx	xxx	xxx
XXX-XXX	Day 1	No: XXXX					
Etc.	Etc.						

Programming Note:
- Include First dose Day 1 data only.
- Include subjects from Part A and Part B.

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Listing 16.2.5.3 Study Drug Accountability – Part B (Safety Analysis Set)

Cohort/Treatment: Part B: LMN-101 300mg

Subject ID	Study Dispense Day/ Return Day	Date of Dispensing/ Date of Return (YYYY-MM-DD)	Type of Tablet Dispensed	Number of tablets dispensed/ returned	Were any doses missed?	Study Drug Compliance (%)
XXX-XXX	Day 1/ Day 2	YYYY-MM-DD/ YYYY-MM-DD	XXXmg	XX/ XX	XX	XX.X
	Day 2/ Day 8	YYYY-MM-DD/ YYYY-MM-DD	XXXmg	XX/ XX	XX	XX.X
	Day 8/ Day 15	YYYY-MM-DD/ YYYY-MM-DD	XXXmg	XX/ XX	XX	XX.X
	Day 15/ Day 28	YYYY-MM-DD/ YYYY-MM-DD	XXXmg	XX/ XX	XX	XX.X
	Day 15/ Day 28	YYYY-MM-DD/ YYYY-MM-DD	XXXmg	XX/ XX	XX	XX.X
XXX-XXX	Day 1/ Day 2	YYYY-MM-DD/ YYYY-MM-DD	XXXmg	XX/ XX	XX	XX.X
	Day 2/ Day 8	YYYY-MM-DD/ YYYY-MM-DD	XXXmg	XX/ XX	XX	XX.X
	Day 8/ Day 15	YYYY-MM-DD/ YYYY-MM-DD	XXXmg	XX/ XX	XX	XX.X
	Day 15/ Day 28	YYYY-MM-DD/ YYYY-MM-DD	XXXmg	XX/ XX	XX	XX.X
	Day 15/ Day 28	YYYY-MM-DD/ YYYY-MM-DD	XXXmg	XX/ XX	XX	XX.X
Etc.	Etc.					

Programming Note:
- Include all timepoints where Study Drug Accountability was reviewed.
- Included data for Part B Cohorts 300 mg, 1000mg, 3000mg and Placebo.

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Listing 16.2.5.4 Missed Doses (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Study Day	Date of Missed Dose (YYYY-MM-DD)	Dose Missed	Reason for Missed Dose
XXX-XXX	Day 8	YYYY-MM-DD	300mg	XXX
	Day 29	YYYY-MM-DD	300mg	XXX
XXX-XXX	Day 15	YYYY-MM-DD	300mg	XXX
Etc.	Etc.			

Programming Note:

- Included all data for Part A and Part B Cohorts 300 mg, 1000mg and 3000mg.

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Listing 16.2.5.5 Pregnancy Test (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Visit	Was Sample collected for Pregnancy Test? (Yes/ No: Reason)	Date and Time of Sample Collection (YYYY-MM-DD HH:MM)	Pregnancy Test Type	Result
XXX-XXX	Screening	Yes	YYYY-MM-DD HH:MM	Serum	Negative
	Day 1	Yes	YYYY-MM-DD HH:MM	Urine	Negative
XXX-XXX	Screening	Yes	YYYY-MM-DD HH:MM	Serum	Negative
	Day 1	No: XXX	YYYY-MM-DD HH:MM	Urine	Not Done

Etc.

Pregnancy tests were performed on women of childbearing potential only.

Programming Note:

- Tests were performed on women of childbearing potential only.
- Part A scheduled testing: Screening and Day 1.
- Part B scheduled testing: Screening, Day 1 and Day 28.

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Listing 16.2.6.1 PK Serum Sample Collection Times (PK Population)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Sampling Timepoint	Was PK Sample Collected?	Actual Time (h)[1]	PK Sample Collection Date and Time (YYYY-MM-DD HH:MM)	Day 1 Study Drug Administration Date and Time (YYYY-MM-DD HH:MM)	Comments
XXX-XXX	Day 1 Pre-dose	Yes	xx.xx	YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM	
	Day 1 2h Post-dose	Yes	xx.xx	YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM	
	Day 2	Yes	xx.xx	YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM	
XXX-XXX	Day 1 Pre-dose	Yes	xx.xx	YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM	
	Day 1 2h Post-dose	Yes	xx.xx	YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM	
	Day 2		xx.xx	YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM	
Etc						

[1]Relative to date and time of study drug administration on Day 1

Programming Note:

- There are 3 scheduled sample collections for Part A: Day 1 Pre-dose, Day 1 2h Post-dose and Day 2.
- There are 6 scheduled sample collections for Part B: Day 1 Pre-dose, Day 1 2h Post-dose, Day 2, Day 8, Day 28 and Day 29.

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Listing 16.2.6.2 Individual Serum Concentrations of VHH (PK Population)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Was PK Sample Collected?	Sampling Timepoint	Date and Time of PK Sample Collection (YYYY-MM-DD HH:MM)	Study Time (h)[1]	VHH Concentration (unit)
XXX-XXX	Yes	Day 1 Pre-dose[2]	YYYY-MM-DD HH:MM	xx.xx	xxx
	Yes	Day 1 2h Post-dose	YYYY-MM-DD HH:MM	xx.xx	xxx
	Yes	Day 2	YYYY-MM-DD HH:MM	xx.xx	xxx
XXX-XXX	Yes	Day 1 Pre-dose[2]	YYYY-MM-DD HH:MM	xx.xx	xxx
	Yes	Day 1 2h Post-dose	YYYY-MM-DD HH:MM	xx.xx	xxx
	Yes	Day 2	YYYY-MM-DD HH:MM	xx.xx	xxx
Etc.	Etc.				

[1] Relative to date and time of study drug administration on Day 1
[2] Baseline is defined as the last valid, non-missing assessment prior to study drug administration on Day 1

Programming Note:
- There are 3 scheduled sample collections for Part A: Day 1 Pre-dose, Day 1 2h Post-dose and Day 2.
- There are 6 scheduled sample collections for Part B: Day 1 Pre-dose, Day 1 2h Post-dose, Day 2, Day 8, Day 28 and Day 29.

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Listing 16.2.6.3 Individual PK Parameters (PK Population)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	C_{max} at Day 1 2h post dose	C_{max} after Day 1	Tmax (h^1)	λ_z	$t_{½}$	AUC_{0-2hr}	$AUC_{0-course}$	AUC_{0-inf}
XXX-XXX	XX	XX	XX	XX	XX	XX	XX	XX
XXX-XXX	XX	XX	XX	XX	XX	XX	XX	XX

Etc

Cmax: Peak VHH Concentration (Units)
Tmax: time when peak VHH concentration occurs after Day 1.
[1]Time of Peak VHH Concentration relative to date and time of study drug administration on Day 1
λ_z: Apparent first order terminal elimination rate constant
$t_{½}$: Terminal elimination half-life
AUC_{0-2hr}: The area under the concentration-time curve, from time of dosing to the last time point with measurable analyte concentration following administration of the initial dose.
$AUC_{0-course}$: The area under the concentration-time curve, from time of dosing to the last time point with measurable analyte concentration following a course of treatment
AUC_{0-inf}: Area under the concentration-time curve extrapolated to infinite time.

Programming Note:
- PK analysis set consists of the following treatment groups: Part A: LMN-101 3000 mg, Part B: LMN-101 300 mg, Part B: LMN-101 1000 mg & Part B: LMN-101 3000 mg

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Listing 16.2.6.4 Stool Collection (PK Population)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Visit	Date and Time of Sample Collection (YYYY-MM-DD HH:MM)	Date and Time of Most Recent Meal (YYYY-MM-DD HH:MM)
XXX-XXX	Day 1	YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM
	Day 2	YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM
	Day 29	YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM
XXX-XXX	Day 1	YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM
	Day 2	YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM
	Day 29	YYYY-MM-DD HH:MM	YYYY-MM-DD HH:MM

Etc.

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Listing 16.2.7.1 Adverse Events (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	AE Number	Adverse Event Verbatim/ System Organ Class/ Preferred Term	Start Date/Time; End Date/Time (YYYY-MM-DD/ HH:MM)	SAE/ TEAE	CTCAE Severity Grade	Relationship to Study Drug	Action Taken with Study Drug/ Other Action Taken	Outcome	Ongoing?
XXX-XXX	xx	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	YYYY-MM-DD/HH:MM; YYYY-MM-DD/HH:MM	Yes/ Yes	Moderate	Not Related	None/ None	Recovered/ Resolved	No
XXX-XXX	xx	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	YYYY-MM-DD/HH:MM; YYYY-MM-DD/HH:MM	No/ Yes	Mild	Unlikely Related	None/ Medication given: CM No xx	Recovered/ Resolved	No
XXX-XXX	xx	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	YYYY-MM-DD/HH:MM; YYYY-MM-DD/HH:MM	No/ Yes	Mild	Unlikely Related	None/ Other Action: XXXXXXXX	Recovered/ Resolved	No
XXX-XXX	xx	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	YYYY-MM-DD/HH:MM; YYYY-MM-DD/HH:MM	No/ Yes	Mild	Related	None/ Other Action: XXXXXXXX	Recovered/ Resolved	No

Etc.

Subject ID: Subject ID
SAE: Serious Adverse Event.
[1]Relative to date and time of study drug administration on Day 1
CM No: Concomitant Medication Number
TEAE: Treatment Emergent Adverse Event
MedDRA Version xx.x

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Listing 16.2.7.2 Serious Adverse Events (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

SAE Reason: Is Life Threatening

Subject ID	AE Number	Adverse Event Verbatim/ System Organ Class/ Preferred Term	Start Date/Time; End Date/Time (YYYY-MM-DD/ HH:MM)	CTCAE Severity Grade	Relationship to Study Drug	Action Taken with Study Drug/ Other Action Taken	Outcome	Ongoing?	TEAE
XXX-XXX	xx	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	YYYY-MM-DD/HH:MM; YYYY-MM-DD/HH:MM	Moderate	Not Related	None/ None	Recovered/ Resolved	No	Yes
XXX-XXX	xx	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	YYYY-MM-DD/HH:MM; YYYY-MM-DD/HH:MM	Mild	Unlikely Related	None/ Medication given: CM No xx	Recovered/ Resolved	No	Yes
XXX-XXX	xx	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	YYYY-MM-DD/HH:MM; YYYY-MM-DD/HH:MM	Mild	Unlikely Related	None/ Other Action: XXXXXXXX	Recovered/ Resolved	No	Yes
XXX-XXX	xx	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	YYYY-MM-DD/HH:MM; YYYY-MM-DD/HH:MM	Mild	Related	None/ Other Action: XXXXXXXX	Recovered/ Resolved	No	Yes

Etc.

Subject ID: Subject ID
[1]Relative to date and time of study drug administration on Day 1
CM No: Concomitant Medication Number
TEAE: Treatment Emergent Adverse Event
MedDRA Version xx.x

Programming Note:
- Include all SAE Reasons.

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Listing 16.2.7.3 Adverse Events Leading to Study Drug Withdrawal (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Rand Number	AE Number	Adverse Event Verbatim/ System Organ Class/ Preferred Term	Start Date/Time; End Date/Time (YYYY-MM-DD/ HH:MM)	SAE/ TEAE	CTCAE Severity Grade	Relationship to Study Drug	Other Action Taken	Outcome	Ongoing?
XXX-XXX	xx	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYY	YYYY-MM-DD/HH:MM; YYYY-MM-DD/HH:MM	Yes/ Yes	Moderate	Not Related	None	Recovered/ Resolved	No
XXX-XXX	xx	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYY	YYYY-MM-DD/HH:MM; YYYY-MM-DD/HH:MM	No/ Yes	Mild	Unlikely Related	Medication given: CM No xx	Recovered/ Resolved	No
XXX-XXX	xx	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYY	YYYY-MM-DD/HH:MM; YYYY-MM-DD/HH:MM	No/ Yes	Mild	Unlikely Related	Other Action: XXXXXXXX	Recovered/ Resolved	No
XXX-XXX	xx	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYY	YYYY-MM-DD/HH:MM; YYYY-MM-DD/HH:MM	No/ Yes	Mild	Related	Other Action: XXXXXXXX	Recovered/ Resolved	No

Etc.

Subject ID: Subject ID
[1]Relative to date and time of study drug administration on Day 1
CM No: Concomitant Medication Number
TEAE: Treatment Emergent Adverse Event
MedDRA Version xx.x

Program: filepath_name, Output Name: filepath_name Creation Date/Time: DDMMMYYYY HH:MM Page 1 of xx

Sponsor: Lumen Bioscience, Inc.
Protocol: CAM01

Database Lock: yyyy-mm-dd

Listing 16.2.8.1.1 Hematology & Coagulation (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Parameter (Unit)	Visit	Sample Date/ Time (YYYY-MM-DD/ HH:MM)	Actual Value	Change from Baseline[1]/ Change from Follow up[2]	Reference Range	High/Low Flag, Clinically Significant Finding?	Comments
XXX-XXX	Hemoglobin (unit)	Screening	YYYY-MM-DD/ HH:MM	xx	/ xx	xx, xx		
		Day 1 Pre dose[1]	YYYY-MM-DD/ HH:MM	xx	/ xx	xx, xx		
		Day 8	YYYY-MM-DD/ HH:MM	xx	xx/ xx	xx, xx	Low, No	ABCD
		Day 15	YYYY-MM-DD/ HH:MM	xx	xx/ xx	xx, xx		
		Day 29[2]	YYYY-MM-DD/ HH:MM	xx	xx/	xx, xx		

Etc.

[1] Baseline is defined as the last valid, non-missing assessment prior to study drug administration on Day 1
[2] Follow up result is defined as the Day 29 result for Part A and Day 56 result for Part B.
Low = Below Normal Range, High = Above Normal Range

Programming Note:

- Include all visits/time points and all Hematology and Coagulation parameters.

Program: filepath_name, Output Name: filepath_name Creation Date/Time: DDMMMYYYY HH:MM Page 1 of xx

Sponsor: Lumen Bioscience, Inc. Database Lock: yyyy-mm-dd
Protocol: CAM01

Listing 16.2.8.1.2 Abnormal Hematology & Coagulation (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Parameter (Unit)	Visit	Sample Date/ Time (YYYY-MM-DD/ HH:MM)	Actual Value	Change from Baseline[1]/ Change from Follow up[2]	Reference Range	High/Low Flag, Clinically Significant Finding?	Comments
XXX-XXX	Hemoglobin (unit)	Day 2	YYYY-MM-DD/ HH:MM	xx	xx	xx, xx	L	ABCD
		Day 8	YYYY-MM-DD/ HH:MM	xx	xx	xx, xx	L	ABCD
		Day 15	YYYY-MM-DD/ HH:MM	xx	xx	xx, xx	L	ABCD
		Day 29	YYYY-MM-DD/ HH:MM	xx	xx	xx, xx	L	ABCD
Etc.								

[1] Baseline is defined as the last valid, non-missing assessment prior to study drug administration on Day 1
[2] Follow up result is defined as the Day 29 result for Part A and Day 56 result for Part B.
Low = Below Normal Range, High = Above Normal Range

Programming Note:

- Include all visits/time points and all Hematology and Coagulation parameters.

Program: filepath_name, Output Name: filepath_name Creation Date/Time: DDMMMYYYY HH:MM Page 1 of xx

Sponsor: Lumen Bioscience, Inc.
Protocol: CAM01

Database Lock: yyyy-mm-dd

Listing 16.2.8.2.1 Serum Chemistry (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Parameter (Unit)	Visit	Sample Date/ Time (YYYY-MM-DD/ HH:MM)	Actual Value	Change from Baseline[1]/ Change from Follow up[2]	Reference Range	High/Low Flag, Clinically Significant Finding?	Comments
XXX-XXX	Sodium (unit)	Screening	YYYY-MM-DD/ HH:MM	xx	xx /	xx, xx		
		Day -2[1]	YYYY-MM-DD/ HH:MM	xx	xx /	xx, xx		
		Day 2	YYYY-MM-DD/ HH:MM	xx	xx / xx	xx, xx	High, No	ABCD
		Day 5	YYYY-MM-DD/ HH:MM	xx	xx / xx	xx, xx	High, No	ABCD
		Day 8	YYYY-MM-DD/ HH:MM	xx	xx / xx	xx, xx		
		Day 10	YYYY-MM-DD/ HH:MM	xx	xx / xx	xx, xx		
		Day 13	YYYY-MM-DD/ HH:MM	xx	xx / xx	xx, xx		
		Day 15[2]	YYYY-MM-DD/ HH:MM	xx		xx, xx		
Etc.								

[1] Baseline is defined as the last valid, non-missing assessment prior to study drug administration on Day 1
[2] Follow up result is defined as the Day 29 result for Part A and Day 56 result for Part B.
Low = Below Normal Range, High = Above Normal Range

Programming Note:

- Include all visits/time points and all Serum Chemistry parameters.

Program: filepath_name, Output Name: filepath_name Creation Date/Time: DDMMMYYYY HH:MM

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Sponsor: Lumen Bioscience, Inc.
Protocol: CAM01

Database Lock: yyyy-mm-dd

Listing 16.2.8.2.2 Abnormal Serum Chemistry (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Parameter (Unit)	Visit	Sample Date/ Time (YYYY-MM-DD/ HH:MM)	Actual Value	Change from Baseline[1]/ Change from Follow up[2]	Reference Range	High/Low Flag, Clinically Significant Finding?	Comments
XXX-XXX	Sodium (unit)	Day 2	YYYY-MM-DD/ HH:MM	xx	xx/ xx	xx, xx	High, No	ABCD
		Day 5	YYYY-MM-DD/ HH:MM	xx	xx/ xx	xx, xx	High, No	ABCD
Etc.								

[1] Baseline is defined as the last valid, non-missing assessment prior to study drug administration on Day 1
[2] Follow up result is defined as the Day 29 result for Part A and Day 56 result for Part B.
Low = Below Normal Range, High = Above Normal Range

Programming Note:

- Include all visits/time points and all Serum Chemistry parameters.

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Protocol: CAM01

Listing 16.2.9.1 Vital Signs (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Parameter (Unit)- Position	Visit	Timepoint	Visit Date/ Time (YYYY-MM-DD/ HH:MM)	Actual Value	Change from Baseline[1]/ Change from Follow up[2]	High/Low Flag
XXX-XXX	Systolic Blood Pressure (mmHg)	Screening		YYYY-MM-DD/ HH:MM	xx	/ xx	
		Day 1[1]	Pre-Dose	YYYY-MM-DD/ HH:MM	xx	/ xx	
			2 Hour Post-Dose	YYYY-MM-DD/ HH:MM	xx	xx/ xx	
		Day 2	Pre-Dose	YYYY-MM-DD/ HH:MM	xx	xx/ xx	High
		Day 8	Pre-Dose	YYYY-MM-DD/ HH:MM	xx	xx/ xx	
		Day 15	Pre-Dose	YYYY-MM-DD/ HH:MM	xx	xx/ xx	
		Day 29[2]	Pre-Dose	YYYY-MM-DD/ HH:MM	xx		

Etc.

[1] Baseline is defined as the last valid, non-missing assessment prior to study drug administration on Day 1
[2] Follow up result is defined as the Day 29 result for Part A and Day 56 result for Part B.
Low = Below Normal Range, High = Above Normal Range

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Protocol: CAM01

Database Lock: yyyy-mm-dd

Listing 16.2.9.3 Physical Examination (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Randomization Number	Visit	Was a Physical Examination Performed?	Date of Assessment (YYYY-MM-DD)	Body System	Result	Clinically Significant? (if Abnormal, Specify)
XXX-XXX	Screening	Yes	YYYY-MM-DD	General	Normal	
				HEENT	Normal	
				Dentition	Normal	
				Thyroid	Normal	
				Heart	Normal	
				Abdomen	Normal	
				Skin	Abnormal	No, Sunburn
				Neurological	Normal	
				Extremities	Normal	
				Back	Normal	
				Neck	Normal	
				Musculoskeletal	Normal	
				Lymph Nodes	Normal	
				Lungs	Normal	
	Day 1 Pre-Dose	No	YYYY-MM-DD	Not Performed		
	Day 1 Post-Dose	Yes	YYYY-MM-DD	HEENT	Normal	
				Skin	Abnormal	No, Sunburn
Etc.	Etc.			Etc.		

NCS = Not Clinically Significant, CS = Clinically Significant

Programming Note:

- A full physical examination will be performed at Screening and a targeted physical examination (to AEs) will be performed thereafter.

Program: filepath_name, Output Name: filepath_name Creation Date/Time: DDMMMYYYY HH:MM

Sponsor: Lumen Bioscience, Inc.
Protocol: CAM01
Database Lock: yyyy-mm-dd

Listing 16.2.10.1 Concomitant Medication (All Randomized)

Cohort/Treatment: Part A: LMN-101 3000mg

Randomization Number	Con Med No.	Medication Non- Drug Therapy Name/ ATC3/ PT	Indication	Start Date and Time/ End Date and Time (YYYY-MM-DD)	Ongoing at End of Study	Dose	Unit	Frequency	Route
XXX-XXX	xx	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	To treat AE: AE No XX	YYYY-MM-DD HH:MM/ YYYY-MM-DD HH:MM	No	XX	Unit	YYYYYY	ZZZZZ
	xx	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	To treat AE: AE No XX	YYYY-MM-DD HH:MM/ YYYY-MM-DD HH:MM	No	XX	Unit	YYYYYY	ZZZZZ
XXX-XXX	xx	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	To treat AE: AE No XX	YYYY-MM-DD HH:MM/ YYYY-MM-DD HH:MM	No	XX	Unit	YYYYYY	ZZZZZ
	xx	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	To treat AE: AE No XX	YYYY-MM-DD HH:MM/ YYYY-MM-DD HH:MM	No	XX	Unit	YYYYYY	ZZZZZ
XXX-XXX	xx	XXXXXXXXXXXXXXXXXXXXXX/ ZZZZZZZZZZZZZZZZZZZZZ/ YYYYYYYYYYYYYYYYYYYYY	To treat AE: AE No XX	YYYY-MM-DD HH:MM/ YYYY-MM-DD HH:MM	No	XX	Unit	YYYYYY	ZZZZZ
Etc.	Etc.								

Con Med No: Concomitant Medication Number
Concomitant medications are medications taken at least once after study drug administration on Day 1
WHO-DD, xxxxxxxxxx

Program: filepath_name, Output Name: filepath_name Creation Date/Time: DDMMMYYYY HH:MM Page 1 of xx

Sponsor: Lumen Bioscience, Inc.
Protocol: CAM01

Database Lock: yyyy-mm-dd

Listing 16.2.11.1 Immunology – Anti-VHH Antibodies (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Visit	Sample Date/ Time (YYYY-MM-DD/ HH:MM)	Value	Change from Baseline[1]/ Change from Follow up[2]	Reference Range	High/Low Flag	Comments
XXX-XXX	Day 1 Pre-Dose	YYYY-MM-DD/ HH:MM	xx	/ xx	xx, xx		
	Day 29	YYYY-MM-DD/ HH:MM	xx	xx/	xx, xx		
XXX-XXX	Day 1 Pre-Dose	YYYY-MM-DD/ HH:MM	xx	/ xx	xx, xx		
	Day 29	YYYY-MM-DD/ HH:MM	xx	xx/	xx, xx	High	

Etc.

[1] Baseline is defined as the last valid, non-missing assessment prior to study drug administration on Day 1
[2] Follow up result is defined as the Day 29 result for Part A and Day 56 result for Part B.
Low = Below Normal Range, High = Above Normal Range

Program: filepath_name, Output Name: filepath_name Creation Date/Time: DDMMMYYYY HH:MM Page 1 of xx

Sponsor: Lumen Bioscience, Inc. Database Lock: yyyy-mm-dd
Protocol: CAM01

Listing 16.2.11.2 Abnormal Immunology – Anti-VHH Antibodies (Safety Analysis Set)

Cohort/Treatment: Part A: LMN-101 3000mg

Subject ID	Visit	Sample Date/ Time (YYYY-MM-DD/ HH:MM)	Value	Change from Baseline[1]/ Change from Follow up[2]	Reference Range	High/Low Flag	Comments
XXX-XXX	Day 29	YYYY-MM-DD/ HH:MM	xx	xx/	xx, xx	High	ABCD

Etc.

[1] Baseline is defined as the last valid, non-missing assessment prior to study drug administration on Day 1
[2] Follow up result is defined as the Day 29 result for Part A and Day 56 result for Part B.
L = Below Normal Range, H = Above Normal Range

Program: filepath_name, Output Name: filepath_name Creation Date/Time: DDMMMYYYY HH:MM Page 1 of xx

Sponsor: Lumen Bioscience, Inc. Database Lock: yyyy-mm-dd

CAM01: Mock Figures: Table of Contents

Figures

GENERAL COMMENTS

- Names and order of Treatment Groups:
  - Part A: LMN-101 3000mg
  - Part B: LMN-101 300mg
  - Part B: LMN-101 1000mg
  - Part B: LMN-101 3000mg

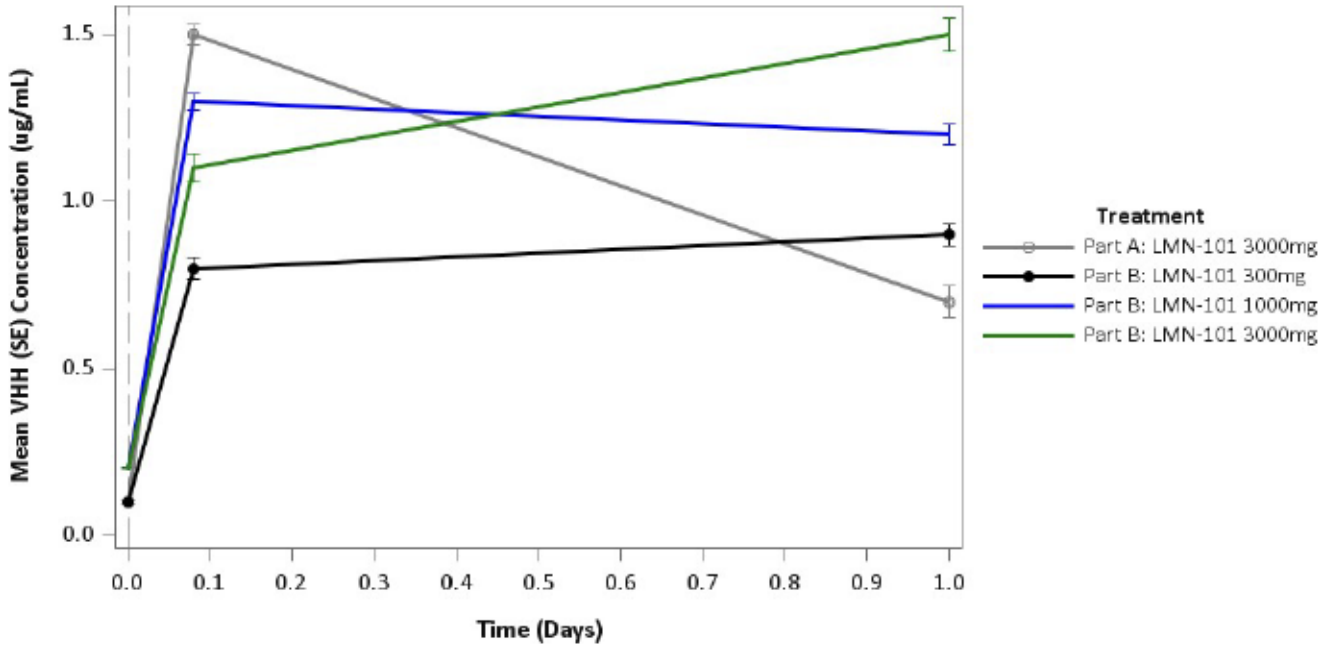
- Names of visits:
  - Screening
  - Day 1: Pre-dose
  - Day 1: 2 hours
  - Day 2: 24 hours
  - Day 8
  - Day 15
  - Day 28
  - Day 29: Follow-up (Part A only)
  - Day 29 (Part B only)
  - Day 56: Follow-up (Part B only)

- Column widths and text-wrapping may be altered in final output in order to best present the data
- Footnotes may be added/amended if required

Sponsor: Lumen Bioscience, Inc. Database lock: yyyy-mm-dd
Protocol: CAM01

Figure 14.2.1.1 Mean (+/-SE) Serum Concentrations of VHH by Day – Baseline to Day 2 (24hrs) (PK Population)

Example figure:



Programming Note:
The x-axis will represent elapsed days after initial dosing [0 to 1];
label: "Time (Days)"; vertical dashline to be added on Dosing (Day=0) to indicate Baseline.
The y-axis will represent the mean serum concentrations of VHH (unit) per treatment group. Whiskers will be included to reflect the SEs;
label: "Mean VHH (SE) Concentration (unit)".

The y-axis will be on the linear scale.
Treatment groups to be included are Part A: LMN-101 3000 mg, Part B: LMN-101 300 mg, Part B: LMN-101 1000 mg, Part B: LMN-101 3000 mg. All treatment groups will be represented on a single page. Each treatment group will be presented as a distinct line type.

Program: filepath_name, Output Name: filepath_name Creation Date/Time: DDMMMYYYY HH:MM Page 1 of xx

Sponsor: Lumen Bioscience, Inc. Database lock: yyyy-mm-dd
Protocol: CAM01

Figure 14.2.1.2 Log_{10}Mean (+/-SE) Serum Concentrations of VHH by Day - Baseline to Day 2 (24hrs) (PK Population)

Programming Note:
The figure is the same as 14.2.1.1, however, with y axis log transformed to base 10.

The x-axis will represent elapsed days after initial dosing [0 to 1];
label: "Time (Days)"; vertical dashline to be added on Dosing (Day=0) to indicate Baseline.
The y-axis will represent the logarithmic transformed mean serum concentrations of VHH (unit) per treatment group. Whiskers will be included to reflect the SEs;
label: "Log_{10} Mean VHH (SE) Concentration (unit)".

The y-axis will be on the log_{10} scale.
Treatment groups to be included are Part A: LMN-101 3000 mg, Part B: LMN-101 300 mg, Part B: LMN-101 1000 mg, Part B: LMN-101 3000 mg. All treatment groups will be represented on a single page. Each treatment group will be presented as a distinct line type.

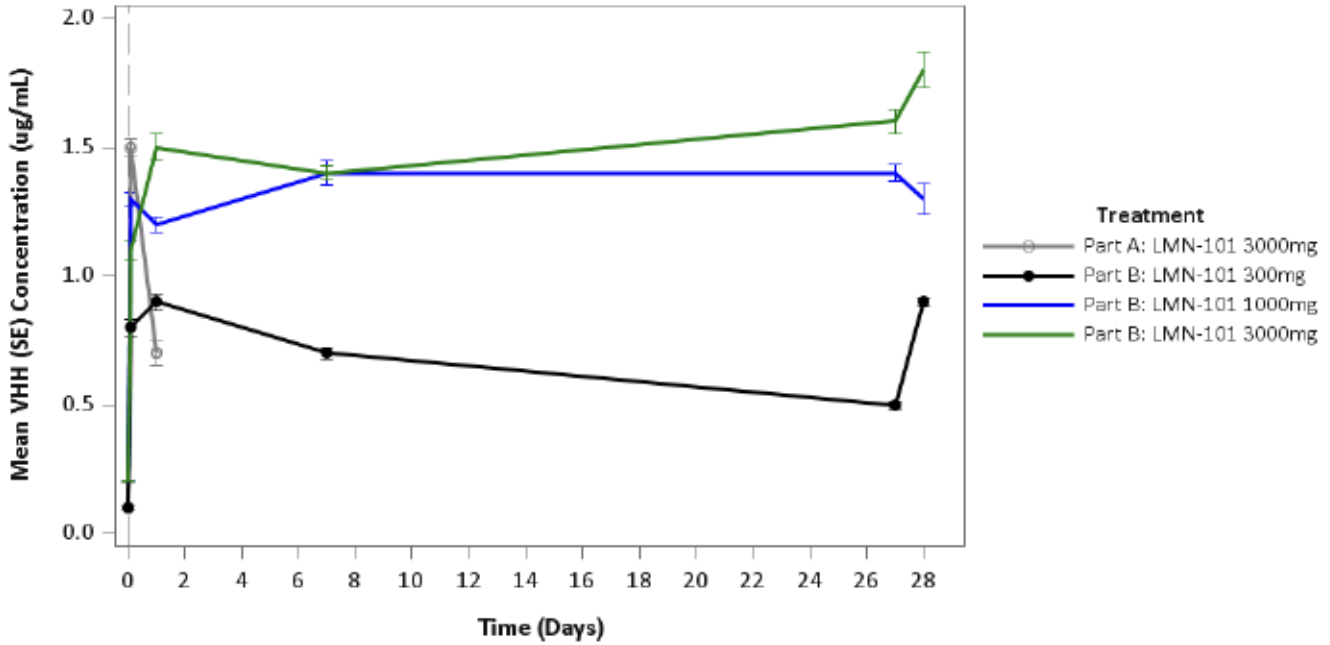
Program: filepath_name, Output Name: filepath_name Creation Date/Time: DDMMMYYYY HH:MM Page 1 of xx

Sponsor: Lumen Bioscience, Inc.
Protocol: CAM01

Database lock: yyyy-mm-dd

Figure 14.2.1.3 Mean (+/-SE) Serum Concentrations of VHH by Days – All Timepoints (PK Population)

Example figure:



Programming Note:
The x-axis will represent elapsed days after initial dosing [0 to 28 Days];
label: "Time (Days)"; vertical dashline to be added on Dosing (Day=0) to indicate Baseline.
The y-axis will represent the mean serum concentrations of uric acid (unit) per treatment group. Whiskers will be included to reflect the SEs;
label: "Mean (SE) VHH Concentration (unit)".

The y-axis will be on the linear scale.
Treatment groups to be included are Part A: LMN-101 3000 mg, Part B: LMN-101 300 mg, Part B: LMN-101 1000 mg, Part B: LMN-101 3000 mg. All treatment groups will be represented on a single page. Each treatment group will be presented as a distinct line type.

Program: filepath_name, Output Name: filepath_name Creation Date/Time: DDMMMYYYY HH:MM

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Figure 14.2.1.4 Log_{10} Mean (+/-SE) Serum Concentrations of VHH by Days – All Timepoints (PK Population)

Programming Note:
The figure is the same as 14.2.1.3, however, with y axis log transformed to base 10.
The x-axis will represent elapsed days after initial dosing [0 to 28 Days];
label: "Time (Days)"; vertical dashline to be added on Dosing (Day=0) to indicate Baseline.
The y-axis will represent the Log_{10} mean serum concentrations of VHH per treatment group. Whiskers will be included to reflect the SEs;
label: "Log_{10}Mean (SE) VHH Concentration (unit)".

The y-axis will be on the Log_{10} scale.
Treatment groups to be included are Part A: LMN-101 3000 mg, Part B: LMN-101 300 mg, Part B: LMN-101 1000 mg, Part B: LMN-101 3000 mg. All treatment groups will be represented on a single page. Each treatment group will be presented as a distinct line type.

Sponsor: Lumen Bioscience, Inc. Database lock: yyyy-mm-dd
Protocol: CAM01

Figure 14.2.2.1 Individual Serum Concentrations of VHH by Day – Baseline to Day 2 (24hrs) (PK Population)

Programming Note:
The x-axis will represent elapsed days after initial dosing [0 to 1];
label: "Time (Days)"; vertical dashline to be added on Dosing (Day=0) to indicate Baseline.
The y-axis will represent the serum concentrations of VHH (unit) per Subject.
label: "VHH Concentration (unit)".
The y-axis will be on the linear scale.

Separate plots are to be produced for each treatment group:

- Part A: LMN-101 3000 mg,
- Part B: LMN-101 300 mg
- Part B: LMN-101 1000 mg
- Part B: LMN-101 3000 mg

Each subject within each treatment group will be presented as a distinct line type.

Program: filepath_name, Output Name: filepath_name Creation Date/Time: DDMMMYYYY HH:MM Page 1 of xx

Sponsor: Lumen Bioscience, Inc. Database lock: yyyy-mm-dd
Protocol: CAM01

Figure 14.2.2.2 Log_{10} Individual Serum Concentrations of VHH by Day – Baseline to Day 2 (24hrs) (PK Population)

Programming Note:
The figure is the same as 14.2.2.1, however, with y axis log transformed to base 10.

The x-axis will represent elapsed days after initial dosing [0 to 1];
label: "Time (Days)"; vertical dashline to be added on Dosing (Day=0) to indicate Baseline.
The y-axis will represent the logarithmic transformed serum concentrations of VHH (unit) per subject.
label: "Log_{10} VHH (Concentration (unit)".
The y-axis will be on the log_{10} scale.

Separate plots are to be produced for each treatment group:

- Part A: LMN-101 3000 mg,
- Part B: LMN-101 300 mg
- Part B: LMN-101 1000 mg
- Part B: LMN-101 3000 mg

Each subject within each treatment group will be presented as a distinct line type.

Program: filepath_name, Output Name: filepath_name Creation Date/Time: DDMMMYYYY HH:MM Page 1 of xx

Sponsor: Lumen Bioscience, Inc. Database lock: yyyy-mm-dd
Protocol: CAM01

Figure 14.2.2.3 Individual Serum Concentrations of VHH by Days - All Timepoints (PK Population)

Programming Note:
The x-axis will represent elapsed days after initial dosing [0 to 28 Days];
label: "Time (Days)"; vertical dashline to be added on Dosing (Day=0) to indicate Baseline.
The y-axis will represent the serum concentrations of VHH (unit) per subject.
label: "VHH Concentration (unit)".
The y-axis will be on the linear scale.

Separate plots are to be produced for each treatment group:

- Part A: LMN-101 3000 mg,
- Part B: LMN-101 300 mg
- Part B: LMN-101 1000 mg
- Part B: LMN-101 3000 mg

Each subject within each treatment group will be presented as a distinct line type.

Program: filepath_name, Output Name: filepath_name Creation Date/Time: DDMMMYYYY HH:MM Page 1 of xx

Figure 14.2.2.4 Log_{10} Individual Serum Concentrations of VHH by Days – All Timepoints (PK Population)

Programming Note:
The figure is the same as 14.2.2.3, however, with y axis log transformed to base 10.
The x-axis will represent elapsed days after initial dosing [0 to 28 Days];
label: "Time (Days)"; vertical dashline to be added on Dosing (hour=0) to indicate Baseline.
The y-axis will represent the Log_{10} individual serum concentrations of VHH per subject.
label: "Log_{10}VHH Concentration (unit)".

The y-axis will be on the Log_{10} scale.

Separate plots are to be produced for each treatment group:

- Part A: LMN-101 3000 mg,
- Part B: LMN-101 300 mg
- Part B: LMN-101 1000 mg
- Part B: LMN-101 3000 mg

Each subject within each treatment group will be presented as a distinct line type.

LMN-101_SAP_Final_V2_2020_03_18 fully executed

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By:	Lucas Thornton (Lucas.Thornton@novotech-cro.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA3seOT4CbgrBPktSHbRzeinfgRhO-XGhC

"LMN-101_SAP_Final_V2_2020_03_18 fully executed" History

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2020-03-23 - 0:49:53 AM GMT


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