

16.1.9 Documentation of Statistical Methods

16.1.9.1 Statistical Analysis Plan



STATISTICAL ANALYSIS PLAN

A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose and Multiple Ascending Dose Trial in Healthy Adult Participants to Evaluate the Safety, Tolerability, and Pharmacokinetics of MK-7762 with Two Open Label (Single Dose) Food Effect Panels

Protocol No: Gates MRI-TBD09-101
Final Protocol Date: 27 September 2022
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Amendment No. 2: 04 April 2023
Amendment No. 3: 08 September 2023
Amendment No. 4: 30 October 2023
Protocol Clarification Letter No. 5: 07 November 2023
Protocol Clarification Letter No. 6: 12 December 2023
Compound Name: MK-7762

Celerion Project CA35747
Final Amendment Version 1.0
Date: 16 February 2024

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Compound Name: MK-7762

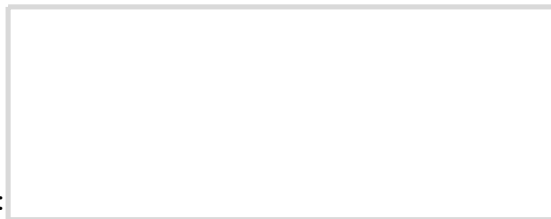
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Issue Date: 16 February 2024

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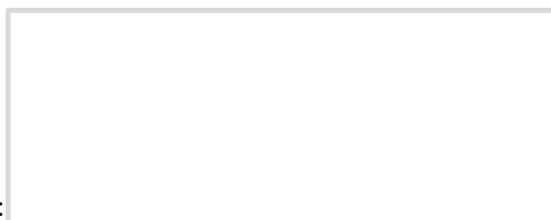
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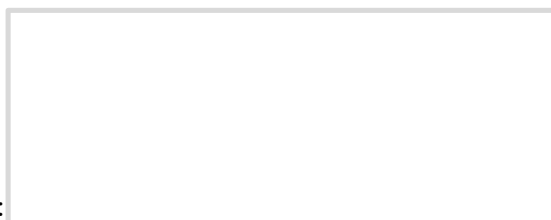
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1. INTRODUCTION

The following statistical analysis plan (SAP) provides the framework for the analysis and presentation of the data from this trial. Any changes made from the planned analysis described in the protocol or after finalization of this SAP will be documented in the Clinical Study Report (CSR). The section referred to as “Table, Figure, and Listing Shells” within this SAP describes the Clinical Data Interchange Standards Consortium (CDISC) input in order to provide traceability to the corresponding tables, figures, and listings (TFLs). Study data tabulation model (SDTM) is the primary source for the data listings and analysis data model (ADaM) is the source for tables and figures (as well as any listings that contain derived data).

Any additional exploratory analyses not addressed within this SAP and/or driven by the data, or requested by Bill & Melinda Gates Medical Research Institute, will be considered out of scope and must be described in the CSR.

Celerion will not revise the SAP in the case that a dose level is adjusted, removed, repeated, or added. Instead, it should be noted that treatments will be appropriately described and summarized in the TFLs. However, more significant study design changes could prompt a SAP revision. Specifically, the SAP will generally only be revised in case of changes leading to a significant impact on the analysis or programming.

Rationale for current SAP revision: The original SAP and TFL Shell documents dated 02 June 2023 were amended on 16 February 2024 to reflect the changes to the design and objectives of Part 2 outlined in Protocol Amendment No. 4 (Version 5.0, dated 30 October 2023), which require updates to the analysis and presentation of the data. Specifically, Part 2, which previously consisted of multiple ascending dose (MAD) cohorts only, now consists of a food effect (FE) cohort and a total of 3 MAD cohorts. The current SAP has updated the analysis and presentation of Part 2 data accordingly.

2. OBJECTIVES AND ENDPOINTS

Objectives	Endpoints
Primary	
Safety	
To characterize safety and tolerability of MK-7762 after administration of single doses or multiple doses in healthy adult participants For Parts 1 and 2 (All Cohorts)	The proportion of treated participants reporting treatment-emergent adverse events (TEAEs), serious AEs (SAEs), and AEs of special interest (AESIs), assessed overall, by severity, by relationship to study drug, and by system organ class and preferred term according to the following windows: <ul style="list-style-type: none">Part 1, Cohorts 1 through 5: Day 1 through Day 7Part 1, FE Cohort 6: Day 1 through last day of washout period for first dosing period; Day 1 of second dosing period through Day 7 of second dosing period.Part 2, FE Cohort 7: Day 1 through last day of washout period for first dosing period; Day 1 of second dosing

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Objectives	Endpoints
	<p>period through last day of washout period for second dosing period; Day 1 of third dosing period through Day 7 of third dosing period</p> <ul style="list-style-type: none"> Part 2, Cohorts 8-10: Day 1 through Day 36
<p>To characterize laboratory results, electrocardiogram (ECG) parameters, and vital signs after administration of single doses or multiple doses of MK-7762</p> <p>For Parts 1 and 2 (All Cohorts)</p>	<p>In treated participants, summaries (descriptive statistics and frequencies) of safety laboratory measures (by visit, worst grade, grade shift from baseline), vital signs (by visit, change from baseline), 12-lead ECG parameters (by visit, change from baseline) according to the same windows defined above for AEs.</p> <p>Safety laboratory measurements include clinical chemistry, hematology, coagulation, and urinalysis. Vital signs include temperature, heart rate, and blood pressure. ECG parameters include heart rate, RR interval, PR interval, QRS duration, QT interval, and QT interval corrected by Fridericia's formula [QTcF].</p>
Secondary	
PK	
<p>To determine the pharmacokinetic (PK) of single doses of MK-7762 in plasma*</p> <p>For Part 1 (SAD Cohorts 1-5)</p> <p>To evaluate the impact of food on the PK of MK-7762 in plasma*</p> <p>For Part 1 (FE Cohort 6)</p> <p>For Part 2 (FE Cohort 7)</p>	<p>Estimand framework:</p> <ul style="list-style-type: none"> Treatment: 1) MK-7762 in escalating single doses or placebo (Part 1, SAD Cohorts 1-5) and 2); MK-7762 under fasted or fed conditions (Part 1, FE Cohort 6) and 3); MK-7762 under fasted or fed conditions (Part 2, FE Cohort 7) Population: All participants who receive at least one dose of MK-7762 and have at least one non-zero PK result (PK Population) Participant-level endpoints: <ul style="list-style-type: none"> Maximum plasma drug concentration (C_{max}), Time to maximum plasma drug concentration (T_{max}), area under the concentration-time curve (AUC) calculated to last quantifiable observed sample (AUC_{last}), extrapolated to infinity (AUC_{0-inf}), and over first 24h (AUC_{0-24}) Terminal elimination half-life ($t_{1/2}$) Oral clearance (CL/F) Oral volume of distribution (V_d/F) Population-level summaries: Descriptive statistics of endpoints noted above. Intercurrent events: A treatment policy strategy will be used to summarize plasma PK results.
<p>To determine the PK of multiple doses of MK-7762 in plasma in fed and fasted states*</p>	<p>Estimand framework:</p> <ul style="list-style-type: none"> Treatment: MK-7762 in escalating multiple doses or placebo (Part 2, MAD Cohorts 8-10)

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Objectives	Endpoints
For Part 2 (MAD Cohorts 8-10)	<ul style="list-style-type: none"> Population: All participants who receive at least one dose of MK-7762 and have at least one non-zero PK result (PK Population) Participant-level endpoints (all endpoints will be assessed in fed and fasted states): <p>Day 1:</p> <ul style="list-style-type: none"> C_{\max} T_{\max} $AUC_{(0-24)}$ <p>Day 28:</p> <ul style="list-style-type: none"> C_{\max} T_{\max} AUC, AUC_{last}, $AUC_{0-\text{inf}}$, and AUC_{0-24} $t_{1/2}$ CL/F V_d/F Accumulation ratio ($AUC_{\text{tau}} / AUC_{0-24}$) <ul style="list-style-type: none"> Day 28 vs Day 1 Population-level summaries: Descriptive statistics of endpoints noted above. Intercurrent events: A treatment policy strategy will be used to summarize plasma PK results.
Exploratory	
To determine the PK of single doses or multiple doses of MK-7762 in urine*	In treated participants with at least one non-zero PK result, descriptive statistics of the following measures:
For Parts 1 (Cohort 4) and Part 2 (Cohort 9)	<ul style="list-style-type: none"> Urine PK concentrations Percent of drug excreted in urine (in a dosing interval) ($A_e\%$) Renal clearance (CL_r) To estimate the metabolite-to-parent ratio ($AUC_{\text{metabolite}}/AUC_{\text{MK-7762}}$) cumulative urinary excretion (CUE)
To identify prominent circulating metabolites of MK-7762 in plasma following administration of single doses or multiple doses of MK-7762*	In treated participants with at least one non-zero PK result, qualitative characterization of potential metabolites.
For Parts 1 (Cohort 4) and Part 2 (Cohort 10)	
To estimate the effect of MK-7762 on ECG parameters, including concentration-QTc (C-QTc) analysis, following single or multiple doses of MK-7762*	In treated participants, descriptive statistics of the following endpoints, including placebo-corrected change from baseline measures, categorical outliers, and frequency of treatment-emergent T- and U-wave abnormalities:
For Parts 1 and 2 (All Cohorts)	<ul style="list-style-type: none"> Heart rate RR interval

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Objectives	Endpoints
	<ul style="list-style-type: none"> PR interval QRS interval QTcF interval <p>This analysis may be undertaken based on observed PK and other project considerations. If so, the primary analysis will be based on concentration-QTc (C-QTc) modeling of the relationship between the plasma concentrations of MK-7762 and potential metabolites and change-from baseline QTcF (ΔQTcF) with the intent to exclude an effect of placebo corrected ΔQTcF ($\Delta\Delta$QTcF) > 10 msec at clinically relevant plasma concentrations.</p>
<p>To characterize the maximal hematological effect of single or multiple doses of MK-7762 or placebo in healthy participants</p> <p>For Parts 1 and 2 (All Cohorts)</p>	<p>In treated participants, the following binary classifications with respect to platelet count, absolute neutrophil count (ANC), white blood cell (WBC) count, reticulocyte count, red blood cell (RBC) count, and hemoglobin result:</p> <ol style="list-style-type: none"> Post-baseline result that is < lower limit of normal (LLN) (yes/no) Post-baseline result that is < 50% of LLN (yes/no) Post-baseline result that is \geq20% decrease relative to baseline (yes/no) Post-baseline result that is \geq50% decrease relative to baseline (yes/no) <p>Summaries will include the following:</p> <ul style="list-style-type: none"> For each of (a) through (d), the proportion of participants who meet the criterion
<p>To characterize the effect of MK-7762 on neurologic assessments in healthy participants receiving multiple doses</p> <p>For Part 2 (MAD Cohorts 8-10)</p>	<p>In treated participants, descriptive summaries for each of the following measures:</p> <ul style="list-style-type: none"> For visual acuity score for each eye <ul style="list-style-type: none"> Descriptive statistics for change in visual acuity score from baseline to lowest post-baseline score Proportion of participants with a post-baseline visual acuity score worse than 20/25 in either eye For color vision assessment for each eye <ul style="list-style-type: none"> Proportion of participants with a post-baseline color vision abnormality in either eye (overall and by severity grade) For Brief Peripheral Neuropathy Screen (BPNS) score in each lower extremity <ul style="list-style-type: none"> Proportion of participants with a reported new post-baseline peripheral neuropathy symptom on BPNS (overall and by severity grade)

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Objectives	Endpoints
	<ul style="list-style-type: none">○ Proportion of participants with a new post-baseline peripheral neuropathy objective physical finding on BPNS (overall and by severity grade)○ Proportion of participants with new post-baseline peripheral neuropathy symptoms and objective physical finding on BPNS (overall and by severity grade)
To evaluate the time to resolution of hematologic and neurologic AESIs following discontinuation of MK-7762 after multiple doses For Part 2 (MAD Cohorts 8-10)	In treated participants who have ongoing hematologic or neurologic AESI at the time of treatment discontinuation: <ul style="list-style-type: none">• Kaplan-Meier analysis of time to resolution of category of AESI (hematologic or neurologic). Participants with unresolved AESI at the time of analysis will be censored on the date of last AE assessment.• Milestone rates at 5 days following treatment discontinuation
To explore possible variability in MK-7762 metabolism due to genetic polymorphisms based on metabolite profile observed* For Parts 1 and 2 (All Cohorts)	Will be defined in an exploratory SAP.

*Objectives for clinical pharmacology and pharmacometrics (CP&P) are covered in Certara's SAP. Certara will produce the analyses to address the CP&P objectives, which will be documented in a separate report that will be appended to the Celerion CSR. Metabolite profiling and cardiodynamic and concentration-QT analyses will be addressed at a later date, if applicable.

3. TRIAL DESIGN

This trial is designed to address the objective(s) outlined in [Section 2](#).

This is a first-in-human (FIH) trial of MK-7762, administered to healthy adults. It is a randomized, double-blind, placebo-controlled, two-part trial. Healthy adult participants between 19 to 55 years of age (inclusive) of both sexes who are capable of and willing to provide informed consent will be eligible for the trial.

The trial will be conducted in two parts. Part 1 consists of 5 single ascending dose (SAD) cohorts (double-blind, placebo-controlled) (N=40) and a FE cohort (open-label) enrolling 8 participants and Part 2 consists of 3 multiple ascending dose (MAD) cohorts (double-blind, placebo-controlled) (N=60) and a FE cohort (open-label) enrolling 9 participants. Because this trial is aimed at characterizing the safety, tolerability, and PK of MK-7762, it is designed to be descriptive and is not based on formal hypothesis testing. Therefore, this trial is not powered to detect any pre-specified differences in potential safety or PK data between treatment groups. A total of approximately 117 participants will be randomized (48 in Part 1

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and 69 in Part 2), and a total of approximately 95 participants will be exposed to MK-7762 (38 from Part 1 and 57 from Part 2).

The trial has a double-blind design in which all participants in SAD Cohorts 1-5 and MAD Cohorts 8-10 and all site personnel will be blinded to the randomization, excepting the unblinded pharmacist(s) and pharmacy staff at the clinical trial unit (CTU) who will prepare oral doses of MK-7762 and placebo appropriately masked for site personnel who are authorized to administer treatment. All doses of MK-7762 administered to all participants in FE Cohort 6 and FE Cohort 7 will be open-label. Refer to the Gates MRI-TBD09-101 Unblinding Plan for additional details about the roles and responsibilities, data flow, and level of access associated with unblinding activities.

All participants will undergo a Screening period lasting up to 20 days (Day -21 to -2) followed by a confinement period in the CTU of varying length according to their cohort. In Part 1, the maximum duration of participation, including the Screening period, will be approximately up to 30 days for participants in Part 1, SAD Cohorts 1 through 5, and approximately 38 days for participants in FE Cohort 6 (to be confirmed once washout period of at least 5 half-lives is determined). The duration of participation for participants in Part 2, FE Cohort 7, will be up to approximately 44 days, which includes a washout period of at least 8 days between the open-label doses of MK-7762. In Part 2, MAD Cohorts 8-10, the maximum duration of participation, including the Screening period, will be approximately up to 54 days for participants. The duration of cohorts may be adjusted (increased or decreased) based on emerging PK data collected during the trial.

3.1 Part 1 – SAD and Food Effect (SAD/FE)

In Part 1 of the trial (SAD/FE), five sequential cohorts will be enrolled to evaluate up to five escalating single doses of MK-7762; eight participants in each cohort will be randomized (3:1, excluding Cohort 1) to receive MK-7762 or placebo. The first two participants in Cohort 1 will be dosed as sentinel participants in a blinded manner, randomized 1:1 to MK-7762 or placebo. The safety review team (SRT) will review safety data up to Day 4 following dosing for these two sentinel participants. If recommended by the SRT and approved by the Sponsor, the remaining 6 participants in Cohort 1 will receive single doses of study drug (randomized 5:1; MK-7762:placebo). A sixth cohort will evaluate the effect of food on PK of single doses of MK-7762 utilizing an open-label, single-dose two period cross-over design in 8 participants. The MK-7762 dose to be evaluated in the FE cohort will be a dose demonstrated to be safe and well-tolerated in previously completed SAD cohorts. All participants in Part 1 will be confined at the CTU from Day -1 until their end-of-trial visit (approximately 8 days for Cohorts 1-5 and 16 days for Cohort 6). The exact duration of the confinement will be determined by the time required for an adequate washout period of at least five half-lives to be determined by PK results from the SAD cohorts. Randomization will occur prior to dosing on Day 1 for all cohorts.

Cohorts 1 through 4 will evaluate the safety and PK of single oral doses of MK-7762 of 50 mg, 150 mg, 300 mg, and 600 mg. Cohort 5 may evaluate a dose of MK-7762 that will be

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selected based on the safety and PK data from previous cohorts. The dose of MK-7762 chosen for evaluation in Cohort 5 will not result in greater predicted exposure than that allowable based on the nonclinical toxicology no observed adverse effect level (NOAEL).

For Cohort 6 (the FE Cohort), eight participants will be dosed with MK-7762 in both fasted and fed states. Two sentinel participants in Cohort 6 will be dosed in the fed state first. The SRT will review safety data up to Day 4 and PK data up to Day 2 for the two sentinel participants from the fed state dosing period. If recommended by the SRT and approved by the Sponsor, the two sentinel participants will be dosed with MK-7762 in the fasted state after the washout period previously determined, and the remaining 6 participants in Cohort 6 will subsequently be dosed with MK-7762 in fed and fasted states in a crossover manner employing the washout period previously determined. The remaining 6 participants will be randomized 1:1 to fed vs fasting in their first dosing period with crossover in their second dosing period following washout. The enrolment to FE Cohort 6 may start after PK and safety data from Cohort 2 become available.

The doses of MK-7762 to be administered in the cohorts following Cohort 1 may be modified based on accumulating safety, tolerability, and PK data. The protocol may be amended to enroll additional participants at any of the planned dose level(s) or to study another dose level if the Sponsor determines that it is necessary based on emerging safety and PK data from previously completed cohorts.

If more than 1 participant from Cohort 6 is withdrawn from the trial after receiving the first dose but before receiving the second dose of study drug, additional participants will be enrolled to replace the withdrawn participants. No replacements are required if only one participant is withdrawn from Cohort 6 before receiving the second dose of study drug.

Fasted Cohorts (SAD Cohorts 1-5)

Dose administration for SAD Cohorts 1-5 will occur after an 8-hour overnight fast on the morning of Day 1. Fasting will continue until 4 hours post-dose at which time a standardized meal will be provided. Clinical and safety laboratory assessments will be performed throughout the confinement period as per protocol schedule of assessments for Cohorts 1-5.

Food Effect Cohort (FE Cohort 6)

Participants administered MK-7762 in the fasted state will be dosed after an 8-hour overnight fast on the morning of Day 1. Participants administered MK-7762 in the fed state will be provided the standard US Food & Drug Administration (FDA) high fat breakfast, which should be consumed within 30 minutes or less, with MK-7762 administration occurring approximately 30 minutes after the start of the meal. In both the fed and fasted settings, fasting will resume for 4 hours post-dose, at which time, a standardized meal will be provided.

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3.2 Interim Review of Data from Part 1

Following completion of Part 1, a comprehensive interim review of cumulative clinical and PK data will be conducted in an unblinded manner by the Sponsor to guide selection of appropriate doses to be evaluated in Part 2. Any additional relevant nonclinical data will also be reviewed as part of this process. The results of the interim review are intended for regulatory submission, comment and regulatory agreement to proceed prior to the Sponsor's agreement to initiate Part 2 of the trial.

The interim data analysis was conducted by Celerion after the database from Part 1 had been locked and included all Part 1 TFLs specified in the final SAP dated 02 June 2023. The interim analysis results provided at the completion of Part 1 are included in Protocol Amendment 4 which was issued to update the study design for Part 2 given the results of the formal interim analysis.

3.3 Part 2 – Food Effect and MAD (FE/MAD)

Part 2 of the trial will consist of a FE cohort (Cohort 7) and three sequential MAD cohorts (Cohorts 8-10) to evaluate escalating once daily doses of MK-7762 or placebo for 28 days.

FE Cohort 7 will be an open-label, three-period evaluation of 600 mg MK-7762 in the fasted state, after ingestion of a standard meal breakfast, and after ingestion of a high-fat meal breakfast, in random fashion. FE Cohort 7 will enroll a sufficient number of participants to ensure that 9 participants complete each of the three dosing periods. Participants will be randomized 1:1:1 to one of the following 3 sequences:

- Fasted, standard meal, high-fat meal
- Standard meal, high-fat meal, fasted
- High-fat meal, fasted, standard meal

Between doses, there will be a washout period of at least 8 days, consistent with at least 5 half-lives. Participants administered MK-7762 in the fasted state will be dosed after an 8-hour overnight fast on the morning of Day 1. Participants administered MK-7762 in the standard meal fed state will be provided a standard meal breakfast, which should be consumed within 30 minutes or less, with MK-7762 administration occurring approximately 30 minutes after the start of the meal. Participants administered MK-7762 in the high-fat meal fed state will be provided with a high-fat meal breakfast, which should be consumed within 30 minutes or less, with MK-7762 administration occurring approximately 30 minutes after the start of the meal. In both the fed and fasted settings, fasting will resume for at least 4 hours post-dose. All participants in FE Cohort 7 will be confined at the CTU from Day -1 of Period 1 until end-of-trial visit on Day 8 of Period 3. If a participant from Cohort 7 withdraws from the trial after receiving no more than a single dose of MK-7762, the participant will be replaced. Participants who withdraw from the trial after receiving at least 2 doses of MK-7762 will not be replaced.

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In MAD Cohorts 8-10, 3 dose levels of MK-7762 will be administered daily for 28 days in a placebo-controlled, MAD design (N=60). MAD Cohort 8 will be enrolled first, and following its enrollment completion, at least 9 participants will be enrolled in FE Cohort 7. After FE Cohort 7 enrollment is complete, MAD Cohorts 9 and 10 will be enrolled sequentially with dose escalation recommendations made by the SRT. The MAD doses in Part 2 were selected based on data from Part 1: MAD Cohort 8 will evaluate MK-7762 100 mg once daily (QD), MAD Cohort 9 will evaluate MK-7762 300 mg QD. The anticipated MK-7762 QD dose to be evaluated in MAD Cohort 10 is 500 mg. This may be modified through a protocol amendment after review of PK and safety data from FE Cohort 7 and MAD Cohorts 8 and 9. The dose in MAD Cohort 10 will not exceed 600 mg QD. Within each MAD cohort, half participants will be dosed in the fasted state and half of the participants will be dosed after a standard breakfast meal. Each of the three MAD cohorts will have approximately 20 participants randomized 4:4:1:1 to receive MK-7762 in fasted state, MK-7762 in fed state after standard meal breakfast, placebo in fasted state, or placebo in fed state after standard meal breakfast. All participants in Part 2, MAD Cohorts 8-10, will be confined at the CTU from Day -1 until their end-of-trial visit on Day 36. If more than two participants from a MAD cohort are withdrawn from the trial before the Day 29 visit assessments are completed, additional participants will be enrolled with blinded treatment assignment matching that of the withdrawn participants. No replacements are required if two or fewer participants are withdrawn before their Day 29 visit.

An additional MAD cohort may be considered for subsequent enrolment after protocol amendment to evaluate once daily doses of MK-7762 or placebo for 91 days based on findings from the 28-day MAD cohorts and the ongoing 4-month sub-chronic toxicology studies in rats and dogs.

In Part 2, effort will be made to enroll as many females as possible in FE Cohort 7 and in MAD Cohorts 8-10. Randomization to the treatment sequence or treatment group within a cohort will be stratified by sex. Randomization will occur prior to dosing on Day 1 for MAD Cohorts 8-10 and Day 1 of Period 1 for FE Cohort 7. Clinical and safety laboratory assessments will be as per schedule of events for all Part 2 Cohorts.

4. ANALYSIS POPULATIONS

Safety Population: All participants who received at least one dose of the study intervention (MK-7762 or placebo). Participants will be analyzed according to the intervention they received.

Per protocol (PP) Population: All participants who received at least one dose of the study intervention and did not significantly deviate from study procedures. Participants will be analyzed according to the intervention they received. If the Safety Population and the PP Population are the same, separate summaries will not be generated for the PP population.

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5. TREATMENT DESCRIPTIONS

Associated Cohort	Short Description*
Part 1 – SAD and FE	
SAD	
1-5	Pooled Placebo
1	50 mg Fasted
2	150 mg Fasted
3	300 mg Fasted
4	600 mg Fasted
5	1200 mg Fasted
Part 1 FE	
6	300 mg Fasted (C6)*
6	300 mg Fed
Part 1 Pooled	
1-6	All MK-7762 Fasted
1-6	All MK-7762^
Part 2 – FE and MAD	
Part 2 FE (single dose)	
7	600 mg Fasted
7	600 mg Fed Standard Meal
7	600 mg Fed High-Fat Meal

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Associated Cohort	Short Description*
MAD^{^^}	
8-10	Pooled Placebo QD Fasted
8-10	Pooled Placebo QD Fed Standard Meal
8	100 mg QD Fasted
8	100 mg QD Fed Standard Meal
9	300 mg QD Fasted
9	300 mg QD Fed Standard Meal
10	500 mg QD Fasted
10	500 mg QD Fed Standard Meal
MAD Pooled^{**}	
8-10	Pooled Placebo QD
8	100 mg QD
9	300 mg QD
10	500 mg QD
8-10	All MK-7762 QD

*In TFLs, short description may be abbreviated to remove fasting status or dosing regimen if the information is available in a sub-header. When a dose level is repeated across multiple cohorts, 'CX', where X is the cohort number, will be included in the treatment labels when needed in order to distinguish the cohort specific summaries. For summaries pooling the data for repeated dose levels, '(CX, CX)' will be added to the treatment labels.

[^] Due to the crossover design of Cohort 6, this pooled summary will only be included in the AE summaries.

^{^^}Part 2 MAD listings will use the treatments listed in this section.

^{**}Part 2 MAD summaries will be presented according to the treatments listed in this section.

TBD = To be determined

Note: In the event that the dose level selected for the Part 1 FE cohort is the same as that of a previous SAD cohort, Cohort 6 fasted data will be summarized separately from the corresponding SAD data. An additional pooled summary will be provided. As a result, a

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pooled summary of 300 mg MK-7762 Fasted data from Cohorts 3 and 6 was included in applicable Part 1 TFLs.

For Part 2, MAD summaries, participants will be pooled by dose level regardless of fasting conditions.

6. SAFETY

All relevant safety case report form (CRF) and clinical laboratory data will be listed by part, participant and chronologically by assessment time point. This will include rechecks, unscheduled, and early termination assessments. Time points will be presented in the listings as recorded in the CRF. Data from screen failure participants will be listed separately and will not be summarized.

Listings, summaries, and figures will be provided separately by part. For Part 2, tables and figures will be provided separately for FE Cohort 7 and MAD Cohorts 8-10. Applicable continuous variables will be summarized using sample size (n), mean, standard deviation (SD), minimum, median, and maximum. Data from participants who received the placebo treatment will be pooled across cohorts for Part 1 and across cohorts, regardless of fasting status for Part 2 MAD. Unless otherwise specified, summaries provided by treatment will include all treatments defined in [Section 5](#), including pooled treatments.

The level of precision will be presented as follows: minimum, maximum, mean, median, and SD will be rounded to one decimal place unless otherwise specified. If the data is recorded in integers in the database, minimum and maximum will be presented in integers. For a specific parameter, if the first significant digit of its values is further than the second decimal place for over 50% of the participants, then the rounding of the summary statistics may be adjusted accordingly. Number of observations (n) will be presented as an integer. Percentages will be presented as an integer. Confidence intervals, when applicable, will be presented to 2 decimal places.

Where individual data points are missing because of dropouts or other reasons (i.e., missing clinical laboratory blood draw), the data will be summarized based on reduced denominators.

For Part 1, SAD Cohorts 1 through 5 of Part 1, baseline will be the result closest and prior to dosing. For Part 1 FE Cohort 6 and Part 2 FE Cohort 7, baseline will be the result closest and prior to dosing in the respective period. When there is no predose assessment in a period, the last assessment in the previous period (i.e., Day 8) will be used as baseline, if applicable. For Part 2, MAD Cohorts 8-10, baseline will be the result closest and prior to the first dose. Summaries for post-baseline time points will not include rechecks, unscheduled, or early termination measurements. However, rechecks and unscheduled assessments will be considered for the selection of baseline measurements.

Tables summarizing safety data by assessment time point will only include summaries for baseline and post-baseline time points. Specifically, for Part 1, the planned visit schedules will cover the time period from pre-dose on Day 1 to Day 7 for SAD Cohort 1-5, and Day 7

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of each dosing period (fed or fasted) for FE Cohort 6. For Part 2, the planned visit schedules will cover the time period from pre-dose on Day 1 to Day 8 of each dosing period (fed standard meal, fed high-fat meal, or fasted) for FE Cohort 7 and to Day 36 for MAD Cohorts 8-10. Safety summaries will be inclusive of all participants in the safety population, unless otherwise specified.

No inferential statistics will be performed on safety endpoints.

6.1 Participant Disposition and Extent of Exposure

Participants will be summarized by the number and percent of participants dosed, completed the trial, discontinued treatment (with discontinuation reasons), and discontinued the trial (with discontinuation reasons). If withdrawn participants are replaced, this will also be summarized. Disposition summaries will be provided as follows:

- by treatment (individual dose levels) for Part 1, SAD Cohorts 1-5
- by treatment sequence (Fasted/Fed, Fed/Fasted) for Part 1, FE Cohort 6
- Overall for Part 1
- by treatment sequence (Fasted/Standard/High-Fat, Standard/High-Fat/Fasted, High-Fat/Fasted/Standard) and overall for Part 2, FE Cohort 7
- by treatment (individual dose levels, regardless of fasting status) and overall for Part 2, MAD Cohorts 8-10

For the FE cohorts, individual participant dosing status (i.e., which treatments were administered to each participant) will also be provided along with their trial completion status and date of trial completion or discontinuation. The number of participants dosed for each treatment in the FE cohorts will also be presented.

6.2 Protocol Deviations

Protocol deviations will be recorded and documented in Celerion's Veeva SiteVault. Once the deviations have been finalized, a MS Excel file with all deviations will be imported into SDTM and a SAS generated listing of the deviations will be provided. Prior to Part 2 database lock, discussions will occur between Celerion and Bill & Melinda Research Medical Institute to determine participant's inclusion in the Per Protocol Population.

6.3 Demographics

Descriptive statistics will be calculated for continuous variables (age, body mass index, height, and weight). Age for participants in the safety population will be approximated by subtracting the date of birth (day is not collected so the first day of the month will be used) from the date of informed consent. If calculated difference is one more than the protocol maximum age then the age approximation will be the calculated difference – 1. Descriptive

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statistics for body mass index, height, and weight will be calculated using screening measurements.

Frequency counts will be provided for categorical variables (sex, race, and ethnicity).

Demographic summaries will be provided as follows:

- by treatment (individual dose levels) for Part 1, SAD Cohorts 1-5
- by treatment sequence (Fast/Fed, Fed/Fast) for Part 1, FE Cohort 6
- Overall for Part 1
- by treatment sequence (Fasted/Standard/High-Fat, Standard/High-Fat/Fasted, High-Fat/Fasted/Standard) and overall for Part 2, FE Cohort 7
- by treatment (individual dose levels, regardless of fasting status) and overall for Part 2, MAD Cohorts 8-10

6.4 Extent of Exposure

All study drug administration data will be listed. For Part 2, MAD Cohorts 8-10, the number of doses and total dosage received will be listed for each participant receiving MK-7762 and summarized using descriptive statistics by treatment. The total dosage will be calculated as daily dose * number of doses received and expressed as an integer.

6.5 Adverse Events

All adverse events (AEs) occurring during this clinical trial will be coded using the Medical Dictionary for Regulatory Activities (MedDRA®), Version 26.0.

All AEs captured in the database will be listed in a by-participant data listing including verbatim term, coded term, treatment, onset date/time, resolution date/time, frequency, severity grade (documented by the Investigator in the CRF using protocol section 10.2.7.1. as a guide), relationship to study product, AESI flag, and action; however, only TEAEs will be summarized (as per analysis window below). Events considered as AESIs for this trial are defined in the protocol and will be flagged accordingly in the CRF.

A TEAE is defined as an AE that is starting at the time of or after first study drug administration. Each TEAE will be attributed to a treatment based on the onset date and time of the AE compared to that of the respective treatment administration date and time. For the FE cohorts, an AE that occurs during the washout period between treatments will be considered treatment-emergent to the last treatment administered prior to onset of the AE.

If the onset time of an AE is missing and the onset date is the same as or occurs after the treatment dosing date, then the AE will be considered treatment emergent. If the onset date of an AE is missing, then the AE will be considered treatment emergent.

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For the FE cohorts, if the onset time of an AE is missing and the onset date is the same as the treatment dosing date, then the AE will be considered treatment emergent in the prior and current treatment. If the onset time of an AE is missing and the onset date does not fall on a treatment dosing date, then the AE will be considered treatment emergent for the last treatment administered. If the onset date of an AE is missing, then the AE will be considered treatment emergent and attributed to each treatment, unless the onset date is known to have occurred within or between specific treatment periods.

TEAEs, serious adverse events (SAEs), TEAEs leading to study drug discontinuation, and AESIs will be tabulated by System Organ Class (SOC) and Preferred Term. In Part 2, MAD Cohorts 8-10, a subset of visual acuity decreased and color vision change related TEAEs will also be summarized similarly. Visual acuity decreased and color vision change related TEAEs will be flagged programmatically by narrowing preferred terms falling under the following MedDRA[®] Standardized MedDRA Queries (SMQ):

- Retinal Disorders
- Lens Disorders
- Optic Nerve Disorder

All summaries will be provided by treatment. The following summaries will be provided:

- Number and percentage of participants reporting TEAE (overall and by maximum grade of severity)
- Number and percentage of participants reporting drug-related TEAE (overall and by maximum grade of severity)
- Number of TEAEs by grade of severity and relationship to study drug
- Number and percentage of participants reporting SAE (overall and by maximum grade of severity)
- Number and percentage of participants reporting drug-related SAE (overall and by maximum grade of severity)
- Number and percentage of participants reporting a TEAE leading to discontinuation of study drug (overall and by maximum grade of severity)
- Number and percentage of participants reporting drug-related TEAE leading to discontinuation of study drug (overall and by maximum grade of severity)
- Number and percentage of participants reporting AESI (overall and by maximum grade of severity)

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- Number and percentage of participants reporting drug-related AESI (overall and by maximum grade of severity)
- Number and percentage of participants reporting visual acuity decreased or color vision change related TEAE (overall and by maximum grade of severity) (Part 2 only)
- Number and percentage of participants reporting drug-related visual acuity decreased or color vision change related TEAE (overall and by maximum grade of severity) (Part 2 only)

All Part 2, MAD Cohorts 8-10, AE summaries listed above will be performed on the Per Protocol Population in addition to the Safety Population.

SAEs (if present) and AESIs will also be listed separately in tables. Applicable narratives will be included in the CSR.

For Part 2, MAD Cohorts 8-10, the time to resolution of ongoing neurologic or hematologic AESIs at the time of treatment discontinuation will be evaluated using the Kaplan-Meier product limit method. The Kaplan-Meier analysis of time to AE resolution will only be performed if there are more than 5 participants with ongoing neurologic or hematologic AESIs at the time of treatment discontinuation. If there are less than 5 participants with ongoing events, only a listing of time to AE resolution and outcome for ongoing neurologic and hematologic AESIs will be provided.

Time to AE resolution will be calculated as the difference between the date of treatment discontinuation and the AE resolution date and will be reported as an integer in days. Time of AE resolution will not be considered in the computation of time to resolution. Unresolved AEs will be censored at the last AE assessment date. Neurologic and hematologic AESIs will be programmatically flagged using the following search criteria:

- CRF AESI flag = Yes and
- Preferred terms fall into either of the following MedDRA[®] SMQs: Peripheral neuropathy, Haematopoietic erythropenia, Haematopoietic leukopenia, Agranulocytosis, Drug reaction with eosinophilia and systemic symptoms syndrome, Haematopoietic thrombocytopenia, Optic nerve disorders, Demyelination, Ocular infections, Immune-mediated/autoimmune disorders

An ongoing neurologic or hematologic AESI at the time of treatment discontinuation will meet the following criteria:

- Participant treatment discontinuation is marked as Yes on the CRF Study Drug Discontinuation page and

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- CRF Outcome = Resolved, AE onset date is less than date of treatment discontinuation and AE resolution date is greater than date of treatment discontinuation (on Study Drug Discontinuation page of the CRF), or
- CRF Outcome = Not resolved/Not recovering or Resolving/Recovering and AE resolution date is missing

Time to resolution will be summarized descriptively by treatment for the participants with at least one ongoing neurologic or hematologic AESIs at the time of treatment discontinuation. For each treatment, the Kaplan-Meier curves will be displayed in a figure with median time (product-limit median estimate) to resolution and the corresponding two-sided 95% confidence intervals based on Brookmeyer and Crowley ([Brookmeyer, 1982](#)). Participants with unresolved AESIs will be right-censored on the date of last AE assessment (i.e., date of last assessment in the database). The number of participants censored will be presented. For participants with multiple ongoing neurologic or hematologic AESI, the worst (longest) time to resolution will be used in the summaries.

The following SAS® code will be used where T is the time to resolution and STATUS is the censoring variable with value of 0 indicates uncensored (i.e., AE resolved) and 1 indicating censored (i.e., AE ongoing) observations:

```
PROC LIFETEST ALPHAQT=0.05;  
TIME T*STATUS(1);  
STRATA TREATMENT;  
RUN;
```

The proportion of participants with neurologic or hematologic AESI resolution within 5 days of treatment discontinuation will be presented.

For the purpose of the analysis of time to resolution, missing treatment discontinuation dates will be set to the date of last dose received. The following imputations rules will be used for AE resolution dates:

Missing Element	Rule
day, month, and year	<ul style="list-style-type: none">• For completely missing resolution dates (incl. ongoing events), time to AE resolution will be calculated to the date of last AE assessment and censored. Date of last AE assessment will be determined as the date of last assessment recorded in the database.
day, month	<ul style="list-style-type: none">• If partial resolution date contains year only, set resolution date = earliest of 31DecYYYY or date of last AE assessment
Day	<ul style="list-style-type: none">• If partial end date contains month and year, set resolution date = earliest of last day of the month or date of last AE assessment

Note: Partial or missing dates will be displayed as such in the listings. Imputed dates will only be used for the purpose of the analysis.

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6.6 Clinical Laboratory Tests (Chemistry, Hematology, Coagulation, Urinalysis)

Clinical laboratory tests (chemistry, hematology, coagulation, and urinalysis) will be measured as per protocol schedule of events.

Clinical laboratory results will be presented as extracted from the clinical laboratory database. Out-of-reference range flags will be recorded as follows: high (H) and low (L) for numerical results and did-not-match (*) for categorical results.

Out-of-reference range values and corresponding recheck results will be listed.

In addition, Division of Acquired Immunodeficiency Disease (DAIDS) toxicity grade, Version 2.1 will be used to grade laboratory values. The DAIDS grading will be applied to all the numeric results with the ranges found in the DAIDS guidance. The resulting flag of DAIDS grade, e.g., G1, will be placed along with the out-of-reference range flags.

For all numeric laboratory values, descriptive statistics will be presented for each laboratory test by assessment time point. Change from baseline will be summarized in a similar manner. For all numeric laboratory tests, the mean value calculated for each assessment time point and treatment will be compared to the reference range and flagged if outside of the reference range (* if above the reference range and ^ if below the reference range). In the event there is more than one reference range for a laboratory test, the comparison will be made against the lowest of the lower ranges and the highest of the higher ranges. In the event that multiple assessments meet the baseline definition, the result from the in-house clinical laboratory will be prioritized for better comparability to other time points and participants.

For each laboratory test and time point, a shift table will be developed to compare the frequency of the results at baseline (using DAIDS grades for graded tests or categories above reference range, within reference range, or below reference range for non-graded tests) with the respective postdose results. For urinalysis tests, the categories are within reference range and outside reference range for non-graded tests.

All summaries will be provided by treatment.

In each trial part, the following binary classifications with respect to platelet count, absolute neutrophil count (ANC), white blood cell (WBC) count, reticulocyte count, red blood cell (RBC) count, and hemoglobin result will be considered:

- a. Post-baseline result that is < lower limit of normal (LLN) (yes/no)
- b. Post-baseline result that is < 50% of LLN (yes/no)
- c. Post-baseline result that is $\geq 20\%$ decrease relative to baseline (yes/no)
- d. Post-baseline result that is $\geq 50\%$ decrease relative to baseline (yes/no)

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Specifically, the following summaries will be provided by assessment time point (and overall as applicable) for each treatment using the Safety Population (Parts 1 and 2) and the Per Protocol Population (Part 2, MAD cohorts only):

- For each of (a) through (d), the proportion (number and percentage) of participants who meet the criterion will be tabulated. An overall time point summary will also be provided showing the proportion of participants meeting the abnormality criterion at any post-baseline time point.

Note: Percent change from baseline will be calculated as $100 \times (\text{post-baseline value} - \text{baseline value}) / \text{baseline value}$.

In each trial part, boxplots will also be provided for platelet count, ANC, WBC count, reticulocyte count, RBC count, and hemoglobin result.

In each trial part, evaluation of Drug-Induced Serious Hepatotoxicity (eDISH) plots for alanine aminotransferase (ALT) and aspartate aminotransferase (AST) will be generated to assess the liver safety of the study intervention. Specifically, scatter plots displaying peak AST or ALT versus peak total bilirubin (TBL) at post-baseline for each participant will be provided. The following steps will be followed in order to generate the eDISH plots:

- For each participant and time point, take the ratio of “Observed value/Upper Limit of Normal [ULN]” for ALT/AST and TBL
- Get the maximum ratio value for ALT/AST and TBL per participant
- Produce scatter plot to have y-axis = TBL/ULN values and x-axis = ALT/ULN or AST/ULN values
- Draw reference lines on this plot to divide data into 4 quadrants with y-axis reference line at 2 x ULN and x-axis reference line at 3 x ULN

6.7 Vital Signs

Vital signs (blood pressure, heart rate, and temperature) will be measured as per protocol schedule of events.

All vital signs data will be listed and descriptive statistics will be presented for vital signs measurements by assessment time point and treatment. Change from baseline will be summarized in a similar manner. Blood pressure and heart rate only will be summarized for Part 1 cohorts and Part 2 FE cohort. Blood pressure, heart rate, and temperature will be summarized for Part 2 MAD cohorts.

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The number and percentage of participants experiencing abnormal post-baseline blood pressure results (as per categories defined below) will be provided by assessment time point and treatment. The categories of interest are as follows:

Vital Sign (unit)	Abnormality Categories
Systolic Blood Pressure (mmHg)	140 - < 160 ≥ 160 - < 180 ≥ 180
Diastolic Blood Pressure (mmHg)	90 - < 100 ≥ 100 - < 110 ≥ 110

Vital signs abnormalities reported as AEs will be graded in severity as per protocol and will be summarized along with the TEAEs.

6.8 Electrocardiogram

Twelve-lead safety ECGs (QTcF, QT, QRS, RR, PR, HR) will be measured as per protocol schedule of events.

ECGs will be collected in triplicate. The triplicate measures will be averaged and rounded to the nearest tenth. The averages will be used in all summaries. For summaries of investigator ECG interpretation (normal; abnormal not clinically significant; abnormal clinically significant), the worst result of the triplicate at each triplicate time point will be used in the analysis.

Only valid ECGs will be used to calculate average ECG values for each parameter that will be used in the analysis. Valid ECGs do not include records of questionable quality. These include, but are not limited to, records with an associated comment indicating an artifact, lead reversal, wandering lead, etc. ECGs collected in error will also not be classified as valid ECGs. After excluding these ECGs, the remaining ECGs for the respective triplicate set will be assessed against a time window of 10 minutes. A triplicate ECG set is expected to be performed within a 5-minute window but a 10-minute window is selected to increase the likelihood of having a full triplicate ECG set for the calculation of the average ECG value; the specific time window will be defined in the protocol. ECGs that fall outside of the 10-minute window will not be considered valid ECGs. At a given time point, if it is not possible to form a complete ECG triplicate set of valid results, the average will be calculated using the available valid results, i.e., the average of 2 valid ECGs or the single valid ECG result will be used in the analysis. Averaged ECG values will be displayed to the nearest tenth and used in the analysis.

Descriptive statistics will be presented for the averages of triplicates of each ECG parameter by assessment time point and treatment. Change from baseline will be summarized in a similar manner. Baseline is defined as the average of the valid ECG set closest and prior to

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dosing (or first dosing, or dosing in the respective period, as applicable) which may include unscheduled assessments. At post-baseline time points, the average of the first valid ECG set will be used in the analysis. Post-baseline unscheduled and early termination measurements will not be included in summaries.

The number and percentage of participants with Normal, Abnormal not clinically significant, and Abnormal clinically significant ECGs will be presented by assessment time point and treatment.

All ECG data will be listed by participant and QTcF values > 450 msec will be flagged. A separate by participant listing will be provided to display the ECG average values to be used during analysis where QTcF average values > 450 msec and increase from baseline > 30 msec will be flagged.

ECG abnormalities reported as AEs will be graded in severity as per protocol and will be summarized along with the TEAEs.

6.9 Prior and Concomitant Medications

Prior and concomitant medications recorded during the trial will be coded with the World Health Organization (WHO) Drug Dictionary Version 01-Mar-2023 b3 and listed.

6.10 Physical Examination

Abnormal physical examination findings will be reported as medical history or AEs. All data found in the CRF will be listed.

6.11 Medical History

All medical history will be coded using MedDRA[®], Version 26.0 and listed.

6.12 Ophthalmologic Assessments

A visual assessment (visual acuity and color vision) will be conducted during the treatment period for Part 2 MAD Cohorts 8-10 participants per protocol schedule of assessments to assess for possible signs of optic neuropathy toxicity from repeat dosing. Visual acuity will be assessed on each eye separately by means of a Snellen chart and Rosenbaum pocket chart. Color vision will be assessed on each eye separately using the Ishihara color plates. An overall assessment (normal/abnormal) will also be provided for each test (i.e, Snellen, Rosembaum, and by eye for Ishihara).

All visual assessment results collected on the CRF will be listed by part, participant, and assessment time point. Visual assessment data will be summarized for Part 2 MAD cohorts only. Summaries will be provided for the Per Protocol Population in addition to the Safety Population.

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For each visual acuity test (Snellen and Rosembaum) and eye, a shift table will be developed to compare the frequency of the results at baseline compared to the worst post-baseline score. For the purpose of this analysis, Snellen and Rosembaum scores will be categorized as follows:

- 0 = Normal (20/25 or better)
- 1 = Worse than 20/25 but better than or equals to 20/40
- 2 = Worse than 20/40 but better than or equals to 20/200
- 3 = Worse than 20/200

For each visual acuity test (Snellen and Rosembaum), the number and percentage of participants with a post-baseline visual acuity score worse than 20/25 in either eye at each time point and overall (i.e., at least once across post-baseline time points) will be provided by treatment. A score worse than 20/25 in either eye is equivalent to an abnormal overall assessment on the CRF, therefore the CRF overall assessment will be used for this analysis.

For color vision, the number and percentage of participants with a post-baseline color vision abnormality in either eye at each time point and overall (i.e., at least once across post-baseline time points) will be provided by treatment. The CRF overall assessment will be used to conduct this analysis. At each time point, participants will be counted if they experience an abnormal result in the right or left eye.

Abnormalities of vision reported as AEs will be graded in severity as per protocol and will be summarized along with the TEAEs.

Separate TEAE summaries by severity grades will be provided for visual acuity decreased and color vision change related TEAEs as described in [Section 6.5](#).

6.13 Brief Peripheral Neuropathy Screen (BPNS)

Peripheral sensory neuropathy screening will be conducted using the BPNS test during the treatment period for Part 2 MAD Cohorts 8-10 participants per protocol schedule of assessments to assess for signs of peripheral neuropathy toxicity from repeat dosing. The non-invasive BPNS test combines questions regarding neuropathic symptoms in the feet and lower legs with objective testing of ankle reflexes and vibration sensation in the big toes. Specifically, the following neuropathic symptoms will be assessed on each lower extremity (i.e., right and left):

- Pain, Aching, or Burning
- Pins and Needles
- Numbness (lack of feeling)

Each symptom will be scored on a 01 to 10 scale where 01 = Mild and 10 = Severe. An overall subjective peripheral grade (defined as the highest score of the individual symptoms) is also available on the CRF. This CRF overall grade will be listed but will not be used in the analysis.

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Objective testing of vibration sensation in the big toe (right and left) will be recorded on the following scale:

- 0 = Vibration Felt For Greater Than 10 Seconds [Normal]
- 1 = Vibrations Felt For 6-10 Seconds [Mild Loss]
- 2 = Vibrations Felt For 5 Seconds Or Less [Moderate Loss]
- 3 = No Feeling Of Vibrations [Severe Loss]

Objective testing of tendon reflexes (right and left) will be recorded on the following scale:

- 0 = Absent
- 1 = Hypoactive
- 2 = Normal Deep Tendon Reflexes
- 3 = Hyperactive Deep Tendon Reflexes, e.g With Prominent Spread
- 4 = Clonus

All BPNS results recorded on the CRF will be listed by part, participant, and assessment time point. BPNS results will be summarized for Part 2 MAD cohorts only. Summaries will be provided for the Per Protocol Population in addition to the Safety Population.

For each treatment, the following summaries will be provided by time point and overall:

- The number and percentage of participants with a reported new post-baseline peripheral neuropathy symptom (defined as a score within 01-10) in either extremity on BPNS will be provided. This summary will be provided by symptom and overall (i.e, any symptoms). For participants meeting the criteria, frequency counts of the post-baseline grade will be provided using the following grading classifications:
 - Grade of 1 = Score 01-03
 - Grade of 2 = Score 04-06
 - Grade of 3 = Score 07-10

The worst grade across extremities or over all time points (for overall time point summary) will be used for summaries.

- For each objective testing (vibration in big toes or tendon reflexes) and overall, the number and percentage of participants with a reported new post-baseline peripheral objective physical finding (defined as scores within 1-3 for vibration or scores of 1-4 for tendon reflexes) in either extremity on BPNS will be provided. For summaries by objective testing, frequency counts of the post-baseline results for participants with at least one reported new post-baseline objective physical finding will also be included. The worst score across extremities or over all time points (for overall time point summary) will be used for summaries.
- The number and percentage of participants with new post-baseline peripheral neuropathy symptom and at least one objective physical finding on BPNS will be provided.

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A reported new (treatment-emergent) post-baseline event is an event that is worse than the baseline value. The comparison to baseline will take into consideration the extremity side – e.g., if a participant presents a baseline abnormality on the left leg and develops a new or worsening post-baseline abnormality on the right leg, it will be considered treatment-emergent.

7. SUMMARY OF CHANGES FROM PROTOCOL-PLANNED ANALYSIS

The original SAP and TFL Shell documents dated 02 June 2023 were amended on 16 February 2024 to reflect the changes to the design and objectives of Part 2 outlined in Protocol Amendment No. 4 (Version 5.0, dated 30 October 2023).

All analyses described in this SAP amendment are aligned with those analyses described in the protocol amendment.

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8. REFERENCES

Brookmeyer R, Crowley J. A confidence interval for the median survival time. Biometrics 1982;38:29-41.

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SAFETY SHELLS

A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose and Multiple Ascending Dose Trial in Healthy Adult Participants to Evaluate the Safety, Tolerability, and Pharmacokinetics of MK-7762 with Two Open Label (Single Dose) Food Effect Panels

Protocol No: Gates MRI-TBD09-101
Final Protocol Date: 27 September 2022
Amendment No. 1 Date: 19 December 2022
Amendment No. 2: 04 April 2023
Amendment No. 3: 08 September 2023
Amendment No. 4: 30 October 2023
Protocol Clarification Letter No. 5: 07 November 2023
Protocol Clarification Letter No. 6: 12 December 2023
Compound Name: MK-7762

Celerion Project CA35747
Final Amendment Version 1.0
Date: 16 February 2024

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SAFETY SHELLS SIGNATURE PAGE

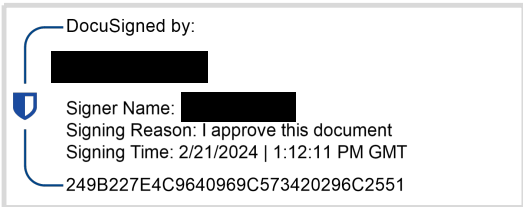
Compound Name: MK-7762

Protocol: Gates MRI-TBD09-101

Study Title: A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose and Multiple Ascending Dose Trial in Healthy Adult Participants to Evaluate the Safety, Tolerability, and Pharmacokinetics of MK-7762 with Two Open Label (Single Dose) Food Effect Panels

Issue Date: 16 February 2024

As the statistical analysis plan is being executed using the Veeva platform, please find the e-signature page at the end of the document.

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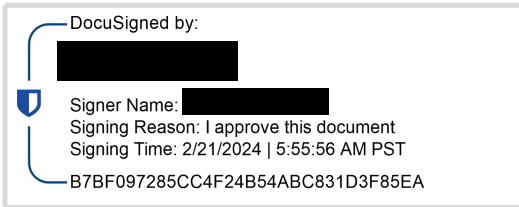
Compound Name: MK-7762

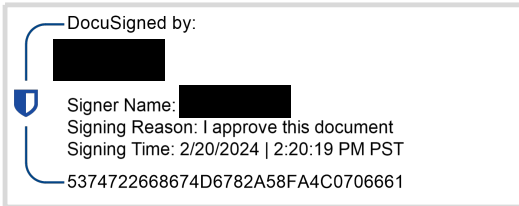
Protocol: Gates MRI-TBD09-101

Study Title: A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose and Multiple Ascending Dose Trial in Healthy Adult Participants to Evaluate the Safety, Tolerability, and Pharmacokinetics of MK-7762 with Two Open Label (Single Dose) Food Effect Panels

Issue Date: 16 February 2024

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Signature:  DocuSigned by:
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Signer Name: [Redacted]
Signing Reason: I approve this document
Signing Time: 2/21/2024 | 5:55:56 AM PST
B7BF097285CC4F24B54ABC831D3F85EA
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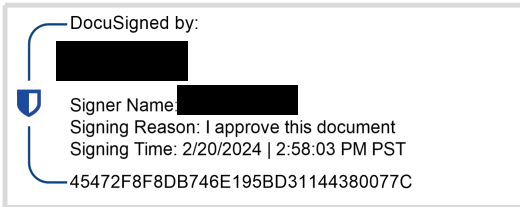
Compound Name: MK-7762

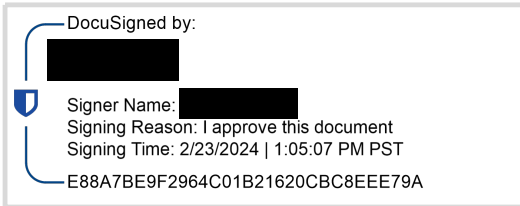
Protocol: Gates MRI-TBD09-101

Study Title: A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose and Multiple Ascending Dose Trial in Healthy Adult Participants to Evaluate the Safety, Tolerability, and Pharmacokinetics of MK-7762 with Two Open Label (Single Dose) Food Effect Panels

Issue Date: 16 February 2024

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1. SUMMARY TABLES, FIGURES, AND LISTINGS

Summary tables and figures are numbered following the International Council on Harmonization (ICH) structure but may be renumbered as appropriate during the compilation of the tables and figures for the CSR. Note that all safety summary tables and figures will be generated using SAS® Version 9.4 or higher, as appropriate.

All tables, figures, and listings (TFLs) will be generated as RTF for inclusion in the CSR. In compliance with Celerion SOP/PG/WI, SAS® outputs will not be manually edited.

Rationale for current revision: The original SAP and TFL Shell documents dated 02 June 2023 were amended on 16 February 2024 to reflect the changes to the design and objectives of Part 2 outlined in Protocol Amendment No. 4 (Version 5.0, dated 30 October 2023), which require updates to the analysis and presentation of the data. Specifically, Part 2, which previously consisted of multiple ascending dose (MAD) cohorts only, now consists of a food effect (FE) cohort and a total of 3 MAD cohorts. The current SAP has updated the analysis and presentation of Part 2 data accordingly.

It is important to note that these amended SAP and TFL Shell documents are written after the database lock and completion of analysis for Part 1 of the study. Therefore, the focus is to update the TFL shells associated with the changes impacting Part 2, thus the Part 1 TFL shells were only updated to reflect the final dose levels selected during the conduct of Part 1 and minor typographical errors were corrected for consistency with Part 2. No other content changes were made to Part 1 TFL shells.

1.1 In-text Summary Tables and Figures

The following is a list of table and figure titles that will be included in the text of the CSR. Tables and figures will be numbered appropriately during compilation of the CSR.

Section 10:

Number	Title	Shell
Table 10-1	Disposition Summary – Part 1 (Safety Population)	IDS
Table 10-2	Disposition Summary – Part 2, FE (Safety Population)	IDS2
Table 10-3	Disposition Summary – Part 2, MAD (Safety Population)	IDS3

Section 11:

Number	Title	Shell
Table 11-1	Demographic Summary – Part 1 (Safety Population)	IDEM

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Number	Title	Shell
Table 11-2	Demographic Summary – Part 2, FE (Safety Population)	IDEM2
Table 11-3	Demographic Summary – Part 2, MAD (Safety Population)	IDEM3

Section 12:

Number	Title	Shell
Table 12-1	Treatment-Emergent Adverse Event Frequency by Treatment - Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)	IAES
Table 12-2	Treatment-Emergent Adverse Event Frequency by Treatment - Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, FE (Safety Population)	IAES2
Table 12-3	Treatment-Emergent Adverse Event Frequency by Treatment - Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Safety Population)	IAES3

1.2 Section 14 Summary Tables and Figures

The following is a list of table and figure titles that will be included in Section 14 of the report. Table and figure titles may be renumbered as appropriate during the compilation of the report.

Note: Per Protocol Population summaries will only be generated if the population differs from the Safety Population.

14.1 Demographic Data Summary Tables

Number	Title	Shell
Table 14.1.1.1	Disposition Summary – Part 1 (Safety Population)	CDS
Table 14.1.1.2	Participant Dosing Status and Trial Disposition – Part 1, FE (Safety Population)	SDS
Table 14.1.1.3	Demographic Summary – Part 1 (Safety Population)	CDEM
Table 14.1.2.1	Disposition Summary – Part 2, FE (Safety Population)	CDS2

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Number	Title	Shell
Table 14.1.2.2	Participant Dosing Status and Trial Disposition – Part 2, FE (Safety Population)	SDS
Table 14.1.2.3	Demographic Summary – Part 2, FE (Safety Population)	CDEM2
Table 14.1.3.1	Disposition Summary – Part 2, MAD (Safety Population)	CDS3
Table 14.1.3.2	Demographic Summary – Part 2, MAD (Safety Population)	CDEM3
Table 14.1.3.4	Extent of Exposure Summary – Part 2, MAD (Safety Population)	CEX

14.2 Pharmacokinetic Data Summary Tables and Figures

Not applicable.

14.3 Safety Data Summary Tables

14.3.1 Displays of Adverse Events

Number	Title	Shell
Part 1		
Table 14.3.1.1.1	Treatment-Emergent Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)	CAES
Table 14.3.1.1.2	Treatment-Emergent Study Drug Related Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)	CAES
Table 14.3.1.1.3	Treatment-Emergent Adverse Event Frequency by Treatment, Severity, and Relationship to Study Drug – Number of Adverse Events – Part 1 (Safety Population)	CAESR
Table 14.3.1.1.4	Treatment-Emergent Serious Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)	CAES
Table 14.3.1.1.5	Treatment-Emergent Study Drug Related Serious Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)	CAES

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Number	Title	Shell
Table 14.3.1.1.6	Treatment-Emergent Adverse Event Leading to Drug Discontinuation Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)	CAES
Table 14.3.1.1.7	Treatment-Emergent Study Drug Related Adverse Event Leading to Drug Discontinuation Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)	CAES
Table 14.3.1.1.8	Treatment-Emergent Adverse Event of Special Interest Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)	CAES
Table 14.3.1.1.9	Treatment-Emergent Study Drug Related Adverse Event of Special Interest Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)	CAES
Part 2, FE		
Table 14.3.1.2.1	Treatment-Emergent Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, FE (Safety Population)	CAES2
Table 14.3.1.2.2	Treatment-Emergent Study Drug Related Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, FE (Safety Population)	CAES2
Table 14.3.1.2.3	Treatment-Emergent Adverse Event Frequency by Treatment, Severity, and Relationship to Study Drug – Number of Adverse Events – Part 2, FE (Safety Population)	CAESR
Table 14.3.1.2.4	Treatment-Emergent Serious Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, FE (Safety Population)	CAES2
Table 14.3.1.2.5	Treatment-Emergent Study Drug Related Serious Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, FE (Safety Population)	CAES2

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Number	Title	Shell
Table 14.3.1.2.6	Treatment-Emergent Adverse Event Leading to Drug Discontinuation Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, FE (Safety Population)	CAES2
Table 14.3.1.2.7	Treatment-Emergent Study Drug Related Adverse Event Leading to Drug Discontinuation Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, FE (Safety Population)	CAES2
Table 14.3.1.2.8	Treatment-Emergent Adverse Event of Special Interest Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, FE (Safety Population)	CAES2
Table 14.3.1.2.9	Treatment-Emergent Study Drug Related Adverse Event of Special Interest Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, FE (Safety Population)	CAES2
Part 2, MAD		
Table 14.3.1.3.1	Treatment-Emergent Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Safety Population)	CAES3
Table 14.3.1.3.2	Treatment-Emergent Study Drug Related Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Safety Population)	CAES3
Table 14.3.1.3.3	Treatment-Emergent Adverse Event Frequency by Treatment, Severity, and Relationship to Study Drug – Number of Adverse Events – Part 2, MAD (Safety Population)	CAESR
Table 14.3.1.3.4	Treatment-Emergent Serious Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Safety Population)	CAES3

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Number	Title	Shell
Table 14.3.1.3.5	Treatment-Emergent Study Drug Related Serious Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Safety Population)	CAES3
Table 14.3.1.3.6	Treatment-Emergent Adverse Event Leading to Drug Discontinuation Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Safety Population)	CAES3
Table 14.3.1.3.7	Treatment-Emergent Study Drug Related Adverse Event Leading to Drug Discontinuation Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Safety Population)	CAES3
Table 14.3.1.3.8	Treatment-Emergent Adverse Event of Special Interest Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Safety Population)	CAES3
Table 14.3.1.3.9	Treatment-Emergent Study Drug Related Adverse Event of Special Interest Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Safety Population)	CAES3
Table 14.3.1.3.10	Treatment-Emergent Visual Acuity and Color Vision Adverse Event (Subset of TEAEs) Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Safety Population) <i>Note: This table will include visual acuity and color vision TEAEs programmatically flagged from all TEAEs as per Section 6.5 of the SAP.</i>	CAES3

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Number	Title	Shell
Table 14.3.1.3.11	Treatment-Emergent Study Drug Related Visual Acuity and Color Vision Adverse Event (Subset of TEAEs) Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Safety Population) <i>Note: This table will include visual acuity and color vision TEAEs programmatically flagged from all TEAEs as per Section 6.5 of the SAP.</i>	CAES3
Table 14.3.1.3.12	Summary of Time to Adverse Event Resolution in Participants With Ongoing Neurologic or Hematologic Adverse Event of Special Interest at Time of Treatment Discontinuation – Part 2, MAD (Safety Population)	CAEKM
Table 14.3.1.3.13	Treatment-Emergent Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Per Protocol Population)	CAES3
Table 14.3.1.3.14	Treatment-Emergent Study Drug Related Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Per Protocol Population)	CAES3
Table 14.3.1.3.15	Treatment-Emergent Adverse Event Frequency by Treatment, Severity, and Relationship to Study Drug – Number of Adverse Events – Part 2, MAD (Per Protocol Population)	CAESR
Table 14.3.1.3.16	Treatment-Emergent Serious Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Per Protocol Population)	CAES3
Table 14.3.1.3.17	Treatment-Emergent Study Drug Related Serious Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Per Protocol Population)	CAES3

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Number	Title	Shell
Table 14.3.1.3.18	Treatment-Emergent Adverse Event Leading to Drug Discontinuation Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Per Protocol Population)	CAES3
Table 14.3.1.3.19	Treatment-Emergent Study Drug Related Adverse Event Leading to Drug Discontinuation Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Per Protocol Population)	CAES3
Table 14.3.1.3.20	Treatment-Emergent Adverse Event of Special Interest Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Per Protocol Population)	CAES3
Table 14.3.1.3.21	Treatment-Emergent Study Drug Related Adverse Event of Special Interest Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Per Protocol Population)	CAES3
Table 14.3.1.3.22	Treatment-Emergent Visual Acuity and Color Vision Adverse Event (Subset of TEAEs) Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Per Protocol Population) <i>Note: This table will include visual acuity and color vision TEAEs programmatically flagged from all TEAEs as per Section 6.5 of the SAP.</i>	CAES3
Table 14.3.1.3.23	Treatment-Emergent Study Drug Related Visual Acuity and Color Vision Adverse Event (Subset of TEAEs) Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Per Protocol Population) <i>Note: This table will include visual acuity and color vision TEAEs programmatically flagged from all TEAEs as per Section 6.5 of the SAP.</i>	CAES3

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Number	Title	Shell
Table 14.3.1.3.24	Summary of Time to Adverse Event Resolution in Participants With Ongoing Neurologic or Hematologic Adverse Event of Special Interest at Time of Treatment Discontinuation – Part 2, MAD (Per Protocol Population)	CAEKM

14.3.2 Listings of Deaths, other Serious and Significant Adverse Events

Number	Title	Shell
Table 14.3.2.1.1	Serious Adverse Events – Part 1 (Safety Population)	16.2.7
Table 14.3.2.1.2	Adverse Events of Special Interest – Part 1 (Safety Population)	16.2.7
Table 14.3.2.2.1	Serious Adverse Events – Part 2 (Safety Population)	16.2.7
Table 14.3.2.2.2	Adverse Events of Special Interest – Part 2 (Safety Population)	16.2.7

14.3.3 Narratives of Deaths, other Serious and Certain other Significant Adverse Events

14.3.4 Abnormal Laboratory Value Listing (each participant)

Number	Title	Shell
Part 1		
Table 14.3.4.1.1	Out-of-Range Values and Recheck Results – Chemistry – Part 1 (Safety Population)	CLBO
Table 14.3.4.1.2	Out-of-Range Values and Recheck Results – Hematology – Part 1 (Safety Population)	
Table 14.3.4.1.3	Out-of-Range Values and Recheck Results – Coagulation – Part 1 (Safety Population)	
Table 14.3.4.1.4	Out-of-Range Values and Recheck Results – Urinalysis – Part 1 (Safety Population)	
Part 2		
Table 14.3.4.2.1	Out-of-Range Values and Recheck Results – Chemistry – Part 2 (Safety Population)	
Table 14.3.4.2.2	Out-of-Range Values and Recheck Results – Hematology – Part 2 (Safety Population)	

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Number	Title	Shell
Table 14.3.4.2.3	Out-of-Range Values and Recheck Results – Coagulation – Part 2 (Safety Population)	
Table 14.3.4.2.4	Out-of-Range Values and Recheck Results – Urinalysis – Part 2 (Safety Population)	

14.3.5 Displays of Other Laboratory, Vital Signs, Electrocardiogram, Physical Examination, and Other Safety Data

Number	Title	Shell
Part 1		
Table 14.3.5.1.1	Clinical Laboratory Summary and Change From Baseline – Chemistry – Part 1 (Safety Population)	CLBD
Table 14.3.5.1.2.1	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Pooled Placebo – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.2.2	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Single Dose 50 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.2.3	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Single Dose 150 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.2.4	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Single Dose 300 mg MK-7762 Fasted (Cohort 3) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.2.5	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Single Dose 600 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.2.6	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Single Dose 1200 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.2.7	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Single Dose 300 mg MK-7762 Fasted (Cohort 6) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.2.8	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Single Dose 300 mg MK-7762 Fed (Cohort 6) – Part 1 (Safety Population)	CLBSD

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Number	Title	Shell
Table 14.3.5.1.2.9	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Single Dose MK-7762 Fasted (All Cohorts) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.3	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Chemistry – Part 1 (Safety Population)	CLBS
Table 14.3.5.1.4	Clinical Laboratory Summary and Change From Baseline – Hematology – Part 1 (Safety Population)	CLBD
Table 14.3.5.1.5.1	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Pooled Placebo – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.5.2	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Single Dose 50 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.5.3	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Single Dose 150 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.5.4	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Single Dose 300 mg MK-7762 Fasted (Cohort 3) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.5.5	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Single Dose 600 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.5.6	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Single Dose 1200 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.5.7	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Single Dose 300 mg MK-7762 Fasted (Cohort 6) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.5.8	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Single Dose 300 mg MK-7762 Fed (Cohort 6) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.5.9	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Single Dose MK-7762 Fasted (All Cohorts) – Part 1 (Safety Population)	CLBSD

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Number	Title	Shell
Table 14.3.5.1.6	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Hematology – Part 1 (Safety Population)	CLBS
Table 14.3.5.1.7	Hematological Classifications Frequency by Treatment and Time Point – Part 1 (Safety Population)	CLBH
Table 14.3.5.1.8	Clinical Laboratory Summary and Change From Baseline – Coagulation – Part 1 (Safety Population)	CLBD
Table 14.3.5.1.9.1	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Pooled Placebo – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.9.2	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Single Dose 50 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.9.3	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Single Dose 150 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.9.4	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Single Dose 300 mg MK-7762 Fasted (Cohort 3) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.9.5	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Single Dose 600 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.9.6	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Single Dose 1200 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.9.7	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Single Dose 300 mg MK-7762 Fasted (Cohort 6) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.9.8	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Single Dose 300 mg MK-7762 Fed (Cohort 6) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.9.9	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Single Dose MK-7762 Fasted (All Cohorts) – Part 1 (Safety Population)	CLBSD

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Number	Title	Shell
Table 14.3.5.1.10	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Coagulation – Part 1 (Safety Population)	CLBS
Table 14.3.5.1.11	Clinical Laboratory Summary and Change From Baseline – Urinalysis – Part 1 (Safety Population)	CLBD
Table 14.3.5.1.12.1	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Pooled Placebo – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.12.2	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Single Dose 50 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.12.3	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Single Dose 150 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.12.4	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Single Dose 300 mg MK-7762 Fasted (Cohort 3) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.12.5	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Single Dose 600 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.12.6	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Single Dose 1200 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.12.7	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Single Dose 300 mg MK-7762 Fasted (Cohort 6) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.12.8	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Single Dose 300 mg MK-7762 Fed (Cohort 6) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.12.9	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Single Dose MK-7762 Fasted (All Cohorts) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.13	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Urinalysis – Part 1 (Safety Population)	CLBS

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Number	Title	Shell
Table 14.3.5.1.14	Vital Sign Summary and Change From Baseline – Part 1 (Safety Population)	CVS
Table 14.3.5.1.15	Categorical Summary of Abnormal Vital Signs – Part 1 (Safety Population)	CVSC
Table 14.3.5.1.16	Average of Safety Triplicate 12-Lead Electrocardiogram Summary and Change From Baseline – Part 1 (Safety Population)	CEG
Table 14.3.5.1.17	Categorical Summary of Abnormal Safety 12-Lead Electrocardiogram – Part 1 (Safety Population)	CEGC
Part 2, FE		
Table 14.3.5.2.1	Clinical Laboratory Summary and Change From Baseline – Chemistry – Part 2, FE (Safety Population)	CLBD2
Table 14.3.5.2.2.1	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – 600 mg MK-7762 Fasted – Part 2, FE (Safety Population)	CLBSD
Table 14.3.5.2.2.2	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – 600 mg MK-7762 Fed Standard Meal – Part 2, FE (Safety Population)	CLBSD
Table 14.3.5.2.2.3	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – 600 mg MK-7762 Fed High-Fat Meal – Part 2, FE (Safety Population)	CLBSD
Table 14.3.5.2.3	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Chemistry – Part 2, FE (Safety Population)	CLBS
Table 14.3.5.2.4	Clinical Laboratory Summary and Change From Baseline – Hematology – Part 2, FE (Safety Population)	CLBD2
Table 14.3.5.2.5.1	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – 600 mg MK-7762 Fasted – Part 2, FE (Safety Population)	CLBSD
Table 14.3.5.2.5.2	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – 600 mg MK-7762 Fed Standard Meal – Part 2, FE (Safety Population)	CLBSD
Table 14.3.5.2.5.3	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – 600 mg MK-7762 Fed High-Fat Meal – Part 2, FE (Safety Population)	CLBSD

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Number	Title	Shell
Table 14.3.5.2.6	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Hematology – Part 2, FE (Safety Population)	CLBS
Table 14.3.5.2.7	Hematological Classifications Frequency by Treatment and Time Point – Part 2, FE (Safety Population)	CLBH2
Table 14.3.5.2.8	Clinical Laboratory Summary and Change From Baseline – Coagulation – Part 2, FE (Safety Population)	CLBD2
Table 14.3.5.2.9.1	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – 600 mg MK-7762 Fasted – Part 2, FE (Safety Population)	CLBSD
Table 14.3.5.2.9.2	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – 600 mg MK-7762 Fed Standard Meal – Part 2, FE (Safety Population)	CLBSD
Table 14.3.5.2.9.3	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – 600 mg MK-7762 Fed High-Fat Meal – Part 2, FE (Safety Population)	CLBSD
Table 14.3.5.2.10	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Coagulation – Part 2, FE (Safety Population)	CLBS
Table 14.3.5.2.11	Clinical Laboratory Summary and Change From Baseline – Urinalysis – Part 2, FE (Safety Population)	CLBD2
Table 14.3.5.2.12.1	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – 600 mg MK-7762 Fasted – Part 2, FE (Safety Population)	CLBSD
Table 14.3.5.2.12.2	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – 600 mg MK-7762 Fed Standard Meal – Part 2, FE (Safety Population)	CLBSD
Table 14.3.5.2.12.3	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – 600 mg MK-7762 Fed High-Fat Meal – Part 2, FE (Safety Population)	CLBSD
Table 14.3.5.2.13	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Urinalysis – Part 2, FE (Safety Population)	CLBS
Table 14.3.5.2.14	Vital Sign Summary and Change From Baseline – Part 2, FE (Safety Population)	CVS2

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Number	Title	Shell
Table 14.3.5.2.15	Categorical Summary of Abnormal Vital Signs – Part 2, FE (Safety Population)	CVSC2
Table 14.3.5.2.16	Average of Safety Triplicate 12-Lead Electrocardiogram Summary and Change From Baseline – Part 2, FE (Safety Population)	CEG2
Table 14.3.5.2.17	Categorical Summary of Abnormal Safety 12-Lead Electrocardiogram – Part 2, FE (Safety Population)	CEGC2
Part 2, MAD		
Table 14.3.5.3.1	Clinical Laboratory Summary and Change From Baseline – Chemistry – Part 2, MAD (Safety Population)	CLBD3
Table 14.3.5.3.2.1	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Pooled Placebo Multiple Once Daily Doses – Part 2, MAD (Safety Population)	CLBSD
Table 14.3.5.3.2.2	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Multiple Once Daily Doses 100 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSD
Table 14.3.5.3.2.3	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Multiple Once Daily Doses 300 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSD
Table 14.3.5.3.2.4	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Multiple Once Daily Doses 500 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSD
Table 14.3.5.3.2.5	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Multiple Once Daily Doses MK-7762 (Cohorts 8-10) – Part 2, MAD (Safety Population)	CLBSD
Table 14.3.5.3.3.1	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Chemistry – Pooled Placebo Multiple Once Daily Doses – Part 2, MAD (Safety Population)	CLBSM
Table 14.3.5.3.3.2	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Chemistry – Multiple Once Daily Doses 100 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSM

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Number	Title	Shell
Table 14.3.5.3.3.3	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Chemistry – Multiple Once Daily Doses 300 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSM
Table 14.3.5.3.3.4	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Chemistry – Multiple Once Daily Doses 500 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSM
Table 14.3.5.3.3.5	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Chemistry – Multiple Once Daily Doses MK-7762 (Cohorts 8-10) – Part 2, MAD (Safety Population)	CLBSM
Table 14.3.5.3.4	Clinical Laboratory Summary and Change From Baseline – Hematology – Part 2, MAD (Safety Population)	CLBD3
Table 14.3.5.3.5.1	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Pooled Placebo Multiple Once Daily Doses – Part 2, MAD (Safety Population)	CLBSD
Table 14.3.5.3.5.2	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Multiple Once Daily Doses 100 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSD
Table 14.3.5.3.5.3	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Multiple Once Daily Doses 300 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSD
Table 14.3.5.3.5.4	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Multiple Once Daily Doses 500 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSD
Table 14.3.5.3.5.5	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Multiple Once Daily Doses MK-7762 (Cohorts 8-10) – Part 2, MAD (Safety Population)	CLBSD
Table 14.3.5.3.6.1	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Hematology – Pooled Placebo Multiple Once Daily Doses – Part 2, MAD (Safety Population)	CLBSM

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Number	Title	Shell
Table 14.3.5.3.6.2	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Hematology – Multiple Once Daily Doses 100 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSM
Table 14.3.5.3.6.3	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Hematology – Multiple Once Daily Doses 300 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSM
Table 14.3.5.3.6.4	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Hematology – Multiple Once Daily Doses 500 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSM
Table 14.3.5.3.6.5	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Hematology – Multiple Once Daily Doses MK-7762 (Cohorts 8-10) – Part 2, MAD (Safety Population)	CLBSM
Table 14.3.5.3.7	Hematological Classifications Frequency by Treatment and Time Point – Part 2, MAD (Safety Population)	CLBH3
Table 14.3.5.3.8	Clinical Laboratory Summary and Change From Baseline – Coagulation – Part 2, MAD (Safety Population)	CLBD3
Table 14.3.5.3.9.1	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Pooled Placebo Multiple Once Daily Doses – Part 2, MAD (Safety Population)	CLBSD
Table 14.3.5.3.9.2	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Multiple Once Daily Doses 100 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSD
Table 14.3.5.3.9.3	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Multiple Once Daily Doses 300 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSD
Table 14.3.5.3.9.4	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Multiple Once Daily Doses 500 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSD

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Number	Title	Shell
Table 14.3.5.3.9.5	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Multiple Once Daily Doses MK-7762 (Cohorts 8-10) – Part 2, MAD (Safety Population)	CLBSD
Table 14.3.5.3.10.1	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Coagulation – Pooled Placebo Multiple Once Daily Doses – Part 2, MAD (Safety Population)	CLBSM
Table 14.3.5.3.10.2	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Coagulation – Multiple Once Daily Doses 100 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSM
Table 14.3.5.3.10.3	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Coagulation – Multiple Once Daily Doses 300 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSM
Table 14.3.5.3.10.4	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Coagulation – Multiple Once Daily Doses 500 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSM
Table 14.3.5.3.10.5	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Coagulation – Multiple Once Daily Doses MK-7762 (Cohorts 8-10) – Part 2, MAD (Safety Population)	CLBSM
Table 14.3.5.3.11	Clinical Laboratory Summary and Change From Baseline – Urinalysis – Part 2, MAD (Safety Population)	CLBD3
Table 14.3.5.3.12.1	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Pooled Placebo Multiple Once Daily Doses – Part 2, MAD (Safety Population)	CLBSD
Table 14.3.5.3.12.2	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Multiple Once Daily Doses 100 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSD
Table 14.3.5.3.12.3	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Multiple Once Daily Doses 300 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSD

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Number	Title	Shell
Table 14.3.5.3.12.4	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Multiple Once Daily Doses 500 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSD
Table 14.3.5.3.12.5	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Multiple Once Daily Doses MK-7762 (Cohorts 8-10) – Part 2, MAD (Safety Population)	CLBSD
Table 14.3.5.3.13.1	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Urinalysis – Pooled Placebo Multiple Once Daily Doses – Part 2, MAD (Safety Population)	CLBSM
Table 14.3.5.3.13.2	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Urinalysis – Multiple Once Daily Doses 100 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSM
Table 14.3.5.3.13.3	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Urinalysis – Multiple Once Daily Doses 300 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSM
Table 14.3.5.3.13.4	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Urinalysis – Multiple Once Daily Doses 500 mg MK-7762 – Part 2, MAD (Safety Population)	CLBSM
Table 14.3.5.3.13.5	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Urinalysis – Multiple Once Daily Doses MK-7762 (Cohorts 8-10) – Part 2, MAD (Safety Population)	CLBSM
Table 14.3.5.3.14	Vital Sign Summary and Change From Baseline – Part 2, MAD (Safety Population)	CVS3
Table 14.3.5.3.15	Categorical Summary of Abnormal Vital Signs – Part 2, MAD (Safety Population)	CVSC3
Table 14.3.5.3.16	Average of Safety Triplicate 12-Lead Electrocardiogram Summary and Change From Baseline – Part 2, MAD (Safety Population)	CEG3
Table 14.3.5.3.17	Categorical Summary of Abnormal Safety 12-Lead Electrocardiogram – Part 2, MAD (Safety Population)	CEGC3

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Number	Title	Shell
Table 14.3.5.3.18	Shifts to Worst Post-Baseline Visual Acuity by Treatment – Part 2, MAD (Safety Population)	CVISS
Table 14.3.5.3.19	Frequency of Abnormalities in Visual Acuity and Color Vision Assessments by Treatment and Time Point– Part 2, MAD (Safety Population)	CVISC
Table 14.3.5.3.20	Frequency of New Post-Baseline Abnormalities in Peripheral Neuropathy Assessments by Treatment, Time Point, and Severity – Part 2, MAD (Safety Population)	CBPNS
Table 14.3.5.3.21	Hematological Classifications Frequency by Treatment and Time Point – Part 2, MAD (Per Protocol Population)	CLBH3
Table 14.3.5.3.22	Frequency of Abnormalities in Visual Acuity and Color Vision Assessments by Treatment and Time Point– Part 2 (Per Protocol Population)	CVISC3
Table 14.3.5.3.23	Frequency of New Post-Baseline Abnormalities in Peripheral Neuropathy Assessments by Treatment, Time Point, and Severity – Part 2 (Per Protocol Population)	CBPNS3

14.4 Safety Figures

Number	Title	Shell
Part 1		
Figure 14.4.1.1	Boxplot of Platelet Count by Treatment and Time Point – Part 1 (Safety Population)	BOXP
Figure 14.4.1.2	Boxplot of Absolute Neutrophil Count by Treatment and Time Point – Part 1 (Safety Population)	BOXP
Figure 14.4.1.3	Boxplot of White Blood Cell Count by Treatment and Time Point – Part 1 (Safety Population)	BOXP
Figure 14.4.1.4	Boxplot of Reticulocyte Count by Treatment and Time Point – Part 1 (Safety Population)	BOXP
Figure 14.4.1.5	Boxplot of Red Blood Cell Count by Treatment and Time Point – Part 1 (Safety Population)	BOXP
Figure 14.4.1.6	Boxplot of Hemoglobin by Treatment and Time Point – Part 1 (Safety Population)	BOXP

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Figure 14.4.1.7	E-DISH Scatter Plot of Maximum Total Bilirubin Versus Maximum Aspartate Aminotransferase Post-Baseline – Part 1 (Safety Population)	EDISH
Figure 14.4.1.8	E-DISH Scatter Plot of Maximum Total Bilirubin Versus Maximum Alanine Aminotransferase Post-Baseline – Part 1 (Safety Population)	EDISH
Part 2, FE		
Figure 14.4.2.1	Boxplot of Platelet Count by Treatment and Time Point – Part 2, FE (Safety Population)	BOXP
Figure 14.4.2.2	Boxplot of Absolute Neutrophil Count by Treatment and Time Point – Part 2, FE (Safety Population)	BOXP
Figure 14.4.2.3	Boxplot of White Blood Cell Count by Treatment and Time Point – Part 2, FE (Safety Population)	BOXP
Figure 14.4.2.4	Boxplot of Reticulocyte Count by Treatment and Time Point – Part 2, FE (Safety Population)	BOXP
Figure 14.4.2.5	Boxplot of Red Blood Cell Count by Treatment and Time Point – Part 2, FE (Safety Population)	BOXP
Figure 14.4.2.6	Boxplot of Hemoglobin by Treatment and Time Point – Part 2, FE (Safety Population)	BOXP
Figure 14.4.2.7	E-DISH Scatter Plot of Maximum Total Bilirubin Versus Maximum Aspartate Aminotransferase Post-Baseline – Part 2, FE (Safety Population)	EDISH
Figure 14.4.2.8	E-DISH Scatter Plot of Maximum Total Bilirubin Versus Maximum Alanine Aminotransferase Post-Baseline – Part 2, MAD (Safety Population)	EDISH
Part 2, MAD		
Figure 14.4.3.1*	Kaplan-Meier Cumulative Incidence Plot – Time to Adverse Event Resolution in Participants With Ongoing Neurologic or Hematologic Adverse Event of Special Interest at Time of Treatment Discontinuation – Pooled Placebo Multiple Once Daily Doses – Part 2, MAD (Safety Population)	KMPLOT

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Figure 14.4.3.2*	Kaplan-Meier Cumulative Incidence Plot – Time to Adverse Event Resolution in Participants With Ongoing Neurologic or Hematologic Adverse Event of Special Interest at Time of Treatment Discontinuation – Multiple Once Daily Doses 100 mg MK-7762 – Part 2, MAD (Safety Population)	KMPLOT
Figure 14.4.3.3*	Kaplan-Meier Cumulative Incidence Plot – Time to Adverse Event Resolution in Participants With Ongoing Neurologic or Hematologic Adverse Event of Special Interest at Time of Treatment Discontinuation – Multiple Once Daily Doses 300 mg MK-7762 – Part 2, MAD (Safety Population)	KMPLOT
Figure 14.4.3.4*	Kaplan-Meier Cumulative Incidence Plot – Time to Adverse Event Resolution in Participants With Ongoing Neurologic or Hematologic Adverse Event of Special Interest at Time of Treatment Discontinuation – Multiple Once Daily Doses 500 mg MK-7762 – Part 2, MAD (Safety Population)	KMPLOT
Figure 14.4.3.5*	Kaplan-Meier Cumulative Incidence Plot – Time to Adverse Event Resolution in Participants With Ongoing Neurologic or Hematologic Adverse Event of Special Interest at Time of Treatment Discontinuation – Multiple Once Daily Doses MK-7762 (Cohorts 8-10) – Part 2, MAD (Safety Population)	KMPLOT
Figure 14.4.3.11	Boxplot of Platelet Count by Treatment and Time Point – Part 2, MAD (Safety Population)	BOXP
Figure 14.4.3.12	Boxplot of Absolute Neutrophil Count by Treatment and Time Point – Part 2, MAD (Safety Population)	BOXP
Figure 14.4.3.13	Boxplot of White Blood Cell Count by Treatment and Time Point – Part 2, MAD (Safety Population)	BOXP
Figure 14.4.3.14	Boxplot of Reticulocyte Count by Treatment and Time Point – Part 2, MAD (Safety Population)	BOXP
Figure 14.4.3.15	Boxplot of Red Blood Cell Count by Treatment and Time Point – Part 2, MAD (Safety Population)	BOXP
Figure 14.4.3.16	Boxplot of Hemoglobin by Treatment and Time Point – Part 2, MAD (Safety Population)	BOXP
Figure 14.4.3.17	E-DISH Scatter Plot of Maximum Total Bilirubin Versus Maximum Aspartate Aminotransferase Post-Baseline – Part 2, MAD (Safety Population)	EDISH

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Figure 14.4.3.18	E-DISH Scatter Plot of Maximum Total Bilirubin Versus Maximum Alanine Aminotransferase Post-Baseline – Part 2, MAD (Safety Population)	EDISH
* Figures will only be generated if there are more than 5 participants with ongoing neurologic or hematologic adverse events of special interest at the time of treatment discontinuation.		

1.3 Section 16 Data Listings

Note: Hepatitis and HIV serology results that are provided by the clinical laboratory will not be presented in Participant data listings and will not be included in any database transfer. All data will be presented as outlined in the CRF (i.e., time point information will be consistent with the CRF data).

Data listings are numbered following the ICH structure but may be renumbered as appropriate during the compilation of the TFLs for the CSR. The following is a list of appendix numbers and titles that will be included as data listings:

16.1 Study Information

16.1.9 Statistical Methods

Number	Title
Appendix 16.1.9.1	Statistical Analysis Plan

16.1.10 Clinical Laboratory Reference Ranges

Number	Title
Appendix 16.1.10.1	Clinical Laboratory Reference Ranges

16.2 Participant Data Listings

16.2.1 Participant Discontinuation

Number	Title
Appendix 16.2.1.1	Participant Disposition – Part 1 (Safety Population)
Appendix 16.2.1.2	Participant Disposition – Part 2 (Safety Population)
Appendix 16.2.1.3	Participant Disposition – Screen Failures

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16.2.2 Protocol Deviations

Number	Title
Appendix 16.2.2.1	Protocol Deviations

16.2.3 Participants Excluded From the Pharmacokinetic Analysis

Not Applicable.

16.2.4 Demographic Data

Number	Title
Appendix 16.2.4.1.1	Demographics – Part 1 (Safety Population)
Appendix 16.2.4.1.2	Demographics – Part 2 (Safety Population)
Appendix 16.2.4.1.3	Demographics – Screen Failures (Safety Population)
Appendix 16.2.4.2.1	Physical Examination – Part 1 (Safety Population)
Appendix 16.2.4.2.2	Physical Examination – Part 2 (Safety Population)
Appendix 16.2.4.3.1	Medical History – Part 1 (Safety Population)
Appendix 16.2.4.3.2	Medical History – Part 2 (Safety Population)
Appendix 16.2.4.4.1	Substance Use – Part 1 (Safety Population)
Appendix 16.2.4.4.2	Substance Use – Part 2 (Safety Population)

16.2.5 Compliance and/or Drug Concentration Data

Number	Title
Appendix 16.2.5.1.1	Participant Eligibility – Part 1 (Safety Population)
Appendix 16.2.5.1.2	Participant Eligibility – Part 2 (Safety Population)
Appendix 16.2.5.1.3	Participant Eligibility – Screen Failures
Appendix 16.2.5.2.1.1	Test Compound Description – Part 1
Appendix 16.2.5.2.1.2	Test Compound Administration Times – Part 1 (Safety Population)
Appendix 16.2.5.2.2.1	Test Compound Description – Part 2
Appendix 16.2.5.2.2.2	Test Compound Administration Times – Part 2 (Safety Population)
Appendix 16.2.5.2.2.3	Extent of Exposure – Part 2, MAD (Safety Population)

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Number	Title
Appendix 16.2.5.3.1	Meal Times – Part 1 (Safety Population)
Appendix 16.2.5.3.2	Meal Times – Part 2 (Safety Population)
Appendix 16.2.5.4.1	Prior and Concomitant Medications – Part 1 (Safety Population)
Appendix 16.2.5.4.2	Prior and Concomitant Medications – Part 2 (Safety Population)

16.2.6 Individual Pharmacokinetic Response Data

Not applicable.

16.2.7 Adverse Events Listings

Number	Title
Appendix 16.2.7.1.1	Adverse Events – Part 1 (Safety Population)
Appendix 16.2.7.1.2	Details for Serious Adverse Events – Part 1 (Safety Population) <i>This listing will be removed if no serious adverse events are reported.</i>
Appendix 16.2.7.2.1	Adverse Events – Part 2, FE (Safety Population)
Appendix 16.2.7.2.2	Details for Serious Adverse Events – Part 2, FE (Safety Population) <i>This listing will be removed if no serious adverse events are reported.</i>
Appendix 16.2.7.3.1	Adverse Events – Part 2, MAD (Safety Population)
Appendix 16.2.7.3.2	Details for Serious Adverse Events – Part 2, MAD (Safety Population) <i>This listing will be removed if no serious adverse events are reported.</i>
Appendix 16.2.7.3.3	Ongoing Neurologic and Hematologic Adverse Events of Special Interest at Time of Treatment Discontinuation – Part 2, MAD (Safety Population)
Appendix 16.2.7.4.1	Adverse Events – Screen Failures
Appendix 16.2.7.4.2	Details for Serious Adverse Events – Screen Failures <i>This listing will be removed if no serious adverse events are reported.</i>

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16.2.8 Clinical Laboratory Reports

Number	Title
Appendix 16.2.8.1.1	Clinical Laboratory Report – Chemistry – Part 1 (Safety Population)
Appendix 16.2.8.1.2	Clinical Laboratory Report – Hematology – Part 1 (Safety Population)
Appendix 16.2.8.1.3	Clinical Laboratory Report – Coagulation – Part 1 (Safety Population)
Appendix 16.2.8.1.4	Clinical Laboratory Report – Urinalysis – Part 1 (Safety Population)
Appendix 16.2.8.1.5	Clinical Laboratory Report – Urine Drug Screening – Part 1 (Safety Population)
Appendix 16.2.8.1.6	Clinical Laboratory Report – Virology – Part 1 (Safety Population)
Appendix 16.2.8.1.7	Vital Signs – Part 1 (Safety Population)
Appendix 16.2.8.1.8	Safety 12-Lead Electrocardiogram – Part 1 (Safety Population)
Appendix 16.2.8.1.9	Safety 12-Lead Electrocardiogram – Average of Triplicates – Part 1 (Safety Population)
Appendix 16.2.8.1.10	Visual Assessment – Part 1 (Safety Population)
Appendix 16.2.8.1.11	Brief Peripheral Neuropathy Assessment – Part 1 (Safety Population)
Appendix 16.2.8.2.1	Clinical Laboratory Report – Chemistry – Part 2 (Safety Population)
Appendix 16.2.8.2.2	Clinical Laboratory Report – Hematology – Part 2 (Safety Population)
Appendix 16.2.8.2.3	Clinical Laboratory Report – Coagulation – Part 2 (Safety Population)
Appendix 16.2.8.2.4	Clinical Laboratory Report – Urinalysis – Part 2 (Safety Population)
Appendix 16.2.8.2.5	Clinical Laboratory Report – Urine Drug Screening – Part 2 (Safety Population)
Appendix 16.2.8.2.6	Clinical Laboratory Report – Virology – Part 2 (Safety Population)
Appendix 16.2.8.2.7	Vital Signs – Part 2 (Safety Population)
Appendix 16.2.8.2.8	Safety 12-Lead Electrocardiogram – Part 2 (Safety Population)

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Number	Title
Appendix 16.2.8.2.9	Safety 12-Lead Electrocardiogram – Average of Triplicates – Part 2 (Safety Population)
Appendix 16.2.8.2.10	Visual Assessment – Part 2 (Safety Population)
Appendix 16.2.8.2.11	Brief Peripheral Neuropathy Assessment – Part 2 (Safety Population)
Appendix 16.2.8.2.12	New Post-Baseline Abnormalities in Neuropathy Symptom and Objective Physical Findings Assessments – Part 2, MAD (Safety Population)

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2. TABLE, FIGURE, AND LISTING SHELLS

The following table shells provide a framework for the display of data from this trial. The shells may change due to unforeseen circumstances. These shells may not be reflective of every aspect of this trial but are intended to show the general layout of the tables that will be presented and included in the final report. Unless otherwise noted, all tables will be presented in Times New Roman font size 9. All TFLs will be generated as RTF for inclusion in the CSR. In compliance with Celerion SOP/PG/WI, SAS[®] outputs will not be manually edited. Tables will be generated from ADaM datasets created in accordance with CDISC guidance (ADaM Model 2.1 and ADaM implementation Guide 1.1) .

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Table CDS Disposition Summary – Part 1 (Safety Population)

All TFLs will include a header documenting sponsor name and protocol number in header. An example of this has been provided above.

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2.1 In-text Summary Tables Shells

In-text Shell IDS will be in the following RTF format:

Table IDS Disposition Summary - Part 1 (Safety Population)

	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6) Treatment Sequence		
Disposition	Pooled Placebo	50 mg	150 mg	300 mg	600 mg	1200 mg	300 mg Fasted/Fed	300 mg Fed/Fasted	Part 1 Overall
Dosed	X (100%)	X (100%)	X (100%)	X (100%)	X (100%)	X (100%)	X (100%)	X (100%)	X (100%)
Replaced	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Completed Trial	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Discontinued From Trial	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Reason	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Completed Treatment	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Discontinued From Treatment	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Reason	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Source: Table 14.1.X Program: /CAXXXXX/sas_prg/stsas/intexttest/t_disp.sas 08OCT2015 16:36									

Programmer Note: Participants in Cohorts 1-6 with participant number greater than or equals to 1100 for Part 1.

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In-text Shell IDS2 will be in the following RTF format:

Table IDS2 Disposition Summary - Part 2, FE (Safety Population)

	Food Effect Cohort 7 600 mg MK-7762 Treatment Sequence			
Disposition	Fasted/Standard/High-Fat	Standard/High-Fat/Fasted	High-Fat/Fasted/Standard	Overall
Dosed	X (100%)	X (100%)	X (100%)	X (100%)
Replaced	X (X%)	X (X%)	X (X%)	X (X%)
Completed Trial	X (X%)	X (X%)	X (X%)	X (X%)
Discontinued From Trial	X (X%)	X (X%)	X (X%)	X (X%)
Reason	X (X%)	X (X%)	X (X%)	X (X%)
Completed Treatment	X (X%)	X (X%)	X (X%)	X (X%)
Discontinued From Treatment	X (X%)	X (X%)	X (X%)	X (X%)
Reason	X (X%)	X (X%)	X (X%)	X (X%)
Source: Table 14.1.X Program: /CAXXXXX/sas_prg/stmts/intexttest/t_disp.sas 08OCT2015 16:36				

Programmer Note: Participants in Cohort 7 with participant number greater than or equals to 2100 are replacement participants and will be counted in the 'Replaced' summary of this table.

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In-text Shell IDS3 will be in the following RTF format:

Table IDS3 Disposition Summary - Part 2, MAD (Safety Population)

	Multiple Doses MK-7762 or Placebo QD (Cohorts 8-10)				
Disposition	Pooled Placebo	100 mg	300 mg	500 mg	Overall
Dosed	X (100%)	X (100%)	X (100%)	X (100%)	X (100%)
Replaced	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Completed Trial	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Discontinued From Trial	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Reason	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Completed Treatment	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Discontinued From Treatment	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Reason	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
All participants received multiple oral doses of MK-7762 or matching placebo once daily (QD) for 28 days under fasting or fed (standard meal) conditions. Participants are pooled by dose level regardless of fasting conditions.					
Source: Table 14.1.X Program: /CAXXXXX/sas_prg/stsas/intexttest/t_disp.sas 08OCT2015 16:36					

Programmer Note: Participants in Cohorts 8-10 with participant number greater than or equals to 2110 for Part 2, MAD are replacement participants and will be counted in the 'Replaced' summary of this table.

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In-text Shell IDEM will be in the following RTF format:

Table IDEM Demographic Summary – Part 1 (Safety Population)

Trait	Category/ Statistics	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6) Treatment Sequence		Part 1 Overall (N=X)
		Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	1200 mg (N=X)	300 mg Fasted/Fed (N=X)	300 mg Fed/Fasted (N=X)	
Sex	Male	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Female	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Race	Asian	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Black or African American	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Ethnicity	White	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Not Hispanic or Latino	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Age (yr)	n	X	X	X	X	X	X	X	X	X
	Mean	XX.X	XX.X	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	XX.X	XX.X
	Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX
Weight (kg)	n	X	X	X	X	X	X	X	X	X
	Mean	XX.X	XX.X	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	XX.X	XX.X
	Minimum	XX.X	XX.X	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	XX.X	XX.X
	Maximum	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Height (cm)	n	X	X	X	X	X	X	X	X	X
	Mean	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X

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		Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6) Treatment Sequence		
Trait	Category/ Statistics	Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	1200 mg (N=X)	300 mg Fasted/Fed (N=X)	300 mg Fed/Fasted (N=X)	Part 1 Overall (N=X)
	SD	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
	Minimum	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
	Median	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X
	Maximum	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
BMI (kg/m ²)	n	X	X	X	X	X	X	X	X	X
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
	Minimum	XX.X	XX.X	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	XX.X	XX.X
	Maximum	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Descriptive statistics for body mass index, height, and weight are calculated using Screening measurements.										
Source: Table 14.1.X.X										
Program: /CAXXXXX/sas_prg/stsas/intexttest/t_dem.sas 08OCT2015 16:36										

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In-text Shell IDEM2 will be in the following RTF format:

Table IDEM2 Demographic Summary – Part 2, FE (Safety Population)

Trait	Category/ Statistics	Food Effect Cohort 7 600 mg MK-7762 Treatment Sequence			Overall (N=X)
		Fasted/Standard/High-Fat (N=X)	Standard/High- Fat/Fasted (N=X)	High- Fat/Fasted/Standard (N=X)	
Sex	Male	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Female	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Race	Asian	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Black or African American	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	White	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Ethnicity	Not Hispanic or Latino	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Age (yr)	n	X	X	X	X
	Mean	XX.X	XX.X	XX.X	XX.X
	SD	XX.X	XX.X	XX.X	XX.X
	Minimum	XX	XX	XX	XX
	Median	XX.X	XX.X	XX.X	XX.X
	Maximum	XX	XX	XX	XX
Weight (kg)	n	X	X	X	X
	Mean	XX.X	XX.X	XX.X	XX.X
	SD	XX.X	XX.X	XX.X	XX.X
	Minimum	XX.X	XX.X	XX.X	XX.X
	Median	XX.X	XX.X	XX.X	XX.X
	Maximum	XX.X	XX.X	XX.X	XX.X
Height (cm)	n	X	X	X	X
	Mean	XXX.X	XXX.X	XXX.X	XXX.X
	SD	X.X	X.X	X.X	X.X

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Trait	Category/ Statistics	Food Effect Cohort 7 600 mg MK-7762 Treatment Sequence			Overall (N=X)
		Fasted/Standard/High-Fat (N=X)	Standard/High- Fat/Fasted (N=X)	High- Fat/Fasted/Standard (N=X)	
	Minimum	XXX	XXX	XXX	XXX
	Median	XXX.X	XXX.X	XXX.X	XXX.X
	Maximum	XXX	XXX	XXX	XXX
BMI (kg/m ²)	n	X	X	X	X
	Mean	XX.X	XX.X	XX.X	XX.X
	SD	X.X	X.X	X.X	X.X
	Minimum	XX.X	XX.X	XX.X	XX.X
	Median	XX.X	XX.X	XX.X	XX.X
	Maximum	XX.X	XX.X	XX.X	XX.X
Descriptive statistics for body mass index, height, and weight are calculated using Screening measurements.					
Source: Table 14.1.X.X					
Program: /CAXXXXX/sas_prg/stmts/intexttest/t_dem.sas 08OCT2015 16:36					

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In-text Shell IDEM3 will be in the following RTF format:

Table IDEM3 Demographic Summary – Part 2, MAD (Safety Population)

Trait	Category/ Statistics	Multiple Doses MK-7762 or Placebo QD (Cohorts 8-10)				
		Pooled Placebo (N=X)	100 mg (N=X)	300 mg (N=X)	500 mg (N=X)	Overall (N=X)
Sex	Male	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Female	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Race	Asian	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Black or African American	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	White	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Ethnicity	Not Hispanic or Latino	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Age (yr)	n	X	X	X	X	X
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	XX.X	XX.X	XX.X	XX.X	XX.X
	Minimum	XX	XX	XX	XX	XX
	Median	XX.X	XX.X	XX.X	XX.X	XX.X
	Maximum	XX	XX	XX	XX	XX
Weight (kg)	n	X	X	X	X	X
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	XX.X	XX.X	XX.X	XX.X	XX.X
	Minimum	XX.X	XX.X	XX.X	XX.X	XX.X
	Median	XX.X	XX.X	XX.X	XX.X	XX.X
	Maximum	XX.X	XX.X	XX.X	XX.X	XX.X
Height (cm)	n	X	X	X	X	X
	Mean	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X

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		Multiple Doses MK-7762 or Placebo QD (Cohorts 8-10)				
Trait	Category/ Statistics	Pooled Placebo (N=X)	100 mg (N=X)	300 mg (N=X)	500 mg (N=X)	Overall (N=X)
	SD	X.X	X.X	X.X	X.X	X.X
	Minimum	XXX	XXX	XXX	XXX	XXX
	Median	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X
	Maximum	XXX	XXX	XXX	XXX	XXX
BMI (kg/m ²)	n	X	X	X	X	X
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	X.X	X.X	X.X	X.X	X.X
	Minimum	XX.X	XX.X	XX.X	XX.X	XX.X
	Median	XX.X	XX.X	XX.X	XX.X	XX.X
	Maximum	XX.X	XX.X	XX.X	XX.X	XX.X
<p>All participants received multiple oral doses of MK-7762 or matching placebo once daily (QD) for 28 days under fasting or fed (standard meal) conditions.</p> <p>Participants are pooled by dose level regardless of fasting conditions.</p> <p>Descriptive statistics for body mass index, height, and weight are calculated using Screening measurements.</p> <p>Source: Table 14.1.X.X Program: /CAXXXXX/sas_prg/stsas/intexttest/t_dem.sas 08OCT2015 16:36</p>						

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In-text Shell IAES will be in the following RTF format:

Table IAES Treatment-Emergent Adverse Event Frequency by Treatment- Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)

	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6)		All Part 1 Cohorts*	
System Organ Class Preferred Term	Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	1200 mg (N=X)	300 mg Fasted (N=X)	300 mg Fed (N=X)	All MK-7762 Fasted (N=X)	All MK-7762 (N = X)
Number of Participants With TEAEs	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Eye disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Visual blurred	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Gastrointestinal disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Dyspepsia	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Nausea	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Musculoskeletal and connective tissue disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Back pain	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Muscle cramps	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Musculoskeletal pain	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
<p>Although a participant may have had 2 or more adverse events, the participant is counted only once within a category. The same participant may appear in different categories.</p> <p>Adverse events are classified according to MedDRA Version 26.0.</p> <p>*‘All MK-7762 Fasted’ summary includes participants who received MK-7762 under fasting conditions only. The ‘All MK-7762’ summary includes participants who received MK-7762 regardless of fasting conditions.</p> <p>TEAEs = Treatment-emergent adverse events</p> <p>Source: Table 14.3.1.X</p> <p>Program: /CAXXXXX/sas_prgr/stsas/intext/t_ae.sas DDMMYYYY HH:MM</p>										

Programmer Note: The table may be split across 2 pages if it is not possible to fit all columns on 1 page. Additional pooled treatments may be added as outlined in the notes of Section 5 of the SAP.

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In-text Shell IAES2 will be in the following RTF format:

Table IAES2 Treatment-Emergent Adverse Event Frequency by Treatment- Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, FE (Safety Population)

	Food Effect Cohort 7 600 mg MK-7762			
System Organ Class Preferred Term	Fasted (N=X)	Standard Meal (N=X)	High-Fat Meal (N=X)	Overall (N=X)
Number of Participants With TEAEs	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Eye disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Visual blurred	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Gastrointestinal disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Dyspepsia	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Nausea	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Musculoskeletal and connective tissue disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Back pain	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Muscle cramps	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Musculoskeletal pain	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
<p>Although a participant may have had 2 or more adverse events, the participant is counted only once within a category. The same participant may appear in different categories. Adverse events are classified according to MedDRA Version 26.0. TEAEs = Treatment-emergent adverse events</p> <p>Source: Table 14.3.1.X Program: /CAXXXXXX/sas_prg/stsas/intext/t_ac.sas DDMMYYYY HH:MM</p>				

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In-text Shell IAES3 will be in the following RTF format:

Table IAES3 Treatment-Emergent Adverse Event Frequency by Treatment- Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Safety Population)

System Organ Class Preferred Term	Multiple Doses MK-7762 or Placebo QD (Cohorts 8-10)				
	Pooled Placebo (N=X)	100 mg (N=X)	300 mg (N=X)	500 mg (N=X)	All MK-7762* (N=X)
Number of Participants With TEAEs	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Eye disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Visual blurred	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Gastrointestinal disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Dyspepsia	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Nausea	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Musculoskeletal and connective tissue disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Back pain	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Muscle cramps	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Musculoskeletal pain	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)

All participants received multiple oral doses of MK-7762 or matching placebo once daily (QD) for 28 days under fasting or fed (standard meal) conditions. Participants are pooled by dose level regardless of fasting conditions. Although a participant may have had 2 or more adverse events, the participant is counted only once within a category. The same participant may appear in different categories. Adverse events are classified according to MedDRA Version 26.0.
*‘All MK-7762’ summary includes participants who received MK-7762 regardless of fasting conditions.
TEAEs = Treatment-emergent adverse events

Source: Table 14.3.1.X
Program: /CAXXXXXX/sas_prg/stsas/intext/t_ae.sas DDMMMYYYY HH:MM

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2.2 Section 14 Summary Tables Shells

Shell CDS will be in the following RTF format:

Page 1 of X

Table CDS Disposition Summary – Part 1 (Safety Population)

Category	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6) Treatment Sequence		Part 1 Overall
	Pooled Placebo	50 mg	150 mg	300 mg	600 mg	1200 mg	300 mg Fasted/Fed	300 mg Fed/Fasted	
Dosed	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Replaced	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Completed Trial	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Discontinued From Trial	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
<Reason>	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Completed Treatment	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Discontinued From Treatment	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
<Reason>	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)

Source: < >

Program: /CAXXXXXX/sas prg/stmts/tab/programname2022Q1.sas DDMMYYYY HH:MM

Programmer Note: Participants in Cohorts 1-6 with participant number greater than or equals to 1100 for Part 1.

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Shell CDS2 will be in the following RTF format:

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Table CDS2 Disposition Summary – Part 2, FE (Safety Population)

Food Effect Cohort 7 600 mg MK-7762 Treatment Sequence				
Category	Fasted/Standard/High-Fat	Standard/High-Fat/Fasted	High-Fat/Fasted/Standard	Overall
Dosed	X (XXX%)	X (XXX%)	X (XXX%)	X (XXX%)
Replaced	X (X%)	X (X%)	X (X%)	X (X%)
Completed Trial	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Discontinued From Trial	X (X%)	X (X%)	X (X%)	X (X%)
<Reason>	X (X%)	X (X%)	X (X%)	X (X%)
Completed Treatment	X (XXX%)	X (XXX%)	X (XXX%)	X (XXX%)
Discontinued From Treatment	X (X%)	X (X%)	X (X%)	X (X%)
<Reason>	X (X%)	X (X%)	X (X%)	X (X%)
Source: < >				
Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM				

Programmer Note: Participants in Cohort 7 with participant number greater than or equals to 2100 are replacement participants and will be counted in the ‘Replaced’ summary of this table.

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Shell CDS3 will be in the following RTF format:

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Table CDS3 Disposition Summary – Part 2, MAD (Safety Population)

Multiple Doses MK-7762 or Placebo QD (Cohorts 8-10)

Category	Pooled Placebo	100 mg	300 mg	500 mg	Overall
Dosed	X (XXX%)	X (XXX%)	X (XXX%)	X (XXX%)	X (XXX%)
Replaced	X (X%)	X (X%)	X (X%)	X (X%)	X (XX%)
Completed Trial	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Discontinued From Trial	X (X%)	X (X%)	X (X%)	X (X%)	X (XX%)
<Reason>	X (X%)	X (X%)	X (X%)	X (X%)	X (XX%)
Completed Treatment	X (XXX%)	X (XXX%)	X (XXX%)	X (XXX%)	X (XXX%)
Discontinued From Treatment	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
<Reason>	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)

All participants received multiple oral doses of MK-7762 or matching placebo once daily (QD) for 28 days under fasting or fed (standard meal) conditions.

Participants are pooled by dose level regardless of fasting conditions.

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

Programmer Note: Participants in Cohorts 8-10 with participant number greater than or equals to 2110 for Part 2, MAD are replacement participants and will be counted in the 'Replaced' summary of this table.

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Shell SDS will be in the following RTF format:

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Table SDS		Participant Dosing Status and Trial Disposition – Part 1, FE (Safety Population)				
		300 mg Dosed Treatment		Trial Completion		
Participant Number	300 mg MK-7762 Treatment Sequence	Fasted	Fed	Status		Date
X	Fasted/Fed	Yes	Yes	Completed		DDMONYYYY
X	Fed/Fasted	Yes	Yes	Completed		DDMONYYYY
X	Fasted/Fed	Yes	Yes	Completed		DDMONYYYY
X	Fed/Fasted	Yes	Yes	Completed		DDMONYYYY
X	Fed/Fasted	Yes	Yes	Completed		DDMONYYYY
X	Fasted/Fed	Yes	Yes	Completed		DDMONYYYY
X	Fed/Fasted	Yes	Yes	Discontinued From Study: Non-Compliance		DDMONYYYY
X	Fasted/Fed	Yes	Yes	Completed		DDMONYYYY
		----	----			
		XX	XX			

Source: < >

Program: /CAXXXXXX/sas_prg/stmts/tab/programname2022Q1.sas DDMMYYYY HH:MM

Programmer Note: For Part 2, FE, treatment sequences (Fasted/Standard/High-Fat, Standard/High-Fat/Fasted, High-Fat/Fasted/Standard) and dosed treatments (i.e., Fasted, Standard Meal, High-Fat Meal) will be updated accordingly.

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Shell CDEM will be in the following RTF format:

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Table CDEM Demographic Summary – Part 1 (Safety Population)

Trait	Category/ Statistic	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6) Treatment Sequence		Part 1 Overall (N=X)
		Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	1200 mg (N=X)	300 mg Fasted/Fed (N=X)	300 mg Fed/Fasted (N=X)	
Sex	Male	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Female	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Race	Asian	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Black	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	White	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Age (yr)	n	X	X	X	X	X	X	X	X	X
	Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
	SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
	Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
	Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
	Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX
Weight (kg)	n	X	X	X	X	X	X	X	X	X
	Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
	SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
	Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
	Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
	Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX

Descriptive statistics for body mass index, height, and weight are calculated using Screening measurements.

Source: <>

Program: /CAXXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Programmer Note: Height and BMI measurements collected at Screening will also be included in this table.

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Shell CDEM2 will be in the following RTF format:

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Table CDEM2 Demographic Summary – Part 2, FE (Safety Population)

Trait	Category/Statistics	Food Effect Cohort 7 600 mg MK-7762 Treatment Sequence			Overall (N=X)
		Fasted/Standard/High-Fat (N=X)	Standard/High-Fat/Fasted (N=X)	High-Fat/Fasted/Standard (N=X)	
Sex	Male	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Female	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Race	Asian	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Black or African American	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Ethnicity	White	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Not Hispanic or Latino	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Age (yr)	n	X	X	X	X
	Mean	XX.X	XX.X	XX.X	XX.X
	SD	XX.X	XX.X	XX.X	XX.X
	Minimum	XX	XX	XX	XX
	Median	XX.X	XX.X	XX.X	XX.X
	Maximum	XX	XX	XX	XX
Weight (kg)	n	X	X	X	X
	Mean	XX.X	XX.X	XX.X	XX.X
	SD	XX.X	XX.X	XX.X	XX.X
	Minimum	XX.X	XX.X	XX.X	XX.X
	Median	XX.X	XX.X	XX.X	XX.X
	Maximum	XX.X	XX.X	XX.X	XX.X

Descriptive statistics for body mass index, height, and weight are calculated using Screening measurements.

Source: < >

Program: /CAXXXXXX/sas_prg/stsas/tab/programname2022Q1programname2022Q1.sas DDMMYYYY HH:MM

Programmer Note: Height and BMI measurements collected at Screening will also be included in this table.

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Shell CDEM3 will be in the following RTF format:

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Table CDEM3 Demographic Summary – Part 2, MAD (Safety Population)

Trait	Category/ Statistics	Multiple Doses MK-7762 or Placebo QD (Cohorts 8-10)				
		Pooled Placebo (N=X)	100 mg (N=X)	300 mg (N=X)	500 mg (N=X)	Overall (N=X)
Sex	Male	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Female	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Race	Asian	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Black or African American	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	White	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Ethnicity	Not Hispanic or Latino	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Age (yr)	n	X	X	X	X	X
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	XX.X	XX.X	XX.X	XX.X	XX.X
	Minimum	XX	XX	XX	XX	XX
	Median	XX.X	XX.X	XX.X	XX.X	XX.X
	Maximum	XX	XX	XX	XX	XX
Weight (kg)	n	X	X	X	X	X
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	XX.X	XX.X	XX.X	XX.X	XX.X
	Minimum	XX.X	XX.X	XX.X	XX.X	XX.X
	Median	XX.X	XX.X	XX.X	XX.X	XX.X
	Maximum	XX.X	XX.X	XX.X	XX.X	XX.X

All participants received multiple oral doses of MK-7762 or matching placebo once daily (QD) for 28 days under fasting or fed (standard meal) conditions.

Participants are pooled by dose level regardless of fasting conditions.

Descriptive statistics for body mass index, height, and weight are calculated using Screening measurements.

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1programname2022Q1.sas DDMMYYYY HH:MM

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Programmer Note: Height and BMI measurements collected at Screening will also be included in this table.

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Shell CEX will be in the following RTF format:

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Table CEX Extent of Exposure Summary – Part 2, MAD (Safety Population)

		Multiple Doses MK-7762 QD (Cohorts 8-10)			
	Category/ Statistics	100 mg (N=X)	300 mg (N=X)	500 mg (N=X)	All MK-7762* (N=X)
Number of Doses	1	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	< >	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	28	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Total Dosage (mg)	n	X	X	X	X
	Mean	XX.X	XX.X	XX.X	XX.X
	SD	XX.X	XX.X	XX.X	XX.X
	Minimum	XX	XX	XX	XX
	Median	XX.X	XX.X	XX.X	XX.X
	Maximum	XX	XX	XX	XX

All participants received multiple oral doses of MK-7762 once daily (QD) for 28 days under fasting or fed (standard meal) conditions.

Participants are pooled by dose level regardless of fasting conditions.

*‘All MK-7762’ summary includes participants who received MK-7762 regardless of fasting conditions.

Total dosage (mg) is calculated as the daily dose (mg) * number of doses received.

Source: < >

Program: /CAXXXX/sas_prg/stsas/tab/programname2022Q1programname2022Q1.sas DDMMYYYY HH:MM

Programmer Note: Participants receiving placebo will not be included in this summary.

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Shell CAES will be in the following RTF format:

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Table CAES Treatment-Emergent Adverse Event Frequency by Treatment and Severity –
Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)

System Organ Class Preferred Term Severity Grade	Single Dose MK-7762 or Placebo Fasted (Cohort 1-5)						Food Effect MK-7762 (Cohort 6)		All Part 1 Cohorts*	
	Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	1200 mg (N=X)	300 mg Fasted (N=X)	300 mg Fed (N=X)	All MK-7762 Fasted (N=X)	All MK-7762 (N=X)
Number of Participants with TEAEs	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Mild	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Moderate	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Severe	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
< >	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Respiratory, thoracic, and mediastinal disorders	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Mild	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Moderate	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Severe	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
< >	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Dry throat	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Mild	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Moderate	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Severe	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
< >	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)

Adverse events are classified according to MedDRA Version 26.0.

Although a participant may have had 2 or more adverse events, the participant is counted only once within a category. The same participant may appear in different categories.

When a participant experienced the same AE at more than one level of severity during a treatment period, the AE with the worst severity is counted.

*The 'All MK-7762 Fasted' summary includes participants who received MK-7762 under fasting conditions only. The 'All MK-7762' summary includes participants who received MK-7762 regardless of fasting conditions.

TEAEs = Treatment-emergent adverse events

Source: <>

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1programname2022Q1.sas DDMMYYYY HH:MM

Please see programmer notes for Shells CAES, CAES2, CAES3 after Shell CAES3.

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Shell CAES2 will be in the following RTF format:

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Table CAES2 Treatment-Emergent Adverse Event Frequency by Treatment- Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, FE (Safety Population)

System Organ Class Preferred Term Severity Grade	Food Effect Cohort 7 600 mg MK-7762			
	Fasted (N=X)	Standard-Meal (N=X)	High-Fat Meal (N=X)	Overall (N=X)
Number of Participants With TEAEs	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Mild	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Moderate	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Severe	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
< >	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Respiratory, thoracic and mediastinal disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Mild	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Moderate	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Severe	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
< >	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Dry throat	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Mild	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Moderate	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Severe	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
< >	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)

Adverse events are classified according to MedDRA Version 26.0.

Although a participant may have had 2 or more adverse events, the participant is counted only once within a category. The same participant may appear in different categories.

When a participant experienced the same AE at more than one level of severity during a treatment period, the AE with the worst severity is counted.

TEAEs = Treatment-emergent adverse events

Source: < >

Program: /CAXXXXXX/sas_prg/stsas/intext/t_ae.sas DDMMMYYYY HH:MM

Please see programmer notes for Shells CAES, CAES2, CAES3 after Shell CAES3.

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Shell CAES3 will be in the following RTF format:

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Table CAES3 Treatment-Emergent Adverse Event Frequency by Treatment- Number of Participants Reporting the Event (% of Participants Dosed) – Part 2, MAD (Safety Population)

System Organ Class Preferred Term Severity Grade	Multiple Doses MK-7762 or Placebo QD (Cohorts 8-10)				
	Pooled Placebo (N=X)	100 mg (N=X)	300 mg (N=X)	500 mg (N=X)	All MK-7762* (N=X)
Number of Participants With TEAEs	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Mild	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Moderate	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Severe	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
< >	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Respiratory, thoracic and mediastinal disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Mild	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Moderate	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Severe	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
< >	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Dry throat	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Mild	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Moderate	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Severe	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
< >	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)

All participants received multiple oral doses of MK-7762 or matching placebo once daily (QD) for 28 days under fasting or fed (standard meal) conditions.

Participants are pooled by dose level regardless of fasting conditions.

Adverse events are classified according to MedDRA Version 26.0.

Although a participant may have had 2 or more adverse events, the participant is counted only once within a category. The same participant may appear in different categories.

When a participant experienced the same AE at more than one level of severity during a treatment period, the AE with the worst severity is counted.

*‘All MK-7762’ summary includes participants who received MK-7762 regardless of fasting conditions.

TEAEs = Treatment-emergent adverse events

Source: < >

Program: /CAXXXXX/sas_prg/stsas/intext/t_ae.sas DDMMYYYY HH:MM

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Programmer Note for Shells CAES, CAES2, CAES3:

- For all AE tables:
 - These tables will only include TEAEs captured during the analysis window described in Section 6.5.
 - The table may be split across 2 pages if it is not possible to fit all columns on 1 page. Additional pooled treatments may be added as outlined in the notes of Section 5 of the SAP.
 - Only present severity grades that are populated in the CRF for the system organ class and/or preferred term.
- For Part 2, MAD visual acuity and color vision related AE tables:
 - These tables will only include participants with visual acuity or color vision related TEAEs. These will be flagged programmatically as outlined in Section 6.5 of the SAP.
 - The following footnote will be added: ‘Visual acuity and color vision TEAEs were determined from the adverse events recorded during the study using the algorithm defined in the SAP.’
- For all Study Drug Related TEAE tables:
 - These tables will only include participants with TEAEs marked as related to study product on the AE CRF.
 - ‘Number of Participants With TEAEs’ will be replaced with ‘Number of Participants With Study Drug Related TEAEs’
- For all SAE tables:
 - These tables will only include participants with serious TEAEs.
 - ‘Number of Participants With TEAEs’ will be replaced with ‘Number of Participants With Serious TEAEs’
- For all Study Drug Related Serious TEAE tables:
 - These tables will only include participants with serious TEAEs marked as related to study product on the AE CRF.
 - ‘Number of Participants With TEAEs’ will be replaced with ‘Number of Participants With Study Drug Related Serious TEAEs’
- For all TEAE leading to drug discontinuation tables:
 - These tables will only include participants with TEAEs leading to drug discontinuation.
 - ‘Number of Participants With TEAEs’ will be replaced with ‘Number of Participants With TEAEs Leading to Drug Discontinuation’
- For all Study Drug Related TEAE leading to drug discontinuation tables:
 - These tables will only include participants with TEAEs leading to drug discontinuation marked as related to study product on the AE CRF.

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- ‘Number of Participants With TEAEs’ will be replaced with ‘Number of Participants With Study Drug Related TEAEs Leading to Drug Discontinuation’
- For all AESI tables:
 - These tables will only include participants with AESIs as flagged in the CRF.
 - ‘Number of Participants With TEAEs’ will be replaced with ‘Number of Participants With AESIs’
 - The following footnote will be added: ‘This table is based on AESIs identified in the AE page of the CRF (i.e., AESI flag = Yes in CRF).’
- For all Study Drug Related AESI tables:
 - These tables will only include participants with AESIs marked as related to study product on the AE CRF.
 - ‘Number of Participants With TEAEs’ will be replaced with ‘Number of Participants With Study Drug Related AESIs’
 - The following footnote will be added: ‘This table is based on AESIs identified in the AE page of the CRF (i.e., AESI flag = Yes in CRF).’

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Shell CAESR will be in the following RTF format:

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Table CAESR Treatment-Emergent Adverse Event Frequency by Treatment, Severity, and Relationship to Study Drug –
Number of Adverse Events – Part 1 (Safety Population)

System Organ Class Preferred Term	Treatment	Number of Participants with TEAEs	Number of TEAEs	Severity Grade					Relationship to Study Drug	
				1	2	3	4	5	Not Related	Related
Eye disorders	Pooled Placebo	X	X	X	X	X	X	X	X	X
	50 mg Fasted	X	X	X	X	X	X	X	X	X
	150 mg Fasted	X	X	X	X	X	X	X	X	X
	300 mg Fasted	X	X	X	X	X	X	X	X	X
	< >									
Vision blurred	Pooled Placebo	X	X	X	X	X	X	X	X	X
	50 mg Fasted	X	X	X	X	X	X	X	X	X
	150 mg Fasted	X	X	X	X	X	X	X	X	X
	300 mg Fasted	X	X	X	X	X	X	X	X	X
	< >									
	Pooled Placebo	X	X	X	X	X	X	X	X	X
	50 mg Fasted	X	X	X	X	X	X	X	X	X
	150 mg Fasted	X	X	X	X	X	X	X	X	X
	300 mg Fasted	X	X	X	X	X	X	X	X	X
	< >									

All participants received a single oral dose of MK-7762 or matching placebo under fasting conditions with exception of Cohort 6 which was designed as a cross-over food effect cohort with one fasted trial period and one fed trial period.

Adverse events are classified according to MedDRA Version 26.0.

Severity Grade: 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Potentially life-threatening; 5 = Fatal

Source: < >

Program: /CAXXXXX/sas_prg/thsas/tab PROGRAMNAME.sas DDMMYYYY HH:MM

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Programmer Note:

- These tables will only include TEAEs captured during the analysis window described in Section 6.5.
- The appropriate treatments will be included for Part 2, FE and Part 2, MAD. For Part 2, MAD, treatments will be presented in terms of dose level regardless of fasting conditions (see Section 5 of the SAP) and the following footnote will be included: 'Participants are pooled by dose level regardless of fasting conditions.'
- Similar treatment footnote for Part 2, MAD: 'All participants received multiple oral doses of MK-7762 or matching placebo once daily (QD) for 28 days under fasting or fed (standard meal) conditions.'
- Pooled MK-7762 treatment summaries (i.e., summaries pooling multiple MK-7762 dose levels) will not be included in this table, with the exception of an overall summary which will be included at the bottom of the Part 2, FE summary.

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Shell CAEKM will be in the following RTF format:

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Table CAEKM Summary of Time to Adverse Event Resolution in Participants With Ongoing Neurologic or Hematologic Adverse Event of
Special Interest at Time of Treatment Discontinuation – Part 2, MAD (Safety Population)

		Multiple Doses MK-7762 or Placebo QD (Cohorts 8-10)				
		Pooled Placebo (N=X)	100 mg (N=X)	300 mg (N=X)	500 mg (N=X)	All MK-7762* (N=X)
1. Number (%) of Participants with Ongoing AESI at Treatment Discontinuation	Statistic	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
2. Number (%) of Participants with AESI Resolved Within 5 Days of Treatment Discontinuation		X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
3. Time to AESI Resolution (Days)						
	n	XX	XX	XX	XX	XX
	Mean	X.X	X.X	X.X	X.X	X.X
	SD	X.XX	X.XX	X.XX	X.XX	X.XX
	Minimum	X	X	X	X	X
	Median	X.X	X.X	X.X	X.X	X.X
	Maximum	X	X	X	X	X
	Kaplan-Meier	XX.X	XX.X	XX.X	XX.X	XX.X
	Median Time (hr)					
	95% CI	X.XX-X.XX	X.XX-X.XX	X.XX-X.XX	X.XX-X.XX	X.XX-X.XX
	Censored	XX	XX	XX	XX	XX

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Statistic	Multiple Doses MK-7762 or Placebo QD (Cohorts 8-10)				
	Pooled Placebo (N=X)	100 mg (N=X)	300 mg (N=X)	500 mg (N=X)	All MK-7762* (N=X)
All participants received multiple oral doses of MK-7762 or matching placebo once daily (QD) for 28 days under fasting or fed (standard meal) conditions.					
Participants are pooled by dose level regardless of fasting conditions.					
*‘All MK-7762’ summary includes participants who received MK-7762 regardless of fasting conditions.					
Time to AE resolution is calculated as the difference between the date of treatment discontinuation and the AE resolution date.					
Criterion 1: Any participant with at least one ongoing neurologic or hematologic AESI at the time of treatment discontinuation is included.					
Criterion 2: Any participant meeting Criterion 1 and with at least one AESI which resolved within 5 days of treatment discontinuation.					
For both criterion 1 and 2, percentages are based on the number of participants dosed.					
Kaplan-Meier median time (product-limit median estimate) to AE resolution is presented along with the two-sided 95% confidence intervals.					
For participants with multiple ongoing AESIs, the worst time to AE resolution is summarized.					
Censored = Number of participants with ongoing AESI (right censored to last date of AE assessment).					
AE = Adverse event; AESI = Adverse event of special interest; CI = Confidence interval					

Source: <>

Program: /CAXXXXX/sas_prg/stsas/tab_PROGRAMNAME.sas DDMMYYYY HH:MM

Programmer Note: Please refer to Section 6.5 of the SAP for details on the analysis. 95% confidence intervals will be presented with 2 decimal places. For each treatment, Kaplan-Meier median time, confidence interval, and number censored will only be presented if there are more than 5 participants experiencing an event.

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Table 14.3.2.1.1 Serious Adverse Events – Part 1 (Safety Population)

There were no events that met this criteria.

Source: <>
Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

Tables 14.3.2.1.1 and 14.3.2.2.1 will match the format of Appendix 16.2.7. Or contain statement as follows: “There were no events that met this criteria.”

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Table 14.3.2.1.2 Adverse Events of Special Interest – Part 1 (Safety Population)

There were no events that met this criteria.

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

Tables 14.3.2.1.2 and 14.3.2.2.2 will match the format of Appendix 16.2.7. Or contain statement as follows: “There were no events that met this criteria.”

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Shell CLBO will be in the following RTF format:

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Table CLBO Out-of-Range Values and Recheck Results – <Clinical Laboratory Panel> – Part 1 (Safety Population)

Cohort	Participant Number	Age/ Sex	Trial Period	Treatment	Day	Date	Time	Parameter1 <Range> (Unit)	Parameter2 <Range> (Unit)	Parameter3 <Range> (Unit)	Parameter4 <Range> (Unit)
1	X	XX/X	Screen			DDMMYYYY	HH:MM:SS	XX H		XX L	XX H G1
			1	50 mg Fasted	-X	DDMMYYYY	HH:MM:SS	XX L	XX L G1		XX L

F = Female; M = Male

H = Above reference range; L = Below reference range

DAIDS Grade: G1 = Grade 1; G2 = Grade 2; G3 = Grade 3; G4 = Grade 4

Source: <>

Program: /CAXXXXX/sas prg/thsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

Programmer Note: Replace Parameter1, 2 etc. with actual lab tests in the trial. Sort unscheduled assessment and early termination chronologically with other scheduled assessments and rechecks. Recheck should be sorted with the scheduled time point the recheck is for. Unscheduled and Early Termination records should only be included if they are out of range or recheck results. Derived DAIDs grades will be presented along with the abnormality flags.

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Shell CLBD will be in the following RTF format:

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Table CLBD Clinical Laboratory Summary and Change From Baseline – < Clinical Laboratory > – Part 1 (Safety Population)

Laboratory Test (units)	Reference Range	Time Point	Statistic	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6)		All Part 1 Cohorts\$
				Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	1200 mg (N=X)	300 mg Fasted (N=X)	300 mg Fed (N=X)	All MK-7762 Fasted (N=X)
Testname (unit)	< - >#	Baseline	n	X	X	X	X	X	X	X	X	X
			Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX
		Day 2	Absolute									
			n	X	X	X	X	X	X	X	X	X
			Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX
			Change									
			n	X	X	X	X	X	X	X	X	X
			Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX

Baseline is the last measurement collected prior to dosing in each treatment period.

= Lowest of the lower ranges and highest of the higher ranges are used. Refer to Appendix 16.1.10.1 for the breakdown.

\$The 'All MK-7762 Fasted' summary includes data from participants who received MK-7762 under fasting conditions only.

* = Above reference range; ^ = Below reference range

EOT = End of trial

Source: <>

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

Please see programmer notes for Shells CLBD, CLBD2, CLBD3 after Shell CLBD3.

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Shell CLBD2 will be in the following RTF format:

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Table CLBD2 Clinical Laboratory Summary and Change From Baseline – < Clinical Laboratory > – Part 2, FE (Safety Population)

Laboratory Test (units)	Reference Range	Time Point	Statistic	Food Effect Cohort 7 600 mg MK-7762		
				Fasted (N=X)	Standard Meal (N=X)	High-Fat Meal (N=X)
Testname (unit)	< – >#	Baseline	n	X	X	X
			Mean	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX
			Median	X.X	X.X	X.X
			Maximum	XX	XX	XX
		Day 2	Absolute			
			n	X	X	X
			Mean	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX
			Median	X.X	X.X	X.X
			Maximum	XX	XX	XX
			Change			
			n	X	X	X
			Mean	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX
			Median	X.X	X.X	X.X
			Maximum	XX	XX	XX

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				Food Effect Cohort 7 600 mg MK-7762		
Laboratory Test (units)	Reference Range	Time Point	Statistic	Fasted (N=X)	Standard Meal (N=X)	High-Fat Meal (N=X)
Baseline is the last measurement collected prior to dosing in each treatment period. For Periods 2 and 3, baseline will be the last measurement collected on Day 8 of Periods 1, and 2, respectively.						
# = Lowest of the lower ranges and highest of the higher ranges are used. Refer to Appendix 16.1.10.1 for the breakdown.						
* = Above reference range; ^ = Below reference range						
EOT = End of trial						
Source: < >						
Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM						

Please see programmer notes for Shells CLBD, CLBD2, CLBD3 after Shell CLBD3.

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Shell CLBD3 will be in the following RTF format:

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Table CLBD3 Clinical Laboratory Summary and Change From Baseline – < Clinical Laboratory > – Part 2, MAD (Safety Population)

Multiple Doses MK-7762 or Placebo QD (Cohorts 8-10)

Laboratory Test (units)	Reference Range	Time Point	Statistic	Pooled Placebo (N=X)	100 mg (N=X)	300 mg (N=X)	500 mg (N=X)	All MK-7762* (N=X)
Testname (unit)	< – >#	Baseline	n	X	X	X	X	X
			Mean	X.X	X.X	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX
		Day 2	Absolute					
			n	X	X	X	X	X
			Mean	X.X	X.X	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX
			Change					
			n	X	X	X	X	X
			Mean	X.X	X.X	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX

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Multiple Doses MK-7762 or Placebo QD (Cohorts 8-10)

Laboratory Test (units)	Reference Range	Time Point	Statistic	Pooled Placebo (N=X)	100 mg (N=X)	300 mg (N=X)	500 mg (N=X)	All MK-7762* (N=X)
-------------------------	-----------------	------------	-----------	-------------------------	-----------------	-----------------	-----------------	-----------------------

All participants received multiple oral doses of MK-7762 or matching placebo once daily (QD) for 28 days under fasting or fed (standard meal) conditions.

Participants are pooled by dose level regardless of fasting conditions.

Baseline is the last measurement collected prior to first dosing.

= Lowest of the lower ranges and highest of the higher ranges are used. Refer to Appendix 16.1.10.1 for the breakdown.

All MK-7762 summary includes data from participants who received MK-7762 regardless of fasting conditions.

* = Above reference range; ^ = Below reference range

EOT = End of trial

Source: <>

Program: /CAXXXXX/sas prg/stmts/tab/programname2022Q1.sas DDMMYYYY HH:MM

Programmer Note for Shells CLBD, CLBD2, CLBD3:

- For all tables:
 - The table may be split across 2 pages if it is not possible to fit all columns on 1 page. Additional pooled treatments may be added as outlined in the notes of Section 5 of the SAP.
 - Treatment means at specific time points will be flagged (with a *) if they are above or below the reference range. This only applies to the clinical laboratory treatment results (i.e., not the change from baseline or any other endpoints).
- For all Part 1 tables:
 - Time points will be Baseline, Day 2, Day 4 and EOT (Day 7). The sample size at EOT for the Cohort 6 summaries will be 4 or less.
- For Part 2, FE tables:
 - Time points will be Baseline, Day 2, Day 4, and Day 8.
 - Baseline for Periods 2 and 3 will be the last measurement collected on Day 8 of Periods 1 and 2, respectively. Rechecks and unscheduled assessments will only be considered for the selection of baseline. For the post-baseline time point summary (i.e., Days 2, 4, and 8), rechecks and unscheduled assessments will not be considered.

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- For all Part 2, MAD tables:
 - Time points will be Baseline, Day 2, Day 4, Day 7, Day 10, Day 14, Day 17, Day 21, Day 24, Day 29, 31, 33, and EOT (Day 36).

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Shell CLBSD will be in the following RTF format:

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Table CLBSD Clinical Laboratory Shift From Baseline Based on DAIDS Grades – < Clinical Laboratory > – Pooled Placebo – Part 1 (Safety Population)

Laboratory Test (units)	Time Point	Baseline Grade	Post-Baseline Grade				
			0	1	2	3	4
Testname (unit)	Day 2	0	XX	X	X	X	X
		1	X	X	X	X	X
		2	X	X	X	X	X
		3	X	X	X	X	X
		4	X	X	X	X	X
	Day 4	0	XX	X	X	X	X
		1	X	X	X	X	X
		2	X	X	X	X	X
		3	X	X	X	X	X
		4	X	X	X	X	X

< >

All participants received a single oral dose of MK-7762 or matching placebo under fasting conditions with exception of Cohort 6 which was designed as a cross-over food effect cohort with one fasted trial period and one fed trial period.

DAIDS Grade: G1 = Grade 1; G2 = Grade 2; G3 = Grade 3; G4 = Grade 4

Grade 0 refers to ungraded (i.e., normal) results.

EOT = End of trial

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

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Programmer Note:

- For all Part 1 tables:
 - Time points will be Day 2, Day 4 and EOT (Day 7). The sample size at EOT for the Cohort 6 summaries will be 4 or less.
 - The following footnote will be added for the ‘Single Dose MK-77662 Fasted (All Cohorts)’ table: ‘\$This summary includes data from participants who received MK-7762 under fasting conditions only.’
- For Part 2, FE tables:
 - The first footnote will be deleted.
 - Time points will be Baseline, Day 2, Day 4, and Day 8.
 - The baseline footnote will be: Baseline is the last measurement collected prior to dosing in each treatment period. For Periods 2 and 3, baseline will be the last measurement collected on Day 8 of Periods 1, and 2, respectively.
 - Baseline for Periods 2 and 3 will be the last measurement collected on Day 8 of Periods 1 and 2, respectively. Rechecks and unscheduled assessments will only be considered for the selection of baseline. For the post-baseline time point summary (i.e., Days 2, 4, and 8), rechecks and unscheduled assessments will not be considered.
- For all Part 2, MAD tables:
 - The first footnote will be replaced by: All participants received multiple oral doses of MK-7762 or matching placebo once daily (QD) for 28 days under fasting or fed (standard meal) conditions. Participants are pooled by dose level regardless of fasting conditions.
 - Time points will be Baseline, Day 2, Day 4, Day 7, Day 10, Day 14, Day 17, Day 21, Day 24, Day 29, 31, 33, and EOT (Day 36).
 - The baseline footnote will be: Baseline is the last measurement collected prior to first dosing.
 - The following footnote will be added for the ‘Multiple Once Daily Doses MK-77662 (Cohorts 8-10)’ table: ‘\$This summary includes data from participants who received MK-7762 regardless of fasting conditions.’

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Shell CLBS will be in the following RTF format:

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Table CLBS Clinical Laboratory Shift From Baseline for Non-Graded Tests – < Clinical Laboratory > – Part 1 (Safety Population)

Laboratory Test (units)	Treatment	Time Point	Baseline L			Baseline N			Baseline H		
			Postdose			Postdose			Postdose		
Testname (unit)			L	N	H	L	N	H	L	N	H
Pooled Placebo		Day 2	X	XX	X	X	XX	X	X	XX	X
		Day 4	X	XX	X	X	XX	X	X	XX	X
		EOT	X	XX	X	X	XX	X	X	XX	X
50 mg MK-7762 Fasted		Day 2	X	XX	X	X	XX	X	X	XX	X
		Day 4	X	XX	X	X	XX	X	X	XX	X
		EOT	X	XX	X	X	XX	X	X	XX	X
150 mg MK-7762 Fasted		Day 2	X	XX	X	X	XX	X	X	XX	X
		Day 4	X	XX	X	X	XX	X	X	XX	X
		EOT	X	XX	X	X	XX	X	X	XX	X
300 mg MK-7762 Fasted		Day 2	X	XX	X	X	XX	X	X	XX	X
		Day 4	X	XX	X	X	XX	X	X	XX	X
		EOT	X	XX	X	X	XX	X	X	XX	X

< >

All participants received a single oral dose of MK-7762 or matching placebo under fasting conditions with exception of Cohort 6 which was designed as a cross-over food effect cohort with one fasted trial period and one fed trial period.

Baseline is the last measurement collected prior to dosing in each treatment period.

\$The 'All MK-7762 Fasted' summary includes data from participants who received MK-7762 under fasting conditions only.

EOT = End of trial

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

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Programmer Note:

- For all tables:
 - This table only includes laboratory tests with no grading criteria available in DAIDS.
 - For urinalysis, the following footnote is used since the categories of N and O will be used instead of L, N, H: N = Within reference range; O = Outside reference range
- For Part 1 tables:
 - Time points will be Day 2, Day 4 and EOT (Day 7). The sample size at EOT for the Cohort 6 summaries will be 4 or less.
 - Treatments will be the same as those presented in Shell CLBD for Part 1. Short treatment descriptions in Section 5 of the SAP can be used for treatment labels.
- For Part 2, FE tables:
 - The first footnote will be deleted.
 - The following footnote will be deleted: ‘\$The ‘All MK-7762 Fasted’ summary includes data from participants who received MK-7762 under fasting conditions only.’
 - Time points will be Baseline, Day 2, Day 4, and Day 8.
 - The baseline footnote will be: Baseline is the last measurement collected prior to dosing in each treatment period. For Periods 2 and 3, baseline will be the last measurement collected on Day 8 of Periods 1, and 2, respectively.
 - Baseline for Periods 2 and 3 will be the last measurement collected on Day 8 of Periods 1 and 2, respectively. Rechecks and unscheduled assessments will only be considered for the selection of baseline. For the post-baseline time point summary (i.e., Days 2, 4, and 8), rechecks and unscheduled assessments will not be considered.
 - Treatments will be the same as those presented in Shell CLBD2. Short treatment descriptions in Section 5 of the SAP can be used for treatment labels.

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Shell CLBSM will be in the following RTF format:

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Table CLBSM Clinical Laboratory Shift From Baseline for Non-Graded Tests – < Clinical Laboratory > – Pooled Placebo Multiple Once Daily Doses – Part 2, MAD (Safety Population)

Laboratory Test (units)	Time Point	Baseline L			Baseline N			Baseline H		
		Postdose			Postdose			Postdose		
Testname (unit)		L	N	H	L	N	H	L	N	H
	Day 2	X	XX	X	X	XX	X	X	XX	X
	Day 4	X	XX	X	X	XX	X	X	XX	X
	Day 7	X	XX	X	X	XX	X	X	XX	X
	Day 10	X	XX	X	X	XX	X	X	XX	X
	Day 14	X	XX	X	X	XX	X	X	XX	X
	Day 17	X	XX	X	X	XX	X	X	XX	X
	Day 21	X	XX	X	X	XX	X	X	XX	X
	Day 24	X	XX	X	X	XX	X	X	XX	X
	Day 29	X	XX	X	X	XX	X	X	XX	X
	Day 31	X	XX	X	X	XX	X	X	XX	X
	Day 33	X	XX	X	X	XX	X	X	XX	X
	EOT	X	XX	X	X	XX	X	X	XX	X
	< >									

All participants received multiple oral doses of MK-7762 or matching placebo once daily (QD) for 28 days under fasting or fed (standard meal) conditions.

Participants are pooled by dose level regardless of fasting conditions.

Baseline is the last measurement collected prior to first dosing.

EOT = End of trial

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

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Programmer Note:

- This table only includes laboratory tests with no grading criteria available in DAIDS.
- For urinalysis, the following footnote is used since the categories of N and O will be used instead of L, N, H: N = Within reference range; O = Outside reference range
- Time points will be Day 2, Day 4, Day 7, Day 10, Day 14, Day 17, Day 21, Day 24, Day 29, 31, 33, and EOT (Day 36).
- The following footnote will be added for the 'Multiple Once Daily Doses MK-7762 (Cohorts 8-10)' table: 'This summary includes data from participants who received MK-7762 regardless of fasting conditions.'

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Shell CLBH will be in the following RTF format:

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Table CLBH Hematological Classifications Frequency by Treatment and Time Point – Part 1 (Safety Population)

Lab. Test Point	Time	Result Abnormality Category	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6)		All Part 1 Cohorts*
			Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	1200 mg (N=X)	300 mg Fasted (N=X)	300 mg Fed (N=X)	All MK-7762 Fasted (N=X)
Platelet Count (unit)	Day 2	Abs. <LLN	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Abs. <50% of LLN	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 20% decrease	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 50% decrease	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	< >										
Overall		Abs. <LLN	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Abs. <50% of LLN	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 20% decrease	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 50% decrease	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)

The number of participants with a post-baseline result meeting the abnormality criteria is presented at each time point. The overall time point summary presents the number of participants meeting the abnormality criteria at any post-baseline time point.

Decrease refers to a percent decrease from baseline where baseline is the last measurement collected prior to dosing in each treatment period.

Percentages are based on the number of participants dosed with available assessments at each time point. For the overall time point summary, percentages are based on the number of participants dosed and with at least one available post-baseline assessment.

*The 'All MK-7762 Fasted' summary includes data from participants who received MK-7762 under fasting conditions only.

Abs. = Observed value; ANC = Absolute neutrophil count; EOT = End of trial; Lab. = Laboratory; LLN = Lower limit of normal; RBC = Red blood cell count; WBC = White blood cell count

Source: < >

Program: /CAXXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

Please see programmer notes for shells CLBH, CLBH2, CLBH3 after Shell CLBH3.

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Shell CLB2 will be in the following RTF format:

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Table CLB2 Hematological Classifications Frequency by Treatment and Time Point – Part 2, FE (Safety Population)

			Food Effect Cohort 7 600 mg MK-7762		
Lab. Test Point	Time	Result Abnormality Category	Fasted (N=X)	Standard Meal (N=X)	High- Fat Meal (N=X)
Platelet Count (unit)	Day 2	Abs. <LLN	X (XX%)	X (XX%)	X (XX%)
		Abs. <50% of LLN	X (XX%)	X (XX%)	X (XX%)
		≥ 20% decrease	X (XX%)	X (XX%)	X (XX%)
		≥ 50% decrease	X (XX%)	X (XX%)	X (XX%)
		< >			
	Overall	Abs. <LLN	X (XX%)	X (XX%)	X (XX%)
		Abs. <50% of LLN	X (XX%)	X (XX%)	X (XX%)
		≥ 20% decrease	X (XX%)	X (XX%)	X (XX%)
		≥ 50% decrease	X (XX%)	X (XX%)	X (XX%)

The number of participants with a post-baseline result meeting the abnormality criteria is presented at each time point. The overall time point summary presents the number of participants meeting the abnormality criteria at any post-baseline time point.
Decrease refers to a percent decrease from baseline where baseline is the last measurement collected prior to dosing in each treatment period. For Periods 2 and 3, baseline will be the last measurement collected on Day 8 of Periods 1, and 2, respectively.
Percentages are based on the number of participants dosed with available assessments at each time point. For the overall time point summary, percentages are based on the number of participants dosed and with at least one available post-baseline assessment.
Abs. = Observed value; ANC = Absolute neutrophil count; EOT = End of trial; Lab. = Laboratory; LLN = Lower limit of normal; RBC = Red blood cell count; WBC = White blood cell count

Source: < >
Program: /CAXXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

Please see programmer notes for shells CLB, CLB2, CLB3 after Shell CLB3.

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Shell CLB3 will be in the following RTF format:

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Table CLB3 Hematological Classifications Frequency by Treatment and Time Point – Part 2, MAD (Safety Population)

Lab. Test Point	Time	Result Abnormality Category	Multiple Doses MK-7762 or Placebo Fasted QD (Cohorts 8-10)				
			Pooled Placebo (N=X)	100 mg (N=X)	300 mg (N=X)	500 mg (N=X)	All MK-7762* (N=X)
Platelet Count (unit)	Day 2	Abs. <LLN	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Abs. <50% of LLN	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 20% decrease	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 50% decrease	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	< >						
	Overall	Abs. <LLN	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Abs. <50% of LLN	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 20% decrease	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 50% decrease	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)

All participants received multiple oral doses of MK-7762 or matching placebo once daily (QD) for 28 days under fasting or fed (standard meal) conditions.

Participants are pooled by dose level regardless of fasting conditions.

The number of participants with a post-baseline result meeting the abnormality criteria is presented at each time point. The overall time point summary presents the number of participants meeting the abnormality criteria at any post-baseline time point.

Decrease refers to a percent decrease from baseline where baseline is the last measurement collected prior to first dosing.

Percentages are based on the number of participants dosed with available assessments at each time point. For the overall time point summary, percentages are based on the number of participants dosed and with at least one available post-baseline assessment.

*‘All MK-7762’ summary includes data from participants who received MK-7762 regardless of fasting conditions.

Abs. = Observed value; ANC = Absolute neutrophil count; EOT = End of trial; Lab. = Laboratory; LLN = Lower limit of normal; RBC = Red blood cell count; WBC = White blood cell count

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

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Programmer Note for Shells CLBH, CLBH2, CLBH3:

- For all tables:
 - The table may be split across 2 pages if it is not possible to fit all columns on 1 page. Additional pooled treatments may be added as outlined in the notes of Section 5 of the SAP.
 - Laboratory tests will be platelet count, absolute neutrophil count (ANC), white blood cell (WBC) count, reticulocyte count, red blood cell (RBC) count, and hemoglobin. Abbreviations may be used for laboratory test names with corresponding footnotes included.
 - Abnormality criteria (a. through d.) are outlined in Section 6.6 of the SAP.
- For all Part 1 tables:
 - Time points will be Day 2, Day 4, EOT (Day 7) and Overall. The sample size at EOT for the Cohort 6 summaries will be 4 or less. Overall will show the proportion of participants with at least one result meeting the abnormality criteria at any post-baseline time point.
- For Part 2, FE tables:
 - Time points will be Baseline, Day 2, Day 4, and Day 8 and Overall. Overall will show the proportion of participants with at least one result meeting the abnormality criteria at any post-baseline time point.
 - Baseline for Periods 2 and 3 will be the last measurement collected on Day 8 of Periods 1 and 2, respectively. Rechecks and unscheduled assessments will only be considered for the selection of baseline. For the post-baseline time point summary (i.e., Days 2, 4, and 8), rechecks and unscheduled assessments will not be considered.
- For all Part 2, MAD tables:
 - Time points will be Baseline, Day 2, Day 4, Day 7, Day 10, Day 14, Day 17, Day 21, Day 24, Day 29, 31, 33, EOT (Day 36) and Overall. Overall will show the proportion of participants with at least one result meeting the abnormality criteria at any post-baseline time point.

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Shell CVS will be in the following RTF format:

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Table CVS Vital Sign Summary and Change From Baseline – Part 1 (Safety Population)

Vital Sign (units)	Time Point	Statistic	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6)		All Part 1 Cohorts*
			Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	1200 mg (N=X)	300 mg Fasted (N=X)	300 mg Fed (N=X)	All MK-7762 Fasted (N=X)
Testname (unit)	Baseline	n	X	X	X	X	X	X	X	X	X
		Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
		SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
		Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
		Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
		Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX
	Day 1 Hour 0.5	Absolute	n	X	X	X	X	X	X	X	X
			Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX
		Change	n	X	X	X	X	X	X	X	X
			Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX

Baseline is the last measurement collected prior to dosing in each treatment period.

*The 'All MK-7762 Fasted' summary includes data from participants who received MK-7762 under fasting conditions only.

EOT = End of trial

Source: <>

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

Please see programmer notes for Shells CVS, CVS2, CVS3 after Shell CVS3.

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Shell CVS2 will be in the following RTF format:

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Table CVS2 Vital Sign Summary and Change From Baseline – Part 2, FE (Safety Population)

			Food Effect Cohort 7 600 mg MK-7762		
Vital Sign (units)	Time Point	Statistic	Fasted (N=X)	Standard Meal (N=X)	High-Fat Meal (N=X)
Testname (unit)	Baseline	n	X	X	X
		Mean	X.X	X.X	X.X
		SD	X.XX	X.XX	X.XX
		Minimum	XX	XX	XX
		Median	X.X	X.X	X.X
		Maximum	XX	XX	XX
	Day 1 Hour 0.5	Absolute	n	X	X
			Mean	X.X	X.X
			SD	X.XX	X.XX
			Minimum	XX	XX
			Median	X.X	X.X
			Maximum	XX	XX
	Change		n	X	X
			Mean	X.X	X.X
			SD	X.XX	X.XX
			Minimum	XX	XX
			Median	X.X	X.X
			Maximum	XX	XX

Baseline is the last measurement collected prior to dosing in each treatment period.

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Please see programmer notes for Shells CVS, CVS2, CVS3 after Shell CVS3.

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Shell CVS3 will be in the following RTF format:

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Table CVS3 Vital Sign Summary and Change From Baseline – Part 2, MAD (Safety Population)

		Multiple Doses MK-7762 or Placebo QD (Cohorts 8-10)					
Vital Sign (units)	Time Point	Statistic	Pooled Placebo (N=X)	100 mg (N=X)	300 mg (N=X)	500 mg (N=X)	All MK-7762* (N=X)
Testname (unit)	Baseline	n	X	X	X	X	X
		Mean	X.X	X.X	X.X	X.X	X.X
		SD	X.XX	X.XX	X.XX	X.XX	X.XX
		Minimum	XX	XX	XX	XX	XX
		Median	X.X	X.X	X.X	X.X	X.X
		Maximum	XX	XX	XX	XX	XX
	Day 1 Hour 0.5 Absolute	n	X	X	X	X	X
		Mean	X.X	X.X	X.X	X.X	X.X
		SD	X.XX	X.XX	X.XX	X.XX	X.XX
		Minimum	XX	XX	XX	XX	XX
		Median	X.X	X.X	X.X	X.X	X.X
		Maximum	XX	XX	XX	XX	XX
	Change	n	X	X	X	X	X
		Mean	X.X	X.X	X.X	X.X	X.X
		SD	X.XX	X.XX	X.XX	X.XX	X.XX
		Minimum	XX	XX	XX	XX	XX
		Median	X.X	X.X	X.X	X.X	X.X
		Maximum	XX	XX	XX	XX	XX

All participants received multiple oral doses of MK-7762 or matching placebo once daily (QD) for 28 days under fasting or fed (standard meal) conditions.

Participants are pooled by dose level regardless of fasting conditions.

Baseline is the last measurement collected prior to first dosing.

All MK-7762 summary includes data from participants who received MK-7762 regardless of fasting conditions.

EOT = End of trial

Source: <>

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

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Programmer Note for Shells CVS, CVS2, CVS3:

- For all tables:
 - The table may be split across 2 pages if it is not possible to fit all columns on 1 page. Additional pooled treatments may be added as outlined in the notes of Section 5 of the SAP.
- For all Part 1 tables:
 - Blood pressure and heart rate only will be summarized.
 - Time points will be Baseline, Day 1 Hour 0.5, Day 1 Hour 1, Day 1 Hour 2, Day 1 Hour 3, Day 1 Hour 4, Day 1 Hour 5, Day 1 Hour 6, Day 1 Hour 8, Day 1 Hour 12, Day 2 Hour 24, Day 2 Hour 36, Day 3, Day 4 and EOT (Day 7). The sample size at EOT for the Cohort 6 summaries will be 4 or less.
- For Part 2, FE tables:
 - Blood pressure and heart rate only will be summarized.
 - Time points will be Baseline, Day 1 Hour 0.5, Day 1 Hour 1, Day 1 Hour 2, Day 1 Hour 4, Day 1 Hour 6, Day 1 Hour 8, Day 1 Hour 12, Day 2 Hour 24, Day 2 Hour 36, Day 3, Day 4 and Day 8.
- For all Part 2, MAD tables:
 - Blood pressure, heart rate, and temperature will be summarized.
 - Time points will be Baseline, Day 1 Hour 0.5, Day 1 Hour 1, Day 1 Hour 2, Day 1 Hour 4, Day 1 Hour 6, Day 1 Hour 8, Day 1 Hour 12, Day 2 Predose, Day 2 Hour 12, Day 3 Predose, Day 3 Hour 12, Day 7 Predose, Day 14 Predose, Day 21 Predose, Day 28 Predose, Day 28 Hour 12, Day 29, Day 31, Day 33, and EOT (Day 36).

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Shell CVSC will be in the following RTF format:

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Table CVSC Categorical Summary of Abnormal Vital Signs – Part 1 (Safety Population)

Vital Sign (units)	Time Point	Abnormality Category	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6)		All Part 1 Cohorts*
			Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	1200 mg (N=X)	300 mg Fasted (N=X)	300 mg Fed (N=X)	All MK-7762 Fasted (N=X)
SBP (unit)	D1H0.5	140 – <160	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 160 – <180	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 180	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		< >	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
DBP (unit)	D1H0.5	90 – <100	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 100 – <110	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 110	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		< >	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)

*The ‘All MK-7762 Fasted’ summary includes data from participants who received MK-7762 under fasting conditions only.

Time point Day X Hour X is presented as DXHX.

DBP = Diastolic blood pressure; EOT = End of trial; SBP = Systolic blood pressure

Source: <>

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

Please see programmer notes for Shells CVSC, CVSC2, CVSC3 after Shell CVSC3.

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Shell CVSC2 will be in the following RTF format:

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Table CVSC2 Categorical Summary of Abnormal Vital Signs – Part 2, FE (Safety Population)

Vital Sign (units)	Time Point	Abnormality Category	Food Effect Cohort 7 600 mg MK-7762		
			Fasted (N=X)	Standard Meal (N=X)	High-Fat Meal (N=X)
SBP (unit)	D1H0.5	140 – <160	X (XX%)	X (XX%)	X (XX%)
		≥ 160 – <180	X (XX%)	X (XX%)	X (XX%)
		≥ 180	X (XX%)	X (XX%)	X (XX%)
	< >		X (XX%)	X (XX%)	X (XX%)
DBP (unit)	D1H0.5	90 – <100	X (XX%)	X (XX%)	X (XX%)
		≥ 100 – <110	X (XX%)	X (XX%)	X (XX%)
		≥ 110	X (XX%)	X (XX%)	X (XX%)
	< >		X (XX%)	X (XX%)	X (XX%)

Time point Day X Hour X is presented as DXHX.

DBP = Diastolic blood pressure; SBP = Systolic blood pressure

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

Please see programmer notes for Shells CVSC, CVSC2, CVSC3 after Shell CVSC3.

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Shell CVSC3 will be in the following RTF format:

Page 1 of X

Table CVSC3 Categorical Summary of Abnormal Vital Signs – Part 2, MAD (Safety Population)

Vital Sign (units)	Time Point	Abnormality Category	Multiple Doses MK-7762 or Placebo QD (Cohorts 8-10)				
			Pooled Placebo (N=X)	100 mg (N=X)	300 mg (N=X)	500 mg (N=X)	All MK-7762* (N=X)
SBP (unit)	D1H0.5	140 – <160	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 160 – <180	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 180	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	< >		X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
DBP (unit)	D1H0.5	90 – <100	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 100 – <110	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 110	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	< >		X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)

All participants received multiple oral doses of MK-7762 or matching placebo once daily (QD) for 28 days under fasting or fed (standard meal) conditions.

Participants are pooled by dose level regardless of fasting conditions.

*‘All MK-7762’ summary includes data from participants who received MK-7762 regardless of fasting conditions.

Time point Day X Hour X is presented as DXHX.

DBP = Diastolic blood pressure; EOT = End of trial; SBP = Systolic blood pressure

Source: < >

Program: /CAXXXXX/sas_prg/stmts/tab/programname2022Q1.sas DDMMYYYY HH:MM

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Programmer Note for Shells CVSC, CVSC2, CVSC3:

- For all tables:
 - The table may be split across 2 pages if it is not possible to fit all columns on 1 page. Additional pooled treatments may be added as outlined in the notes of Section 5 of the SAP.
 - Systolic and diastolic blood pressure will be included in this table.
 - In order to save space, time point Day X Hour X may be presented as DXHX.
 - At each time point, all abnormality categories will be presented even if no participants meet the criteria.
- For all Part 1 tables:
 - Time points will be Day 1 Hour 0.5, Day 1 Hour 1, Day 1 Hour 2, Day 1 Hour 3, Day 1 Hour 4, Day 1 Hour 5, Day 1 Hour 6, Day 1 Hour 8, Day 1 Hour 12, Day 2 Hour 24, Day 2 Hour 36, Day 3, Day 4 and EOT (Day 7). The sample size at EOT for the Cohort 6 summaries will be 4 or less.
- For Part 2, FE tables:
 - Time points will be Day 1 Hour 0.5, Day 1 Hour 1, Day 1 Hour 2, Day 1 Hour 4, Day 1 Hour 6, Day 1 Hour 8, Day 1 Hour 12, Day 2 Hour 24, Day 2 Hour 36, Day 3, Day 4 and Day 8.
- For all Part 2, MAD tables:
 - Time points will be Day 1 Hour 0.5, Day 1 Hour 1, Day 1 Hour 2, Day 1 Hour 4, Day 1 Hour 6, Day 1 Hour 8, Day 1 Hour 12, Day 2 Predose, Day 2 Hour 12, Day 3 Predose, Day 3 Hour 12, Day 7 Predose, Day 14 Predose, Day 21 Predose, Day 28 Predose, Day 28 Hour 12, Day 29, Day 31, Day 33, and EOT (Day 36).

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Shell CEG will be in the following RTF format:

Page 1 of X

Table CEG Average of Safety Triplicate 12-Lead Electrocardiogram Summary and Change From Baseline – Part 1 (Safety Population)

Measurement (units)	Time Point	Statistic	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6)		All Part 1 Cohorts*
			Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	1200 mg (N=X)	300 mg Fasted (N=X)	300 mg Fed (N=X)	All MK-7762 Fasted (N=X)
Testname (unit)	Baseline	n	X	X	X	X	X	X	X	X	X
		Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
		SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
		Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
		Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
		Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX
	Day 1 Hour 2	Absolute	n	X	X	X	X	X	X	X	X
			Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX
		Change	n	X	X	X	X	X	X	X	X
			Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX

Average of triplicates are used in the analysis.

Baseline is the last triplicate measurement collected prior to dosing in each treatment period.

*The 'All MK-7762 Fasted' summary includes data from participants who received MK-7762 under fasting conditions only.

EOT = End of trial

Source: <>

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Please see programmer notes for Shells CEG, CEG2, CEG3 after Shell CEG3.

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Shell CEG2 will be in the following RTF format:

Page 1 of X

Table CEG2 Average of Safety Triplicate 12-Lead Electrocardiogram Summary and Change From Baseline – Part 2, FE (Safety Population)

			Food Effect Cohort 7 600 mg MK-7762		
Measurement (units)	Time Point	Statistic	Fasted (N=X)	Standard Meal (N=X)	High-Fat Meal (N=X)
Testname (unit)	Baseline	n	X	X	X
		Mean	X.X	X.X	X.X
		SD	X.XX	X.XX	X.XX
		Minimum	XX	XX	XX
		Median	X.X	X.X	X.X
		Maximum	XX	XX	XX
	Day 1 Hour 2	Absolute	n	X	X
			Mean	X.X	X.X
			SD	X.XX	X.XX
			Minimum	XX	XX
			Median	X.X	X.X
			Maximum	XX	XX
		Change	n	X	X
			Mean	X.X	X.X
			SD	X.XX	X.XX
			Minimum	XX	XX
			Median	X.X	X.X
			Maximum	XX	XX

Average of triplicates are used in the analysis.

Baseline is the last triplicate measurement collected prior to dosing in each treatment period.

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

Please see programmer notes for Shells CEG, CEG2, CEG3 after Shell CEG3.

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Shell CEG3 will be in the following RTF format:

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Table CEG3 Average of Safety Triplicate 12-Lead Electrocardiogram Summary and Change From Baseline – Part 2, MAD (Safety Population)

Measurement (units)	Time Point		Multiple Doses MK-7762 or Placebo QD (Cohorts 8-10)				
			Pooled Placebo (N=X)	100 mg (N=X)	300 mg (N=X)	500 mg (N=X)	All MK-7762* (N=X)
Testname (unit)	Baseline	n	X	X	X	X	X
		Mean	X.X	X.X	X.X	X.X	X.X
		SD	X.XX	X.XX	X.XX	X.XX	X.XX
		Minimum	XX	XX	XX	XX	XX
		Median	X.X	X.X	X.X	X.X	X.X
		Maximum	XX	XX	XX	XX	XX
	Day 1 Hour 2 Absolute	n	X	X	X	X	X
		Mean	X.X	X.X	X.X	X.X	X.X
		SD	X.XX	X.XX	X.XX	X.XX	X.XX
		Minimum	XX	XX	XX	XX	XX
		Median	X.X	X.X	X.X	X.X	X.X
		Maximum	XX	XX	XX	XX	XX
	Change	n	X	X	X	X	X
		Mean	X.X	X.X	X.X	X.X	X.X
		SD	X.XX	X.XX	X.XX	X.XX	X.XX
		Minimum	XX	XX	XX	XX	XX
		Median	X.X	X.X	X.X	X.X	X.X
		Maximum	XX	XX	XX	XX	XX

All participants received multiple oral doses of MK-7762 or matching placebo once daily (QD) for 28 days under fasting or fed (standard meal) conditions.

Participants are pooled by dose level regardless of fasting conditions.

Average of triplicates are used in the analysis.

Baseline is the last triplicate measurement collected prior to first dosing.

*All MK-7762' summary includes data from participants who received MK-7762 regardless of fasting conditions.

EOT = End of trial

Source: <>

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

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Programmer Note for Shells CEG, CEG2, CEG3:

- For all tables:
 - The table may be split across 2 pages if it is not possible to fit all columns on 1 page. Additional pooled treatments may be added as outlined in the notes of Section 5 of the SAP.
- For all Part 1 tables:
 - Time points will be Baseline, Day 1 Hour 2, Day 1 Hour 6, Day 1 Hour 12, Day 2, and EOT (Day 7). The sample size at EOT for the Cohort 6 summaries will be 4 or less.
- For Part 2, FE tables:
 - Time points will be Baseline, Day 1 Hour 2, Day 1 Hour 6, Day 1 Hour 12, Day 2, Day 3, and Day 8.
- For all Part 2, MAD tables:
 - Time points will be Baseline, Day 1 Hour 2, Day 1 Hour 6, Day 1 Hour 12, Day 2 Predose, Day 3 Predose, Day 7 Predose, Day 14 Predose, Day 21 Predose, Day 28 Predose, Day 28 Hour 2, Day 28 Hour 6, Day 28 Hour 12, Day 29, Day 30, Day 31, and EOT (Day 36).

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Shell CEGC will be in the following RTF format:

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Table CEGC Categorical Summary of Abnormal Safety 12-Lead Electrocardiogram – Part 1 (Safety Population)

Time Point	Result	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6)		All Part 1 Cohorts*
		Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	1200 mg (N=X)	300 mg Fasted (N=X)	300 mg Fed (N=X)	All MK-7762 Fasted (N=X)
Baseline	Normal	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	ANCS	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	ACS	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Day 1 Hour 2	Normal	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	ANCS	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	ACS	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Day 1 Hour 6	Normal	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	ANCS	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	ACS	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)

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At each time point, the worst assessment of the triplicates is considered.

Baseline is the last triplicate measurement collected prior to dosing in each treatment period.

Percentages are based on the number of participants dosed with available assessments at the time point of interest.

*The 'All MK-7762 Fasted' summary includes data from participants who received MK-7762 under fasting conditions only.

ACS = Abnormal clinically significant; ANCS = Abnormal not clinically significant; EOT = End of trial

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMMYYYY HH:MM

Please see programmer notes for Shells CEGC, CEGC2, CEGC3 after Shell CEGC3.

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Shell CEGC2 will be in the following RTF format:

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Table CEGC2 Categorical Summary of Abnormal Safety 12-Lead Electrocardiogram – Part 2, FE (Safety Population)

Time Point	Result	Food Effect Cohort 7 600 mg MK-7762		
		Fasted (N=X)	Standard Meal (N=X)	High-Fat Meal (N=X)
Baseline	Normal	X (XX%)	X (XX%)	X (XX%)
	ANCS	X (XX%)	X (XX%)	X (XX%)
	ACS	X (XX%)	X (XX%)	X (XX%)
Day 1 Hour 2	Normal	X (XX%)	X (XX%)	X (XX%)
	ANCS	X (XX%)	X (XX%)	X (XX%)
	ACS	X (XX%)	X (XX%)	X (XX%)
Day 1 Hour 6	Normal	X (XX%)	X (XX%)	X (XX%)
	ANCS	X (XX%)	X (XX%)	X (XX%)
	ACS	X (XX%)	X (XX%)	X (XX%)

< >

At each time point, the worst assessment of the triplicates is considered.

Baseline is the last triplicate measurement collected prior to dosing in each treatment period.

Percentages are based on the number of participants dosed with available assessments at the time point of interest.

ACS = Abnormal clinically significant; ANCS = Abnormal not clinically significant

Source: < >

Program: /CAXXXXX/sas_prg/atsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

Please see programmer notes for Shells CEGC, CEGC2, CEGC3 after Shell CEGC3.

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Shell CEGC3 will be in the following RTF format:

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Table CEGC3 Categorical Summary of Abnormal Safety 12-Lead Electrocardiogram – Part 2, MAD (Safety Population)

Time Point	Result	Multiple Doses MK-7762 or Placebo QD (Cohorts 8-10)				
		Pooled Placebo (N=X)	100 mg (N=X)	300 mg (N=X)	500 mg (N=X)	All MK-7762* (N=X)
Baseline	Normal	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	ANCS	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	ACS	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Day 1 Hour 2	Normal	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	ANCS	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	ACS	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Day 1 Hour 6	Normal	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	ANCS	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	ACS	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)

< >

All participants received multiple oral doses of MK-7762 or matching placebo once daily (QD) for 28 days under fasting or fed (standard meal) conditions.

Participants are pooled by dose level regardless of fasting conditions.

At each time point, the worst assessment of the triplicates is considered.

Baseline is the last triplicate measurement collected prior to first dosing.

Percentages are based on the number of participants dosed with available assessments at the time point of interest.

*All MK-7762' summary includes data from participants who received MK-7762 regardless of fasting conditions.

ACS = Abnormal clinically significant; ANCS = Abnormal not clinically significant; EOT = End of trial

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

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Programmer Note for Shells CEGC, CEGC2, CEGC3:

- For all tables:
 - At each time point, all abnormality categories will be presented even if no participants meet the criteria.
- For all Part 1 tables:
 - Time points will be Baseline, Day 1 Hour 2, Day 1 Hour 6, Day 1 Hour 12, Day 2, and EOT (Day 7). The sample size at EOT for the Cohort 6 summaries will be 4 or less.
- For Part 2, FE tables:
 - Time points will be Baseline, Day 1 Hour 2, Day 1 Hour 6, Day 1 Hour 12, Day 2, Day 3, and Day 8.
- For all Part 2, MAD tables:
 - Time points will be Baseline, Day 1 Hour 2, Day 1 Hour 6, Day 1 Hour 12, Day 2 Predose, Day 3 Predose, Day 7 Predose, Day 14 Predose, Day 21 Predose, Day 28 Predose, Day 28 Hour 2, Day 28 Hour 6, Day 28 Hour 12, Day 29, Day 30, Day 31, and EOT (Day 36).

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Shell CVISS will be in the following RTF format:

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Table CVISS Shifts to Worst Post-Baseline Visual Acuity Results by Treatment – Part 2, MAD (Safety Population)

Test Name	Treatment	Eye	Baseline Category	Post-Baseline Category			
				0	1	2	3
Snellen	Pooled Placebo QD	Right	0	XX	X	X	X
			1	X	X	X	X
			2	X	X	X	X
			3	X	X	X	X
		Left	0	XX	X	X	X
			1	X	X	X	X
			2	X	X	X	X
			3	X	X	X	X
		<similar for all treatment and test (i.e., Rosenbaum)>					
			0	XX	X	X	X
			1	X	X	X	X
			2	X	X	X	X
			3	X	X	X	X

All participants received multiple oral doses of MK-7762 or matching placebo once daily (QD) for 28 days under fasting or fed (standard meal) conditions.
Participants are pooled by dose level regardless of fasting conditions.
Baseline is the last measurement collected prior to first dosing.
Result categories are as follows: 0 = Normal (20/25 or better); 1= Worse than 20/25 but better than or equals to 20/40; 2 = Worse than 20/40 but better than or equals to 20/200; 3 = Worse than 20/200
EOT = End of trial

Source: <>

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

Programmer Notes:

- Treatments will be the same as those presented in Shell CVISC for Part 2, MAD with the exception of the ‘All MK-7762’ summary which will be excluded.
- The worst post-baseline result is summarized in this table.

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Shell CVISC will be in the following RTF format:

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Table CVISC Frequency of Abnormalities in Visual Acuity and Color Vision Assessments by Treatment and Time Point – Part 2, MAD (Safety Population)

Visual Test Abnormality	Time Point	Multiple Doses MK-7762 or Placebo QD (Cohorts 8-10)				
		Pooled Placebo (N=X)	100 mg (N=X)	300 mg (N=X)	500 mg (N=X)	All MK-7762* (N=X)
Snellen – Abnormal result in either eye	Day 7	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 14	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 21	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 29	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 31	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 33	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	EOT	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Overall	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Rosenbaum – Abnormal result in either eye	Day 7	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 14	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 21	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 29	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 31	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 33	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	EOT	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Overall	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Ishihara – Abnormal result in either eye	Day 7	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 14	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 21	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 29	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 31	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 33	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	EOT	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Overall	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)

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Visual Test Abnormality	Time Point	Multiple Doses MK-7762 or Placebo QD (Cohorts 8-10)				
		Pooled Placebo (N=X)	100 mg (N=X)	300 mg (N=X)	500 mg (N=X)	All MK-7762* (N=X)

All participants received multiple oral doses of MK-7762 or matching placebo once daily (QD) for 28 days under fasting or fed (standard meal) conditions.

Participants are pooled by dose level regardless of fasting conditions.

For Snellen and Rosenbaum tests, an abnormal result is a score worse than 20/25 in either eye. For Ishihara color vision test, an abnormal result is a score less than 10 in either eye.

Percentages are based on the number of participants dosed with available assessments at the time point of interest. The overall time point summary presents the number of participants with an abnormal result in either eye at any post-baseline time point.

Baseline is the last measurement collected prior to first dosing.

*‘All MK-7762’ summary includes data from participants who received MK-7762 regardless of fasting conditions.

EOT = End of trial

Source: <>

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

Programmer Notes:

- Time points will be Day 7, Day 14, Day 21, Day 29, Day 31, Day 33, EOT (Day 36), and Overall. Overall will show the proportion of participants with at least one abnormal result in either eye at any post-baseline time point.
- The Visual Assessment CRF Normal/Abnormal flags will be used to flag abnormal results. For Ishihara, a participant will be counted if they have an abnormal result in either eye.

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Shell CBPNS will be in the following RTF format:

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Table CBPNS Frequency of New Post-Baseline Abnormalities in Peripheral Neuropathy Assessments by Treatment, Time Point, and Severity – Part 2, MAD (Safety Population)

Multiple Doses MK-7762 or Placebo QD (Cohorts 8-10)							
Neuropathy Assessment	Time Point	Abnormality in either Extremity/ Score or Graded Score	Pooled Placebo (N=X)	100 mg (N=X)	300 mg (N=X)	500 mg (N=X)	All MK-7762* (N=X)
Symptoms	Day 7	Any Neuropathy Symptom	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 1	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 2	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 3	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Pain, Aching, or Burning	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 1	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 2	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 3	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Pins and Needles	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 1	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 2	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 3	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Numbness (Lack of Feeling)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 1	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 2	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 3	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
<similar for all time points>							
Physical Objective Finding	Day 7	Any Objective Finding	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Vibration in Big Toes	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Score 1	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Score 2	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Score 3	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Tendon Reflexes	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Score 1	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Score 2	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Score 3	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)

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Multiple Doses MK-7762 or Placebo QD (Cohorts 8-10)							
Neuropathy Assessment	Time Point	Abnormality in either Extremity/ Score or Graded Score	Pooled Placebo (N=X)	100 mg (N=X)	300 mg (N=X)	500 mg (N=X)	All MK-7762* (N=X)
Score 4			X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
<similar for all time points>							
Both	Day 7	Any Objective Finding and Symptom	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)

All participants received multiple oral doses of MK-7762 or matching placebo once daily (QD) for 28 days under fasting or fed (standard meal) conditions.

Participants are pooled by dose level regardless of fasting conditions.

At each time point, the table presents the number of participants with a post-baseline result which meets the abnormality criteria and which was not present at baseline. The overall time point summary presents the number of participants meeting the abnormality criteria at any post-baseline time point.

Percentages are based on the number of participants dosed with available assessments at the time point of interest. For the overall time point summary, percentages are based on the number of participants dosed and with at least one available post-baseline assessment.

Baseline is the last measurement collected prior to first dosing.

When participants experience multiple events meeting the criteria, the worst grade/score is summarized.

*‘All MK-7762’ summary includes data from participants who received MK-7762 regardless of fasting conditions.

For neuropathy symptom assessments, scores are graded as follows: Grade 1 = Scores 01-03; Grade 2 = Scores 04-06; Grade 3 = Scores 07-10, where scores are on a 01 to 10 scale with 01 = Mild and 10 = Severe.

For vibration in big toes: Score 1 = Mild loss; Score 2 = Moderate loss; Score 3 = Severe loss

For tendon reflexes: Score 1 = Hypoactive; Score 2 = Normal deep tendon reflexes; Score 3 = Hyperactive deep tendon reflex; Score 4 = Clonus

EOT = End of Trial

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

Programmer Notes:

- Time points will be Day 7, Day 14, Day 21, Day 29, Day 31, Day 33, EOT (Day 36), and Overall. Overall will show the proportion of participants with meeting the criteria in either extremity at any post-baseline time point.
- Please refer to Section 6.13 of the SAP for details on the analysis and definitions of abnormal results.

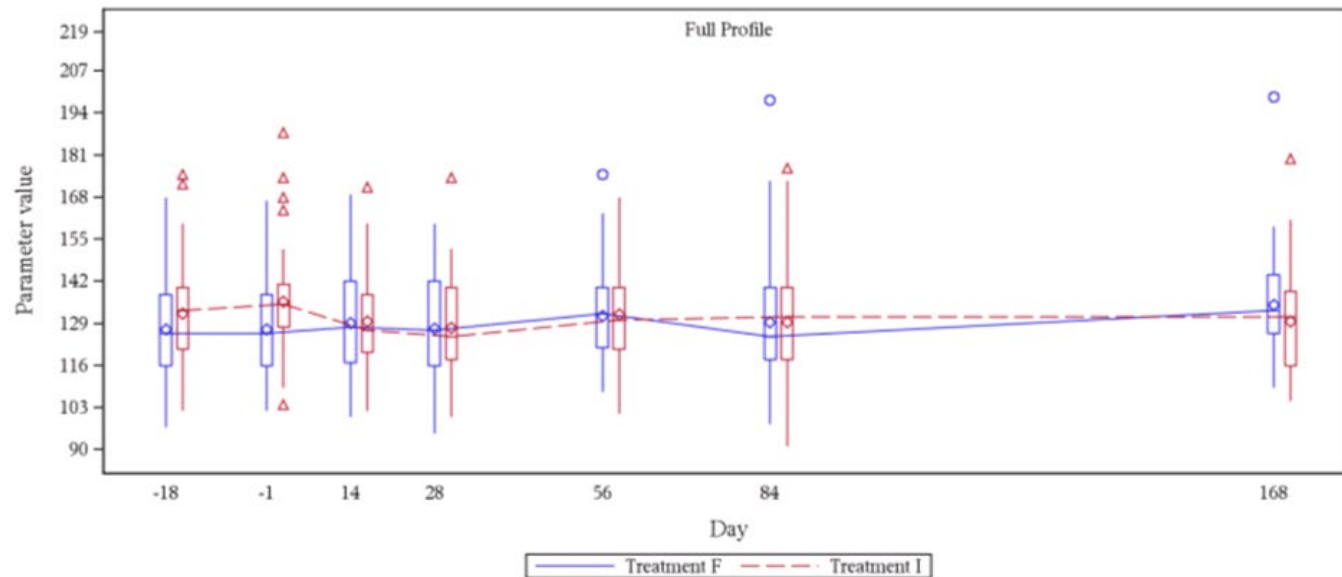
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- Neuropathy symptoms are Pain, Aching, or Burning in Feet, Legs; Pins and Needles in Feet, Legs; Numbness [Lack of Feeling] in Feet, Legs. Physical objective findings are CRF Great Toe Distal Interphalangeal (labelled as Vibration in Big Toes) and Ankle Reflexes (labelled as Tendon Reflexes).
- The following steps will be followed to distinguish a new post-baseline event at each time point:
 1. For each extremity and symptom/objective finding, compare baseline score to the post-baseline score and only select those worse than the baseline value and abnormal. For neuropathy symptom, abnormality refers to a score within 01-10 and for physical objective testing, abnormality is defined as scores within 1-3 for vibration or scores of 1-4 for tendon reflexes.
 2. For each type of event (each symptom or each objective physical finding), select the worst grade of both extremities from the values selected in step 1.
 3. For symptoms, Grade scores selected from step 2 according to the following classification: Grade 1 = Scores 01-03; Grade 2 = Scores 04-06; Grade 3 = Scores 07-10.
 4. Scores selected in step 2 for objective physical findings and step 3 for symptoms will be used in the summaries.
- The summary of 'Any Neuropathy Symptom' will include participants with a score of Grade 1 or higher (Step 3 above) in at least one symptom. The worse grade across all symptoms will be presented for grade frequency counts for this summary.
- The summary of 'Any Objective Finding' will include participants with scores 1 through 3 for vibration in big toes or scores 1-4 for tendon reflexes in either extremities.
- The summary of 'Any Objective Finding and Symptom' will include participants who experience at least one symptom and at least one objective finding at each time point or overall.
- Frequency counts of scores will not be presented for the following abnormality criteria/time point:
 1. 'Any Objective Finding' summary at all time points
 2. 'Any Objective Finding and Symptom' summary at all time points
 3. 'Vibration in Big Toes' and 'Tendon Reflexes' summaries at the 'Overall' time point.

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Figures BOXP will be in the following format:

Figure BOXP Boxplot of <Clinical Laboratory Test Name> by Treatment and Time Point – Part 1 (Safety Population)



Programmer Notes:

- Time points & treatments (with corresponding Treatment description legend) applicable for each part will be presented in consistency with the summary table, with the exception of the pooled summary (i.e., summary pooling multiple MK-7762 dose levels). For Part 2, MAD, treatments will be presented in terms of dose level regardless of fasting conditions (see Section

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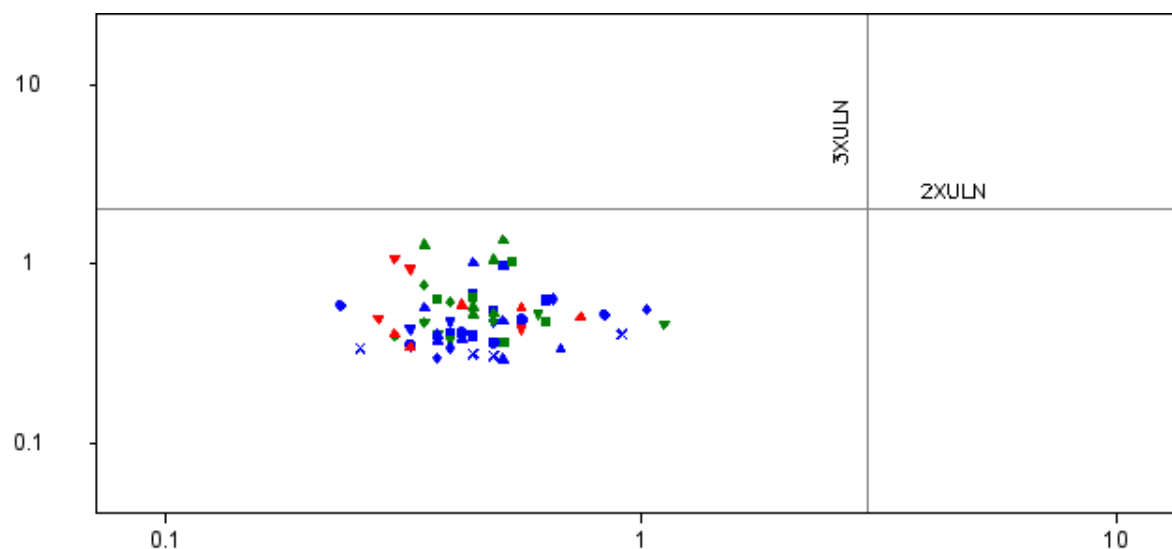
5 of the SAP) and the following footnote will be included: ‘Participants are pooled by dose level regardless of fasting conditions.’

- The y-axis label will be the parameter name (unit)
- The x-axis label will be Time Point (Days).
- The following footnote will be added to explain the features of the boxplot, e.g., *The horizontal line in the box interior represents the median. The symbol in the box interior represents the mean. Values outside the whiskers are identified with symbols. The upper (lower) edge of the box represents the 75th (25th) percentile. A whisker is drawn from the upper (lower) edge of the box to the largest (smallest) value within 1.5 × interquartile range above (below) the edge of the box.*

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Figures EDISH will be in the following format:

Figure EDISH E-DISH Scatter Plot of Maximum Total Bilirubin Versus Maximum <Aspartate Aminotransferase or Alanine Aminotransferase> Post-Baseline – Part 1 (Safety Population)



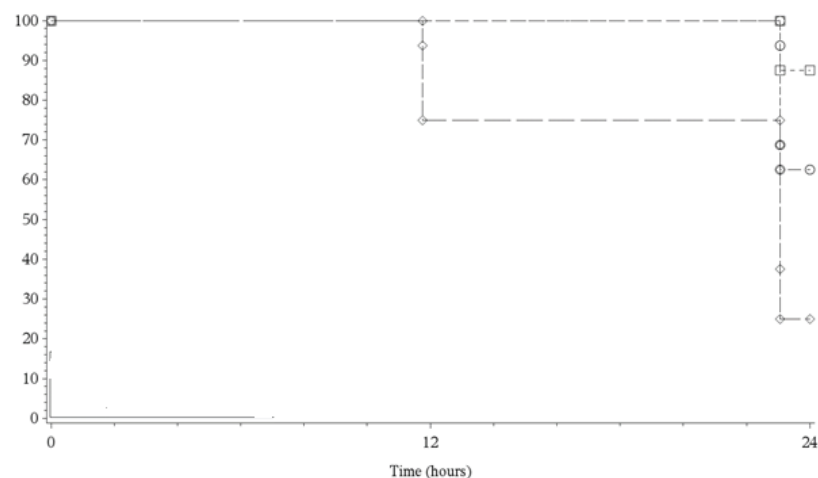
Programmer Notes:

- Treatments (with corresponding Treatment description legend) will be identified with different symbols.
- The y-axis label will be ‘Maximum Total Bilirubin (value/ULN)’
- The x-axis label will be ‘Maximum <Aspartate Aminotransferase or Alanine Aminotransferase>(value/ULN)’

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Figures KMPLLOT will be generated as follows:

Figure KMPLLOT Kaplan-Meier Cumulative Incidence Plot – Time to Adverse Event Resolution in Participants With Ongoing Neurologic or Hematologic Adverse Event of Special Interest at Time of Treatment Discontinuation – Pooled Placebo Multiple Once Daily Doses – Part 2, MAD (Safety Population)



Programmer Notes:

- These figures will only be generated if there are more than 5 participants with ongoing AESIs at the time of treatment discontinuation.
- There will be a separate figure for each treatment.
- The y-axis label will be ‘Percent of Participants With Resolved AESI’
- The x-axis label will be ‘Time (Days)’
- 95% confidence bands will also be presented in the figures as outlined in the SAP.

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3. LISTING SHELLS

The following listing shells provide a framework for the display of data from this trial. The shells may change due to unforeseen circumstances. These shells may not be reflective of every aspect of this trial, but are intended to show the general layout of the listings that will be presented and included in the final report. Listings will be generated from data created in accordance with SDTM Model 1.4 with Implementation Guide 3.3. Listings with derived data (i.e., triplicate ECGs) may be created from the ADaM data. All listings will be generated as RTF and presented in Times New Roman 9. Time point information (period, day, hour) will match that found in the CRF. Part 2 listings will include data from Cohorts 7-10 and will follow the same format as Part 1 listing shells.

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Appendix 16.1.10.1 Clinical Laboratory Reference Ranges

Laboratory Group	Test Name	Sex	Age Category	Reference Range	Unit
Chemistry	Testname1	MALE		XX-XXX	mEq/L
	Testname2	MALE	0-25	XX-XXX	U/L
			26-99	XX-XXX	U/L
<similar for all other tests, note that age will only be presented when different reference range exists>					
Hematology	<similar to chemistry>				
Urinalysis	Testname	MALE		NEGATIVE	
Urine Drug Screening	Amphetamines	MALE		NOT DETECTED	

Source: SDTM.LB; ADaM.MB

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.1.1 Participant Disposition – Part 1 (Safety Population)

Cohort	Participant Number	Treatment/ Treatment Sequence	Study Drug Discontinuation				End of Trial			
			Did Participant Prematurely Discontinue?	Treatment Discontinuation Date	Primary Treatment Discontinuation Reason	Specify	Did Participant Complete the Trial?	Date of Completion/ Discontinuation	Primary Discontinuation Reason	Specify
1	1001	50 mg Fasted	No				Yes	DDMMYYYY		
	1002	Placebo	No				No	DDMMYYYY	Personal Reason	XXXXX
	1003	Placebo	Yes	DDMMYYYY	Adverse Event	XXXXXX	No	DDMMYYYY	Other	XXXX

<>

Source: <>

Program: /CAXXXXX/sas prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Programmer Note: For participants in Part 1 Cohort 6, treatment sequence will be 300 mg Fasted/Fed or 300 mg Fed/Fasted. For participants in Part 2 Cohort 7, treatment sequence will be either 600 mg Fasted/Standard/High-Fat, 600 mg Standard/High-Fat/Fasted, or 600 mg High- Fat/Fasted/Standard.

Following footnotes will be included in all Part 1 listings that contain treatment column:

All participants received a single oral dose of MK-7762 or matching placebo under fasting conditions with exception of Cohort 6 which was designed as a cross-over food effect cohort with one fasted trial period and one fed trial period.

Similar footnote for Part 2 listings (only shown on first listing):

All participants received multiple oral doses of MK-7762 or matching placebo once daily (QD) for 28 days under fasting or fed (standard meal) conditions with the exception of Cohort 7 which was designed as a 3-period cross-over food effect cohort with 600 mg MK-7762 fasted, fed with standard meal, and fed with high-fat meal trial periods.

Treatments for Part 2 listings will match short description in Section 5 of the SAP.

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Appendix 16.2.1.3 Participant Disposition – Screen Failures

Screening ID	Discontinuation Date	Primary Reason for Discontinuation	Specify
X			
X			
XX	DDMMYYYYY	Adverse Event	XXXXXXX
Source: <>			
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMMYYYYY HH:MM			

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Appendix 16.2.2.1 Protocol Deviations

Cohort	Participant Number	Trial Period	Treatment	Day	Hour	Deviation Date	Deviation Category	Deviation	Severity
1	XXX	X	X	X	XX.XX	DDMONYYYY	XXXXXXXX	XXXXXXXX	XXXXXXXX
				X	XX.XX	DDMONYYYY	XXXXXXXX	XXXXXXXX	XXXXXXXX
				X	XX.XX	DDMONYYYY	XXXXXXXX	XXXXXXXX	XXXXXXXX

Include treatment note seen on 16.2.1.

Source: < >

Program: /CAXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Programmer Note: A spreadsheet containing protocol deviations will be provided by the Clinical Study Manager to the SDTM programmer for incorporation in the SDTM. This listing will be generated off the SDTM dataset. If there are more variables or less collected in the spreadsheet, they will be presented or removed from this listing, accordingly.

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Appendix 16.2.4.1.1 Demographics – Part 1 (Safety Population)

Cohort	Participant Number	Birth MMYYYY	Age (yr)	Sex	Race	Ethnicity	Height (cm)	Weight (kg)	Body Mass Index (kg/m ²)	Protocol Version	Consent		
											Informed?	PG?	Withdrawn?
1	1001	Feb2023	47	Male	< >	Hispanic or Latino	XXX	XX.X	XX.XX	< >	DDMMYYYYYY	Yes	DDMONYYYY
	1002	<similar to above>										No	

Age is approximated by subtracting the date of birth (day is not collected so the first day of the month is used) from the date of informed consent. If calculated difference is one more than the protocol maximum age then the age approximation will be the calculated difference – 1.

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.4.1.3 Demographics – Screen Failures

Screening ID	Birth YYYY	Sex	Race	Ethnicity	Informed Consent Date
< >	XXXX	Male	< >	Hispanic or Latino	DDMMYYYY
< >	<similar to above>				

Source: < >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.4.2.1 Physical Examination – Part 1 (Safety Population)

Cohort	Participant Number	Trial Period	Treatment	Day	Hour	Date	Type	Question	Answer
1	1001	Screen				DDMONYYYY	Complete	Was PE performed? (Yes/No)	Yes
		1	50 mg Fasted	-1	-17.75	DDMONYYYY	Complete	Was PE performed? (Yes/No)	No
				3	51.53	DDMONYYYY	Complete	Was PE performed? (Yes/No)	No

<similar for all participants>

Include treatment note seen on 16.2.1.

PE = Physical examination

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.4.3.1 Medical History – Part 1 (Safety Population)

Cohort	Participant Number	Any History?	System Organ Class Preferred Term (Verbatim)	Date		Ongoing?
				Start	End	
1	1001	No				
	1002	Yes	<>			

<note date can be YYYY, MONYYYY, or DDMONYYYY based on individual participant data>

Include treatment note seen on 16.2.1.

History Events are classified according to MedDRA Version 26.0.

Source: <>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.4.4.1 Substance Use – Part 1 (Safety Population)

Cohort	Participant Number	Substance	Description of Use	Start Date	End Date
1	1001	Tobacco Use	0-4 CIGARETTES/DAY	DDMONYYYY	DDMONYYYY
	1002	Tobacco Use	LIFETIME NON-SMOKER	DDMONYYYY	

Include treatment note seen on 16.2.1.

Source: <>

Program: /CAXXXXX/sas prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.5.1.1 Participant Eligibility – Part 1 (Safety Population)

Cohort	Participant Number	Did participant meet all eligibility criteria?	Criterion Not Met	Specify
1	1001	Yes		
	1002	No	Exclusion 5	<specify and criterion not met will only be presented if populated>
<similar for all participants>				

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Programmer Note: Screen failure listing will be identical to this one with the exception of removing the cohort and specify columns and participant number will be replaced with Screening ID.

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Appendix 16.2.5.2.1.1 Test Compound Description – Part 1

CRF Treatment Description	Form	Route
< >	SOLUTION	ORAL
Source: < >		
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM		

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Appendix 16.2.5.2.1.2 Test Compound Administration Times – Part 1 (Safety Population)

Cohort	Participant Number	Trial Period	Treatment	Day	Hour	Dose Date	Dose Time	Dosing Compliance Met?	Compound	Planned Dosage	Comments
1	1001	1	50 mg Fasted	1	0.00	DDMONYYYY	HH:MM:SS	Yes	< >	500 NCI	<This column prints only if data is present>

Include treatment note seen on 16.2.1.

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.5.2.2.3 Extent of Exposure – Part 2, MAD (Safety Population)

Cohort	Participant Number	Trial Period	Treatment	Drug Name	Number of Doses	Total Dosage (mg)
8	2001	1	100 mg Fed Standard Meal	MK-7762	28	2800
< >						

Include treatment note seen on 16.2.1.

Total dosage (mg) is calculated as the daily dose (mg) * number of doses received.

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Programmer Note: This listing may be generated using ADaM. Participants receiving placebo will not be included in this listing.

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Appendix 16.2.5.3.1 Meal Times – Part 1 (Safety Population)

Participant Number	Trial Period	Treatment	Day	Hour	Interval	Event	Start		Stop	
							Date	Time	Date	Time
X	X	XXXXXX	-1	-15.0		DINNER	DDMONYYYY	HH:MM:SS	DDMONYYYY	HH:MM:SS
				-11.0		SNACK	DDMONYYYY	HH:MM:SS	DDMONYYYY	HH:MM:SS
			1	4.1		LUNCH	DDMONYYYY	HH:MM:SS	DDMONYYYY	HH:MM:SS

Include treatment note seen on 16.2.1.

Source: <>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Programmer Note: For Part 2, a ‘Meal Type’ column (Standard Meal or High-Fat Meal) will be added after the event column.

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Appendix 16.2.5.4.1 Prior and Concomitant Medications – Part 1 (Safety Population)

Cohort	Participant Number	Treatment	Prior?	Medication (WHO DD)	Dosage	Route	Start Date (Study Day)	Start Time	End Date (Study Day)	End Time	Frequency	Indication	Ongoing?
1	1001		None										
	1002		None										
	1003		Yes	CETIRIZINE (CETIRIZINE)	X MG	BY MOUTH	DDMONYYYY		DDMONYYYY	HH:MM	XXXXXXX	XXXXXX	No
		50 mg Fasted	No	PARACETAMOL (PARACETAMOL)	X MG	XXXXXX	DDMONYYYY	HH:MM	XXXXXXXXXX	HH:MM	XXXXXXX	XXXXXXXX	XX

<>

Include treatment note seen on 16.2.1.
Concomitant medications are coded with WHO Drug Dictionary Version 01-Mar-2023 b3.
WHO DD = World Health Organization Drug Dictionary
Prior is defined as a medication administered prior to the first study drug administration.

Source: <>

Program: /CAXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.7.1.1 Adverse Events – Part 1 (Safety Population)

Cohort	Participant Number	Age/ Sex	Treatment	TEAE?	AESI?	System Organ Class/Preferred Term (Verbatim)	Time From Last Dose (DD:HH:MM)	Study Day: Date: Time Start/ End Duration (DD:HH:MM)	Serious/ Outcome	Severity/ Frequency	Study Product Relationship/ Action
1	1001	30/F				None					
	1002	24/M				None					
	1003	52/M	50 mg Fasted	Yes	No	XXXXXXXXXXXX/ XXXXXXXXXXXXX (XXXXXXXXXXXXX)	XX:XX:XX	X:DDMONYYYY:HH:MM/ X:DDMONYYYY:HH:MM 00:23:15	No/ Resolved	Moderate/ Intermittent	Related/ Drug Withdrawn
			50 mg Fasted	Yes	Yes	<similar to above>					

<>
Include treatment note seen on 16.2.1.

Adverse events are classified according to MedDRA Version 26.0.

AESI = Adverse event of special interest; F = Female; M = Male; TEAE = Abbreviation for treatment-emergent adverse event

Source: <>

Program: /CAXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Programmer Notes:

- AEs should be presented start date/time order for each participant.
- Part 2, FE (i.e., Part 2 Cohort 7) listing will resemble this listing with the appropriate treatments.
- Screen Failure listing will resemble this listing; however, the cohort and treatment will not be included and participant number will be replaced by Screening ID.

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Appendix 16.2.7.3.1 Adverse Events – Part 2, MAD (Safety Population)

Cohort	Participant Number	Age/ Sex	Treatment	TEAE?	AESI?	VC?	System Organ Class/Preferred Term (Verbatim)	Time From Last Dose (DD:HH:MM)	Study Day: Date: Time Start/ End Duration (DD:HH:MM)	Serious/ Outcome	Severity/ Frequency	Study Product Relationship/ Action
8	2010	30/F					None					
	2011	24/M					None					
	2012	52/M	100 mg QD Fasted	Yes	No	No	XXXXXXXXXXXX/ XXXXXXXXXXXX (XXXXXXXXXXXX)	XX:XX:XX	X:DDMONYYYY:HH:MM/ X:DDMONYYYY:HH:MM 00:23:15	No/ Resolved	Moderate/ Intermittent	Related/ Drug Withdrawn
			100 mg QD Fasted	Yes	Yes#	No	<similar to above>					

Include treatment note seen on 16.2.1.

Adverse events are classified according to MedDRA Version 26.0.

Ongoing neurologic or hematologic AESI

AESI = Adverse event of special interest; F = Female; M = Male; TEAE = Abbreviation for treatment-emergent adverse event; VC = AE related to visual acuity decrease or color vision change

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Programmer Notes:

- AEs should be presented start date/time order for each participant.
- The 'VC?' flag will be populated as 'Yes' for AEs in Cohorts 8-10 related to visual acuity decrease or color vision change as outlined in Section 6.5 of the SAP.
- A '#' symbol will also be tied to the AESI response (i.e., Yes#) when the AESI is an ongoing neurologic and hematologic AESI as outlined in Section 6.5 of the SAP.

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Appendix 16.2.7.1.2 Details for Serious Adverse Events – Part 1 (Safety Population)

Cohort	Participant Number	Age/ Sex	Treatment	TE?	System Organ Class/Preferred Term (Verbatim)	Study Day: Date: Time Start/End Duration*	Serious Event	Persistent/ Congenital Anomaly/ Birth Defect	Significant Disability/ Incapacity	Hospital- ization	Life- Threat	Important Medical Event	Death
1	XXXX	30/F	50 mg Fasted	Yes^	XXXXXXXXXXXX/ XXXXXXXXXXXX (XXXXXXXXXXXX)	X:DDMONYYYY:HH:MM/ X:DDMONYYYY:HH:MM 00:23:15	Yes	No	No	Yes	No	Yes: < >	No

Include treatment note seen on 16.2.1.

Adverse events are classified according to MedDRA Version 26.0.

* Duration is represented by DD:HH:MM

^ Adverse event is of Special Interest

F = Female; M = Male; TE = Abbreviation for treatment-emergent

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Programmer Note: Part 2 FE and Part 2 MAD listings will resemble this listing with appropriate treatments. If Serious = Yes then present AEs in this listing otherwise please do not include this listing. Screen Failure listing will resemble this listing; however, the cohort and treatment columns will not be included and participant number will be replaced by Screening ID.

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Appendix 16.2.7.3.3 Ongoing Neurologic and Hematologic Adverse Events of Special Interest at Time of Treatment Discontinuation – Part 2, MAD (Safety Population)

Cohort	Participant Number	Age/ Sex	Treatment	TE?	System Organ Class/Preferred Term (Verbatim)	Study Day: Date: Time Start/ End Duration (DD:HH:MM)	Outcome/ Action	Date of Treatment Discontinuation	Time to AE Resolution (Days)
X	XXXX	XX/X	100 mg QD Fasted	Yes	XXXXXXXXXXXX/ XXXXXXXXXXXX (XXXXXXXXXXXX)	X:DDMONYYYY:HH:MM/ X:DDMONYYYY:HH:MM 00:23:15	Resolved/ Drug Withdrawn	DDMONYYYY	X
	XXXX	XX/X	100 mg QD Fed	Yes	XXXXXXXXXXXX/ XXXXXXXXXXXX (XXXXXXXXXXXX)	DDMONYYYY:HH:MM/ UNK	Not Resolved/ Not Recovered/ Drug Withdrawn	DDMONYYYY	X*
<similar to above>									

Include treatment note seen on 16.2.1.

Adverse events are classified according to MedDRA Version 26.0.

F= Female; M =Male; TE = Abbreviation for treatment-emergent

* Time is censored in the analysis

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Programmer Note: AEs should be presented start date/time order for each participant. This listing will only presents ongoing hematologic and neurologic AESIs at time of treatment discontinuation. These will be flagged using the criteria outlined in Section 6.5 of the SAP. Time to AE Resolution will be derived as described in Section 6.5 of the SAP. Censored events will be flagged with a ‘*’.

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Clinical Laboratory listings will resemble Appendix 16.2.8.1.

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Appendix 16.2.8.1 Clinical Laboratory Report – Chemistry – Part 1 (Safety Population)

Cohort	Participant Number	Age/ Sex	Trial Period	Treatment	Day	Hour	Date	Time	Chloride 97-105 (mEq/L)	Potassium 3.7-5.2 (mEq/L)	Phosphorous 2.4-4.4 (mg/dL)	Sodium 135-143 (mEq/L)
1	1001	XX/M	Screen				DDMONYYYY	HH:MM:SS	XXX	X.X	X.X	XXX H
			1	50 mg Fasted	1	-17.00	DDMONYYYY	HH:MM:SS	XXX H	X.X	X.X	XXX H G1
			Recheck				DDMONYYYY	HH:MM:SS	XXX	X.X	X.X	XXX
<similar to above for all participants/time points>												

Include treatment note seen on 16.2.1.

F = Female; M = Male

H = Above reference range

DAIDS Grade: G1 = Grade 1; G2 = Grade 2; G3 = Grade 3; G4 = Grade 4

Source: <>

Program: /CAXXXXX/sas prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Programmer Note: Derived DAIDs grades will be presented along with the abnormality flags.

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Appendix 16.2.8.1.7 Vital Signs – Part 1 (Safety Population)

Cohort	Participant Number	Age/ Sex	Trial Period	Treatment	Day	Hour	Date	Time	Blood Pressure (mmHg)	Pulse (bpm)	Respiration (brpm)	Temperature (°C)	Weight (kg)
									Sys/Dia				
1	1001	30/F	Screen				DDMONYYYY	HH:MM:SS	XXX/ XX	XX	XX	XX.X	XX.X
							R	HH:MM:SS	XXX/ XX*				
							R	HH:MM:SS	XXX^/ XX				
			1	50 mg Fasted	-1	-17.00	DDMONYYYY	HH:MM:SS	XXX/ XX				

Include treatment note seen on 16.2.1.

F = Female; M = Male

R = Recheck value; brpm = breaths/min

^ = Systolic > 140 mmHg; * = Diastolic > 90 mmHg

Source: <>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.8.1.8 Safety 12-Lead Electrocardiogram – Part 1 (Safety Population)

Cohort	Participant Number	Age/ Sex	Trial Period	Treatment	Day	Hour	Date	Time	Result	Heart Rate (bpm)	RR (msec)	PR (msec)	QRS (msec)	QT (msec)	QTcF (msec)	Specify/ Comments
1	1001	30/F	Screen				DDMONYYYY	X:XX:XX	WNL	XX	XXX	XX	XX	XXX	XXX	EARLY REPLORIZATION; LEFT AXIS DEVIATION
			1	50 mg Fasted	-1	X.XX	DDMONYYYY	XX:XX:XX	ANCS	XX	XXX	XX	XX	XXX	410	LEFT AXIS DEVIATION
					X	X.XX	DDMONYYYY	XX:XX:XX	< >	XX	XXX	XX	XX	XXX	441	SINUS BRADYCARDIA
					X	X.XX	DDMONYYYY	XX:XX:XX	< >	XX	XXX	XX	XX	XXX	451	#

Include treatment note seen on 16.2.1.

F = Female; M = Male

WNL = Within normal limits; ANCS = Abnormal, not clinically significant

QTcF = QT corrected for heart rate using Fridericia's correction

= QTc value greater than 450 msec

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.8.1.9 Safety 12-Lead Electrocardiogram – Average of Triplicates – Part 1 (Safety Population)

Cohort	Participant Number	Age/ Sex	Trial Period	Treatment	Day	Hour	Result	Heart Rate (bpm)	RR (msec)	PR (msec)	QRS (msec)	QT (msec)	QTcF (msec)
1	1001	30/F	1	50 mg Fasted		Baseline	Normal	XX.X	XX.X	XX.X	XX.X	XX.X	410.2
					X	X.XX	Normal	XX.X	XX.X	XX.X	XX.X	XX.X	451.4 #@

Include treatment note seen on 16.2.1.

This listing only presents average triplicate 12-lead electrocardiogram results used during analysis. Result is the worst assessment of the triplicate records.

Baseline is the last triplicate measurement collected prior to dosing in each treatment period.

F = Female; M = Male

QTcF = QT corrected for heart rate using Fridericia's correction

= QTc value greater than 450 msec; @ = QTc change from baseline greater than 30 msec

Source: <>

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Programmer Note: Averaged triplicate values will be displayed to the nearest tenth. For Part 2, the baseline definition will be: 'Baseline is the last triplicate measurement collected prior to dosing in each treatment period for Cohort 7 and prior to first dosing for Cohorts 8-10.'

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Appendix 16.2.8.1.10 Visual Assessment – Part 1 (Safety Population)

Cohort	Participant Number	Trial Period	Treatment	Day	Hour	Date	Time	Corrective Lenses?	Snellen			Rosenbaum		
									Right	Left	Overall	Right	Left	Overall
	1001	Screen				DDMONYYYY	HH:MM	No	XXXX #	XXXX	XXXX	XXX	XXXX	XXXX
<similar for all participants/time points>														
Include treatment note seen on 16.2.1.														
# = Snellen/Rosenbaum score worse than 20/25														
Source: <>														
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM														

Programmer Note: For Part 1, treatment, day, and hour columns may be removed from the listing. A score worse than 20/25 is a score with a denominator that is greater than 25.

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Appendix 16.2.8.1.10 Visual Assessment – Part 1 (Safety Population)

Cohort	Participant Number	Trial Period	Treatment	Day	Hour	Date	Time	Corrective Lenses?	Ishihara Right		Ishihara Left	
									Correct/14	Overall	Correct/14	Overall
1	1001	Screen				DDMONYYYY	HH:MM	No	<> *	Normal	<>	Normal

Include treatment note seen on 16.2.1.
* = Ishihara score less than 10

Source: <>
Program: /CAXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Programmer Note: For Part 1, treatment, day, and hour columns may be removed from the listing. A ‘Derived Overall’ column will be included in the Part 2 listing and will be populated as Normal if the participant has a normal result in both eyes or Abnormal if the participant has an abnormal result in either eye. The ‘Derived Overall’ column will be populated for Cohorts 8-10 only.

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Appendix 16.2.8.1.11 Brief Peripheral Neuropathy Assessment – Part 1 (Safety Population)

Cohort	Participant Number	Trial Period	Treatment	Day	Hour	Date	Completed?	Pain, Ache, Burn		Pins, Needles		Numbness		Peripheral Neuropathy Grade
								Right	Left	Right	Left	Right	Left	
1	1001	Screen				DDMONYYYY	No: Subject Declined	XXXX	XXXX	XXXX	XXX	XXXX	XXXX	XXX
<similar for all participants/time points>														
Include treatment note seen on 16.2.1.														
Source: <>														
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM														

Programmer Note: For Part 1, treatment, day, and hour columns may be removed from the listing.

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Appendix 16.2.8.1.11 Brief Peripheral Neuropathy Assessment – Part 1 (Safety Population)

Cohort	Participant Number	Trial Period	Treatment	Day	Hour	Date	Perception of Vibration Completed?	Great Toe Distal Interphalangeal		Deep Tendon Reflexes Completed?	Ankle Reflexes	
								Right	Left		Right	Left
1	1001	Screen				DDMONYYYY	No: Subject Declined	XXXX	XXXX	XXXX	XXXX	XXXX
<similar for all participants/time points>												
Include treatment note seen on 16.2.1.												
Source: < >												
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM												

Programmer Note: For Part 1, treatment, day, and hour columns may be removed from the listing.

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Appendix 16.2.8.2.12 New Post-Baseline Abnormalities in Neuropathy Symptom and Objective Physical Finding Assessments – Part 2, MAD (Safety Population)

Cohort	Participant Number	Trial Period	Treatment	Day	Hour	Date	Symptom or Objective Finding	Symptom or Finding	Worst Grade or Score
1	XXXX	1	100 mg QD Fasted	X	XX.XX	DDMONYYYY	Symptom	Pain, Ache, Burn Pins, Needles	Grade 1 (Score 01-03) Grade 2 (Score 04-06)
							Objective Finding	GTDI Ankle Reflexes	2 (Moderate) 1 (Mild)

Include treatment note seen on 16.2.1.
This listing is based on the neuropathy assessment data from the CRF.

Source: < >
Program: /CAXXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Programmer Note: This listing will only present treatment-emergent results in Part 2, MAD (Cohort 8-10) which will be considered for analysis as described in Section 6.13 of the SAP and in the corresponding summary table notes.

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STATISTICAL ANALYSIS PLAN

A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose and Multiple Ascending Dose Trial in Healthy Adult Participants to Evaluate the Safety, Tolerability, and Pharmacokinetics of MK-7762 with an Open Label (Single Dose) Food Effect Panel

Protocol No: Gates MRI-TBD09-101
Final Protocol Date: 27 September 2022
Amendment No. 1 Date: 19 December 2022
Amendment No. 2: 04 April 2023
Compound Name: MK-7762

Celerion Project CA35747
Final Version 1.0
Date: 02 June 2023

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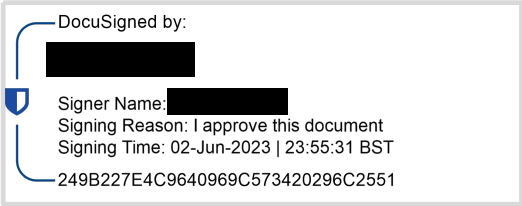
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Compound Name: MK-7762

Protocol: Gates MRI-TBD09-101

Study Title: A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose and Multiple Ascending Dose Trial in Healthy Adult Participants to Evaluate the Safety, Tolerability, and Pharmacokinetics of MK-7762 with an Open Label (Single Dose) Food Effect Panel

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Signer Name: [Redacted]
Signing Reason: I approve this document
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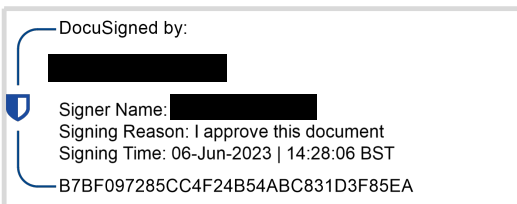
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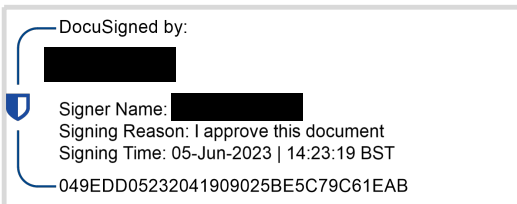
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Gates Medical Research Institute

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Signer Name: [Redacted]
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Clinical Development Leader
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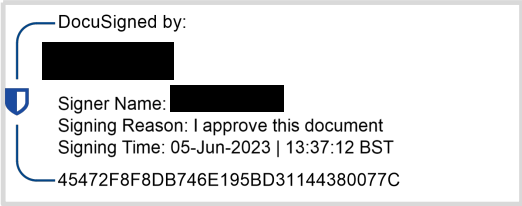
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Protocol: Gates MRI-TBD09-101

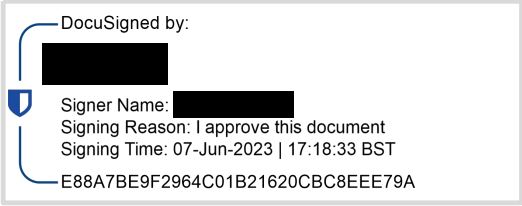
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Head of Therapeutics Development
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1. INTRODUCTION

The following statistical analysis plan (SAP) provides the framework for the analysis and presentation of the data from this trial. Any changes made from the planned analysis described in the protocol or after finalization of this SAP will be documented in the Clinical Study Report (CSR). The section referred to as “Table, Figure, and Listing Shells” within this SAP describes the Clinical Data Interchange Standards Consortium (CDISC) input in order to provide traceability to the corresponding tables, figures, and listings (TFLs). Study data tabulation model (SDTM) is the primary source for the data listings and analysis data model (ADaM) is the source for tables and figures (as well as any listings that contain derived data).

Any additional exploratory analyses not addressed within this SAP and/or driven by the data, or requested by Bill & Melinda Gates Medical Research Institute, will be considered out of scope and must be described in the CSR.

Celerion will not revise the SAP in the case that a dose level is adjusted, removed, repeated, or added. Instead, it should be noted that treatments will be appropriately described and summarized in the TFLs. In the case that the protocol is amended to modify the conduct then the SAP may need to be revised.

This SAP is written prior to finalization of the Part 2 blank CRF. Part 2-related TFLs may be adjusted slightly if warranted to accommodate the structure of the data collection in the final Part 2 blank CRF.

In general, the SAP will only be revised in case of changes leading to a significant impact on the analysis or programming.

2. OBJECTIVES AND ENDPOINTS

Objectives	Endpoints
Primary	
Safety	
To characterize safety and tolerability of MK-7762 after administration of single doses or multiple doses in healthy adult participants For Parts 1 and 2	The proportion of treated participants reporting treatment-emergent adverse events (TEAEs), serious AEs (SAEs), and AEs of special interest (AESIs), assessed overall, by severity, by relationship to study drug, and by system organ class and preferred term according to the following windows: <ul style="list-style-type: none">• Part 1, Cohorts 1 through 5: Day 1 through Day 7• Part 1, Cohort 6 (Food Effect): Day 1 through last day of washout period for first dosing period; Day 1 of second dosing period through Day 7 of second dosing period.• Part 2, Cohorts 1-3: Day 1 through Day 33

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Objectives	Endpoints
<p>To characterize laboratory results, electrocardiogram (ECG) parameters, and vital signs after administration of single doses or multiple doses of MK-7762</p> <p>For Parts 1 and 2</p>	<p>In treated participants, summaries (descriptive statistics and frequencies) of safety laboratory measures (by visit, worst grade, grade shift from baseline), vital signs (by visit, change from baseline), 12-lead ECG parameters (by visit, change from baseline) according to the same windows defined above for AEs. Safety laboratory measurements include clinical chemistry, hematology, coagulation, and urinalysis. Vital signs include temperature, heart rate, and blood pressure. ECG parameters include heart rate, RR interval, PR interval, QRS duration, QT interval, and QT interval corrected by Fridericia's formula [QTcF].</p>
Secondary	
PK	
<p>To determine the pharmacokinetic (PK) of single doses of MK-7762 in plasma*</p> <p>To evaluate the impact of food on the PK of MK-7762 in plasma*</p> <p>For Part 1 Only</p>	<p>Estimand framework:</p> <ul style="list-style-type: none"> • Treatment: 1) MK-7762 in escalating single doses or placebo (Part 1, Cohorts 1-5) and 2); MK-7762 under fasted or fed conditions (Part 1, Cohort 6) • Population: All participants who receive at least one dose of MK-7762 and have at least one non-zero PK result (PK Population) • Participant-level endpoints: <ul style="list-style-type: none"> ○ Maximum plasma drug concentration (C_{max}), ○ Time to maximum plasma drug concentration (t_{max}), area under the concentration-time curve (AUC) calculated to last quantifiable observed sample (AUC_{last}), extrapolated to infinity (AUC_{0-inf}), and over first 24h (AUC₀₋₂₄) ○ Terminal elimination half-life (t_{1/2}) ○ Oral clearance (CL/F) ○ Oral volume of distribution (V_d/F) • Population-level summaries: Descriptive statistics of endpoints noted above. • Intercurrent events: A treatment policy strategy will be used to summarize plasma PK results.
<p>To determine the PK of multiple doses of MK-7762 in plasma*</p> <p>For Part 2 Only</p>	<p>Estimand framework:</p> <ul style="list-style-type: none"> • Treatment: MK-7762 in escalating multiple doses or placebo (Part 2, Cohorts 1-3) • Population: All participants who receive at least one dose of MK-7762 and have at least one non-zero PK result (PK Population)

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Objectives	Endpoints
	<ul style="list-style-type: none"> • Participant-level endpoints: <ul style="list-style-type: none"> • Day 1: <ul style="list-style-type: none"> ○ Cmax ○ tmax ○ AUC(0-24) • Day 28 (Cohorts 1-3): <ul style="list-style-type: none"> ○ Cmax ○ tmax ○ AUC, AUClast, AUC0-inf, and AUC0-24 ○ t_{1/2} ○ CL/F ○ Vd/F ○ Accumulation ratio (AUCtau / AUC0-24) <ul style="list-style-type: none"> ▪ Cohorts 1-3: Day 28 vs Day 1 • Population-level summaries: Descriptive statistics of endpoints noted above. • Intercurrent events: A treatment policy strategy will be used to summarize plasma PK results.
Exploratory	
<p>To determine the PK of single doses or multiple doses of MK-7762 in urine*</p> <p>For Parts 1 and 2</p>	<p>In treated participants with at least one non-zero PK result, descriptive statistics of the following measures:</p> <ul style="list-style-type: none"> • Urine PK concentrations • Percent of drug excreted in urine (in a dosing interval) (Ae%) • Renal clearance (CLr) • To estimate the metabolite-to-parent ratio (AUC metabolite/AUC MK-7762) cumulative urinary excretion (CUE)
<p>To identify prominent circulating metabolites of MK-7762 in plasma following administration of single doses or multiple doses of MK-7762*</p> <p>For Parts 1 and 2</p>	<p>In treated participants with at least one non-zero PK result, qualitative characterization of potential metabolites.</p>
<p>To estimate the effect of MK-7762 on ECG parameters, including concentration-QTc (C-QTc) analysis, following single or multiple doses of MK-7762*</p>	<p>In treated participants, descriptive statistics of the following endpoints, including placebo-corrected change from baseline measures, categorical outliers, and frequency of treatment-emergent T- and U-wave abnormalities:</p> <ul style="list-style-type: none"> • Heart rate • RR interval

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Objectives	Endpoints
For Parts 1 and 2	<ul style="list-style-type: none"> PR interval QRS interval QTcF interval <p>This analysis may be undertaken based on observed PK and other project considerations. If so, the primary analysis will be based on concentration-QTc (C-QTc) modeling of the relationship between the plasma concentrations of MK-7762 and potential metabolites and change-from baseline QTcF (ΔQTcF) with the intent to exclude an effect of placebo corrected ΔQTcF ($\Delta\Delta$QTcF) > 10 msec at clinically relevant plasma concentrations.</p>
<p>To characterize the maximal hematological effect of single or multiple doses of MK-7762 or placebo in healthy participants</p> <p>For Parts 1 and 2</p>	<p>In treated participants, the following binary classifications with respect to platelet count, absolute neutrophil count (ANC), white blood cell (WBC) count, reticulocyte count, red blood cell (RBC) count, and hemoglobin result:</p> <ol style="list-style-type: none"> Post-baseline result that is $<$ lower limit of normal (LLN) (yes/no) Post-baseline result that is $< 50\%$ of LLN (yes/no) Post-baseline result that is $\geq 20\%$ decrease relative to baseline (yes/no) Post-baseline result that is $\geq 50\%$ decrease relative to baseline (yes/no) <p>Summaries will include the following:</p> <ul style="list-style-type: none"> For each of (a) through (d), the proportion of participants who meet the criterion For each of (a) and (b), the descriptive statistics for the laboratory parameter in participants who meet the criterion For each of (c) and (d), descriptive statistics for the percent decrease in the laboratory parameter in participants who meet the criterion
<p>To characterize the effect of MK-7762 on neurologic assessments in healthy participants receiving multiple doses</p> <p>For Part 2 Only</p>	<p>In treated participants, descriptive summaries for each of the following measures:</p> <ul style="list-style-type: none"> For visual acuity score for each eye <ul style="list-style-type: none"> Descriptive statistics for change in visual acuity score from baseline to lowest post-baseline score

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Objectives	Endpoints
	<ul style="list-style-type: none"> ○ Proportion of participants with a post-baseline visual acuity score worse than 20/25 in either eye • For color vision assessment for each eye <ul style="list-style-type: none"> ○ Proportion of participants with a post-baseline color vision abnormality in either eye (overall and by severity grade) • For eye symptom assessment for each eye <ul style="list-style-type: none"> ○ Proportion of participants with a reported new post-baseline eye symptom in either eye (overall and by severity grade) • For Brief Peripheral Neuropathy Screen (BPNS) score in each lower extremity <ul style="list-style-type: none"> ○ Proportion of participants with a reported new post-baseline peripheral neuropathy symptom on BPNS (overall and by severity grade) ○ Proportion of participants with a new post-baseline peripheral neuropathy objective physical finding on BPNS (overall and by severity grade) ○ Proportion of participants with new post-baseline peripheral neuropathy symptoms and objective physical finding on BPNS (overall and by severity grade)
<p>To evaluate the time to resolution of hematologic and neurologic AESIs following discontinuation of MK-7762 after multiple doses</p> <p>For Part 2 Only</p>	<p>In treated participants who have ongoing hematologic or neurologic AESI at the time of treatment discontinuation:</p> <ul style="list-style-type: none"> • Kaplan-Meier analysis of time to resolution of category of AESI (hematologic or neurologic). Participants with unresolved AESI at the time of analysis will be censored on the date of last AE assessment. • Milestone rates at 5 days following treatment discontinuation
<p>To explore possible variability in MK-7762 metabolism due to genetic polymorphisms based on metabolite profile observed*</p> <p>For Parts 1 and 2</p>	<p>Will be defined in an exploratory SAP.</p>

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Objectives for pharmacokinetics and pharmacodynamics are covered in Certara's SAP. These objectives will be analyzed by Certara and documented in a separate report that will be appended to the Celerion CSR. Metabolite profiling, cardiodynamic and concentration-QT analysis will be addressed at a later date, if applicable.

3. TRIAL DESIGN

This trial is designed to address the objective(s) outlined in [Section 2](#).

This is a first-in-human (FIH) trial of MK-7762, administered to healthy adults. It is a randomized, double-blind, placebo-controlled, two-part trial. Healthy adult participants between 19 to 55 years of age (inclusive) of both sexes who are capable of and willing to provide informed consent will be eligible for the trial.

The trial will be conducted in two parts. Part 1 - a single ascending dose (SAD) and food effect (FE) part (N=48) and Part 2 - a multiple ascending dose (MAD) part (N=48). Because this trial is aimed at characterizing the safety, tolerability, and PK of MK-7762, it is designed to be descriptive and is not based on formal hypothesis testing. Therefore, this trial is not powered to detect any pre-specified differences in potential safety or PK data between treatment groups. A total of approximately 96 participants will be randomized (48 in Part 1 and 48 in Part 2), and a total of approximately 74 participants will be exposed to MK-7762 (38 from Part 1 and 36 from Part 2).

The trial has a double-blind design in which participants and all site personnel will be blinded to the randomization, excepting the unblinded pharmacist(s) and pharmacy staff at the clinical trial unit (CTU) who will prepare oral doses of MK-7762 and placebo appropriately masked for site personnel who are authorized to administer treatment. Refer to the Gates MRI-TBD09-101 Unblinding Plan for additional details about the roles and responsibilities, data flow, and level of access associated with unblinding activities in Part 1.

All participants will undergo a Screening period lasting up to 20 days (Day -21 to -2) followed by a confinement period in the CTU of varying length according to their cohort. In Part 1, the maximum duration of participation, including the Screening period, will be approximately up to 30 days for participants in Cohorts 1 through 5, approximately 38 days for participants in Cohort 6 (to be confirmed once washout period of at least 5 half-lives is determined). In Part 2, the maximum duration of participation, including the Screening period, will be approximately up to 54 days for participants in Cohorts 1-3. The duration of cohorts may be adjusted (increased or decreased) based on emerging PK data collected during the trial.

3.1 Part 1 – SAD and Food Effect (SAD/FE)

In Part 1 of the trial (SAD/FE), five sequential cohorts will be enrolled to evaluate up to five escalating single doses of MK-7762; eight participants in each cohort will be randomized (3:1, excluding Cohort 1) to receive MK-7762 or placebo. The first two participants in Cohort 1 will be dosed as sentinel participants in a blinded manner,

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randomized 1:1 to MK-7762 or placebo. The safety review team (SRT) will review safety data up to Day 4 following dosing for these two sentinel participants. If recommended by the SRT and approved by the Sponsor, the remaining 6 participants in Cohort 1 will receive single doses of study drug (randomized 5:1; MK-7762:placebo). A sixth cohort will evaluate the effect of food on PK of single doses of MK-7762 utilizing an open-label, single-dose cross-over design in 8 participants. The MK-7762 dose to be evaluated in the FE cohort will be a dose demonstrated to be safe and well-tolerated in previously completed SAD cohorts. All participants in Part 1 will be confined at the CTU from Day -1 until their end-of-trial visit (approximately 8 days for Cohorts 1-5 and 16 days for Cohort 6). The exact duration of the confinement will be determined by the time required for an adequate washout period of at least five half-lives to be determined by PK results from the SAD cohorts. Randomization will occur prior to dosing on Day 1 for all cohorts.

Cohorts 1 through 4 will evaluate the safety and PK of single oral doses of MK-7762 of 50 mg, 150 mg, 300 mg, and 600 mg. Cohort 5 may evaluate a dose of MK-7762 that will be selected based on the safety and PK data from previous cohorts. The dose of MK-7762 chosen for evaluation in Cohort 5 will not result in greater predicted exposure than that allowable based on the nonclinical toxicology no observed adverse effect level (NOAEL).

For Cohort 6 (the FE Cohort), eight participants will be dosed with MK-7762 in both fasted and fed states. Two sentinel participants in Cohort 6 will be dosed in the fed state first followed by the second dose in the fasted state after washout. The SRT will review safety data up to Day 4 and PK data up to Day 2 for the two sentinel participants from the fed state dosing period. If recommended by the SRT and approved by the Sponsor, the remaining 6 participants in Cohort 6 will receive MK-7762 in fed and fasted states in a crossover manner employing the washout period previously determined. The remaining 6 participants will be randomized 1:1 to fed vs fasting in their first dosing period with crossover in their second dosing period following washout. The FE Cohort may start following review of 4 days of safety data from Cohort 4, and 48-hour PK data from Cohort 3. The FE Cohort may start before Cohort 5 if PK data from Cohorts 1-4 are sufficient for selecting the dose to be evaluated in the FE Cohort.

The doses of MK-7762 to be administered in the cohorts following Cohort 1 may be modified based on accumulating safety, tolerability, and PK data. The protocol may be amended to enroll additional participants at any of the planned dose level(s) or to study another dose level if the Sponsor determines that it is necessary based on emerging safety and PK data from previously completed cohorts.

If more than 1 participant from Cohort 6 is withdrawn from the trial after receiving the first dose but before receiving the second dose of study drug, additional participants will be enrolled to replace the withdrawn participants. No replacements are required if only one participant is withdrawn from Cohort 6 before receiving the second dose of study drug.

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Fasted Cohorts (Cohorts 1-5)

Dose administration for Cohorts 1-5 will occur after an 8-hour overnight fast on the morning of Day 1. Fasting will continue until 4 hours post-dose at which time a standardized meal will be provided. Clinical and safety laboratory assessments will be performed throughout the confinement period as per protocol schedule of assessments for Cohorts 1-5.

Participants administered MK-7762 in the fasted state will be dosed after an 8-hour overnight fast on the morning of Day 1. Participants administered MK-7762 in the fed state will be provided the standard US Food & Drug Administration (FDA) high fat breakfast, which should be consumed within 30 minutes or less, with MK-7762 administration occurring approximately 30 minutes after the start of the meal. In both the fed and fasted settings, fasting will resume for 4 hours post-dose, at which time, a standardized meal will be provided.

3.2 Interim Review of Data from Part 1

Following completion of Part 1, a comprehensive interim review of cumulative clinical and PK data will be conducted in an unblinded manner by the Sponsor to guide selection of appropriate doses to be evaluated in Part 2. Any additional relevant nonclinical data will also be reviewed as part of this process. The results of the interim review are intended for regulatory submission and comment prior to initiation of Part 2 of the trial.

The interim data analysis will be conducted by Celerion after the database from Part 1 has been locked and will include all Part 1 TFLs specified in this SAP.

3.3 Part 2 – MAD

In Part 2 (MAD) of the trial, participants will be enrolled into three sequential cohorts to evaluate escalating once daily doses of MK-7762 or placebo for 28 days. Each of the three MAD cohorts will have sixteen participants randomized 3:1 to receive MK-7762 or placebo. If more than two participants from a MAD cohort are withdrawn from the trial before the Day 29 visit assessments are completed, additional participants will be enrolled with blinded treatment assignment matching that of the withdrawn participants. No replacements are required if two or fewer participants are withdrawn before their Day 29 visits. All participants in Part 2 will be confined at the CTU from Day -1 until their end-of-trial visit (approximately 34 days [Day 33] for MAD Cohorts 1-3). Randomization will occur prior to dosing on Day 1 for all cohorts.

An additional MAD cohort may be considered for subsequent enrolment after protocol amendment to evaluate once daily doses of MK-7762 or placebo for 91 days based on findings from the planned 4-month sub-chronic toxicology studies in rats and dogs.

In Part 2, the dosing of study drug in relation to a meal will be dependent on review of PK data collected from participants in the FE Cohort (Cohort 6) in Part 1 of the trial.

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Clinical and safety laboratory assessments will be performed throughout the confinement period as per schedule of events for MAD Cohorts 1-3.

4. ANALYSIS POPULATIONS

Safety Population: All participants who received at least one dose of the study intervention (MK-7762 or placebo). Participants will be analyzed according to the intervention they received.

Per protocol (PP) Population: All participants who received at least one dose of the study intervention and did not significantly deviate from study procedures. Participants will be analyzed according to the intervention they received. If the Safety Population and the PP Population are the same, separate summaries will not be generated for the PP population.

5. TREATMENT DESCRIPTIONS

Associated Cohort	Short Description*
Part 1 – SAD and FE	
1-5	Pooled Placebo
1	50 mg Fasted
2	150 mg Fasted
3	300 mg Fasted
4	600 mg Fasted
5	TBD mg Fasted
6	TBD mg Fasted (C6)*
6	TBD mg Fed
1-6	All MK-7762 Fasted
1-6	All MK-7762^

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Associated Cohort	Short Description*
Part 2 - MAD	
1-3	Pooled Placebo QD
1	TBD mg QD
2	TBD mg QD
3	TBD mg QD
1-3	All MK-7762 QD

*In TFLs, short description may be abbreviated to remove fasting status or dosing regimen if the information is available in a sub-header. When a dose level is repeated across multiple cohorts, 'CX', where X is the cohort number, will be included in the treatment labels when needed in order to distinguish the cohort specific summaries. For summaries pooling the data for repeated dose levels, '(CX, CX)' will be added to the treatment labels.

^ Due to the crossover design of Cohort 6, this pooled summary will only be included in the AE summaries.
TBD = To be determined

Note: In the event that the dose level selected for the food effect cohort is the same as that of a previous SAD cohort, Cohort 6 fasted data will be summarized separately from the corresponding SAD data. An additional pooled summary will be provided.

6. SAFETY

All relevant safety case report form (CRF) data will be listed by part, participant and chronologically by assessment time point. This will include rechecks, unscheduled, and early termination assessments. Time points will be presented in the listings as recorded in the CRF. Data from screen failure participants will be listed separately and will not be summarized.

Listings, summaries, and figures will be provided separately by part. Applicable continuous variables will be summarized using sample size (n), mean, standard deviation (SD), minimum, median, and maximum. Data from participants who received the placebo treatment will be pooled across cohorts in each part. Unless otherwise specified, summaries provided by treatment will include all treatments defined in [Section 5](#), including pooled treatments.

The level of precision will be presented as follows: minimum, maximum, mean, median, and SD will be rounded to one decimal place unless otherwise specified. If the data is recorded in integers in the database, minimum and maximum will be presented in integers. For a specific parameter, if the first significant digit of its values is further than the second decimal place for over 50% of the participants, then the rounding of the summary statistics may be adjusted accordingly. Number of observations (n) will be presented as an integer. Percentages will be

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presented as an integer. Confidence intervals, when applicable, will be presented to 2 decimal places.

Where individual data points are missing because of dropouts or other reasons (i.e., missing clinical laboratory blood draw), the data will be summarized based on reduced denominators.

For Cohorts 1 through 5 of Part 1, baseline will be the result closest and prior to dosing. For Cohort 6 of Part 1, baseline will be the result closest and prior to dosing in the respective period. For Part 2 cohorts, baseline will be the result closest and prior to the first dose. Summaries for post-baseline time points will not include rechecks, unscheduled, or early termination measurements.

Tables summarizing safety data by assessment time point will only include summaries for baseline and post-baseline time points. Specifically, for Part 1, the planned visit schedules will cover the time period from pre-dose on Day 1 to Day 7 for Cohort 1-5, and Day 7 of each dosing period (fed or fasted) for Cohort 6 (FE Cohort). For Part 2, the planned visit schedules will cover the time period from pre-dose on Day 1 to Day 33 for Cohort 1-3. Safety summaries will be inclusive of all participants in the safety population, unless otherwise specified.

No inferential statistics will be performed on safety endpoints.

6.1 Participant Disposition

Participants will be summarized by the number and percent of participants dosed, completed the trial, discontinued treatment (with discontinuation reasons), and discontinued the trial (with discontinuation reasons). If withdrawn participants are replaced, this will also be summarized. Disposition summaries will be provided as follows:

- by treatment (individual dose levels) for Part 1, SAD cohorts
- by treatment sequence (Fast/Fed, Fed/Fast) for Part 1, FE cohort
- Overall for Part 1
- by treatment (individual dose levels) and overall for Part 2, MAD cohorts

For the FE cohort, individual participant dosing status (i.e., which treatments were administered to each participant) will also be provided along with their trial completion status and date of trial completion or discontinuation. The number of participants dosed for each treatment in the FE cohort will also be presented.

6.2 Protocol Deviations

Protocol deviations will be recorded and documented in Celerion's Veeva SiteVault. Once the deviations have been finalized, a MS Excel file with all deviations will be imported into SDTM and a SAS generated listing of the deviations will be provided. Prior to Part 2

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database lock, discussions will occur between Celerion and Bill & Melinda Research Medical Institute to determine participant's inclusion in the Per Protocol Population.

6.3 Demographics

Descriptive statistics will be calculated for continuous variables (age, body mass index, height, and weight). Age for participants in the safety population will be approximated by subtracting the date of birth (day is not collected so the first day of the month will be used) from the date of informed consent. If calculated difference is one more than the protocol maximum age then the age approximation will be the calculated difference – 1. Descriptive statistics for body mass index, height, and weight will be calculated using screening measurements.

Frequency counts will be provided for categorical variables (sex, race, and ethnicity).

Demographic summaries will be provided as follows:

- by treatment (individual dose levels) for Part 1, SAD cohorts
- by treatment sequence (Fast/Fed, Fed/Fast) for Part 1, FE cohort
- Overall for Part 1
- by treatment (individual dose levels) and overall for Part 2, MAD cohorts

6.4 Adverse Events

All adverse events (AEs) occurring during this clinical trial will be coded using the Medical Dictionary for Regulatory Activities (MedDRA[®]), Version 26.0.

All AEs captured in the database will be listed in a by-participant data listing including verbatim term, coded term, treatment, onset date/time, resolution date/time, frequency, severity grade (documented by the Investigator in the CRF using protocol section 10.2.7.1. as a guide), relationship to study product, AESI flag, and action; however, only TEAEs will be summarized (as per analysis window below). Events considered as AESIs for this trial are defined in the protocol and will be flagged accordingly in the CRF.

A TEAE is defined as an AE that is starting at the time of or after first study drug administration. Each TEAE will be attributed to a treatment based on the onset date and time of the AE compared to that of the respective treatment administration date and time. For the FE cohort, an AE that occurs during the washout period between treatments will be considered treatment-emergent to the last treatment administered prior to onset of the AE.

If the onset time of an AE is missing and the onset date is the same as or occurs after the treatment dosing date, then the AE will be considered treatment emergent. If the onset date of an AE is missing, then the AE will be considered treatment emergent.

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For the FE cohort, if the onset time of an AE is missing and the onset date is the same as the treatment dosing date, then the AE will be considered treatment emergent in the prior and current treatment. If the onset time of an AE is missing and the onset date does not fall on a treatment dosing date, then the AE will be considered treatment emergent for the last treatment administered. If the onset date of an AE is missing, then the AE will be considered treatment emergent and attributed to each treatment, unless the onset date is known to have occurred within or between specific treatment periods.

TEAEs, serious adverse events (SAEs), TEAEs leading to study drug discontinuation, and AESIs will be tabulated by System Organ Class (SOC) and Preferred Term. In Part 2, a subset of visual acuity decreased and color vision change related TEAEs will also be summarized similarly. Visual acuity decreased and color vision change related TEAEs will be flagged programmatically by narrowing preferred terms falling under the following MedDRA® Standardized MedDRA Queries (SMQ):

- Retinal Disorders
- Lens Disorders
- Optic Nerve Disorder

All summaries will be provided by treatment. The following summaries will be provided:

- Number and percentage of participants reporting TEAE (overall and by maximum grade of severity)
- Number and percentage of participants reporting drug-related TEAE (overall and by maximum grade of severity)
- Number of TEAEs by grade of severity and relationship to study drug
- Number and percentage of participants reporting SAE (overall and by maximum grade of severity)
- Number and percentage of participants reporting drug-related SAE (overall and by maximum grade of severity)
- Number and percentage of participants reporting a TEAE leading to discontinuation of study drug (overall and by maximum grade of severity)
- Number and percentage of participants reporting drug-related TEAE leading to discontinuation of study drug (overall and by maximum grade of severity)
- Number and percentage of participants reporting AESI (overall and by maximum grade of severity)

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- Number and percentage of participants reporting drug-related AESI (overall and by maximum grade of severity)
- Number and percentage of participants reporting visual acuity decreased or color vision change related TEAE (overall and by maximum grade of severity) (Part 2 only)
- Number and percentage of participants reporting drug-related visual acuity decreased or color vision change related TEAE (overall and by maximum grade of severity) (Part 2 only)

All Part 2 AE summaries listed above will be performed on the Per Protocol Population in addition to the Safety Population.

SAEs (if present) and AESIs will also be listed separately in tables. Applicable narratives will be included in the CSR.

For Part 2, the time to resolution of ongoing neurologic or hematologic AESIs at the time of treatment discontinuation will be evaluated using the Kaplan-Meier product limit method. The Kaplan-Meier analysis of time to AE resolution will only be performed if there are more than 5 participants with ongoing neurologic or hematologic AESIs at the time of treatment discontinuation. If there are less than 5 participants with ongoing events, only a listing of time to AE resolution and outcome for ongoing neurologic and hematologic AESIs will be provided.

Time to AE resolution will be calculated as the difference between the date of treatment discontinuation and the AE resolution date and will be reported as an integer in days. Time of AE resolution will not be considered in the computation of time to resolution. Unresolved AEs will be censored at the last AE assessment date. Neurologic and hematologic AESIs will be programmatically flagged using the following search criteria:

- CRF AESI flag = Yes and
- Preferred terms fall into either of the following MedDRA[®] SMQs: Peripheral neuropathy, Haematopoietic erythropenia, Haematopoietic leukopenia, Agranulocytosis, Drug reaction with eosinophilia and systemic symptoms syndrome, Haematopoietic thrombocytopenia, Optic nerve disorders, Demyelination, Ocular infections, Immune-mediated/autoimmune disorders

An ongoing neurologic or hematologic AESI at the time of treatment discontinuation will meet the following criteria:

- Participant treatment discontinuation is marked as Yes on the CRF Study Drug Discontinuation page and

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- CRF Outcome = Resolved, AE onset date is less than date of treatment discontinuation and AE resolution date is greater than date of treatment discontinuation (on Study Drug Discontinuation page of the CRF), or
- CRF Outcome = Not resolved/Not recovering or Resolving/Recovering and AE resolution date is missing

Time to resolution will be summarized descriptively by treatment for the participants with at least one ongoing neurologic or hematologic AESIs at the time of treatment discontinuation. For each treatment, the Kaplan-Meier curves will be displayed in a figure with median time (product-limit median estimate) to resolution and the corresponding two-sided 95% confidence intervals based on Brookmeyer and Crowley ([Brookmeyer, 1982](#)). Participants with unresolved AESIs will be right-censored on the date of last AE assessment (i.e., date of last assessment in the database). The number of participants censored will be presented. For participants with multiple ongoing neurologic or hematologic AESI, the worst (longest) time to resolution will be used in the summaries.

The following SAS® code will be used where T is the time to resolution and STATUS is the censoring variable with value of 0 indicates uncensored (i.e., AE resolved) and 1 indicating censored (i.e., AE ongoing) observations:

```
PROC LIFETEST ALPHAQT=0.05;  
TIME T*STATUS(1);  
STRATA TREATMENT;  
RUN;
```

The proportion of participants with neurologic or hematologic AESI resolution within 5 days of treatment discontinuation will be presented.

For the purpose of the analysis of time to resolution, missing treatment discontinuation dates will be set to the date of last dose received. The following imputations rules will be used for AE resolution dates:

Missing Element	Rule
day, month, and year	<ul style="list-style-type: none">• For completely missing resolution dates (incl. ongoing events), time to AE resolution will be calculated to the date of last AE assessment and censored. Date of last AE assessment will be determined as the date of last assessment recorded in the database. This date is derived in SDTM.
day, month	<ul style="list-style-type: none">• If partial resolution date contains year only, set resolution date = earliest of 31DecYYYY or date of last AE assessment
Day	<ul style="list-style-type: none">• If partial end date contains month and year, set resolution date = earliest of last day of the month or date of last AE assessment

Note: Partial or missing dates will be displayed as such in the listings. Imputed dates will only be used for the purpose of the analysis.

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6.5 Clinical Laboratory Tests (Chemistry, Hematology, Coagulation, Urinalysis)

Clinical laboratory tests (chemistry, hematology, coagulation, and urinalysis) will be measured as per protocol schedule of events.

Clinical laboratory results will be presented as extracted from the clinical laboratory database. Out-of-reference range flags will be recorded as follows: high (H) and low (L) for numerical results and did-not-match (*) for categorical results.

Out-of-reference range values and corresponding recheck results will be listed.

In addition, Division of Acquired Immunodeficiency Disease (DAIDS) toxicity grade, Version 2.1 will be used to grade laboratory values. The DAIDS grading will be applied to all the numeric results with the ranges found in the DAIDS guidance. The resulting flag of DAIDS grade, e.g., G1, will be placed along with the out-of-reference range flags.

For all numeric laboratory values, descriptive statistics will be presented for each laboratory test by assessment time point. Change from baseline will be summarized in a similar manner. For all numeric laboratory tests, the mean value calculated for each assessment time point and treatment will be compared to the reference range and flagged if outside of the reference range (* if above the reference range and ^ if below the reference range). In the event there is more than one reference range for a laboratory test, the comparison will be made against the lowest of the lower ranges and the highest of the higher ranges. In the event that multiple assessments meet the baseline definition, the result from the in-house clinical laboratory will be prioritized for better comparability to other time points and participants.

For each laboratory test and time point, a shift table will be developed to compare the frequency of the results at baseline (using DAIDS grades for graded tests or categories above reference range, within reference range, or below reference range for non-graded tests) with the respective postdose results. For urinalysis tests, the categories are within reference range and outside reference range for non-graded tests.

All summaries will be provided by treatment.

In each trial part, the following binary classifications with respect to platelet count, absolute neutrophil count (ANC), white blood cell (WBC) count, reticulocyte count, red blood cell (RBC) count, and hemoglobin result will be considered:

- a. Post-baseline result that is < lower limit of normal (LLN) (yes/no)
- b. Post-baseline result that is < 50% of LLN (yes/no)
- c. Post-baseline result that is $\geq 20\%$ decrease relative to baseline (yes/no)
- d. Post-baseline result that is $\geq 50\%$ decrease relative to baseline (yes/no)

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Specifically, the following summaries will be provided by assessment time point (and overall as applicable) for each treatment using the Safety Population (Parts 1 and 2) and the Per Protocol Population (Part 2 only):

- For each of (a) through (d), the proportion (number and percentage) of participants who meet the criterion will be tabulated. An overall time point summary will also be provided showing the proportion of participants meeting the abnormality criterion at any post-baseline time point.

Note: Percent change from baseline will be calculated as $100 \times (\text{post-baseline value} - \text{baseline value}) / \text{baseline value}$.

In each trial part, boxplots will also be provided for platelet count, ANC, WBC count, reticulocyte count, RBC count, and hemoglobin result.

In each trial part, evaluation of Drug-Induced Serious Hepatotoxicity (eDISH) plots for alanine aminotransferase (ALT) and aspartate aminotransferase (AST) will be generated to assess the liver safety of the study intervention. Specifically, scatter plots displaying peak AST or ALT versus peak total bilirubin (TBL) at post-baseline for each participant will be provided. The following steps will be followed in order to generate the eDISH plots:

- For each participant and time point, take the ratio of “Observed value/Upper Limit of Normal [ULN]” for ALT/AST and TBL
- Get the maximum ratio value for ALT/AST and TBL per participant
- Produce scatter plot to have y-axis = TBL/ULN values and x-axis = ALT/ULN or AST/ULN values
- Draw reference lines on this plot to divide data into 4 quadrants with y-axis reference line at 2 x ULN and x-axis reference line at 3 x ULN

6.6 Vital Signs

Vital signs (blood pressure, heart rate, and temperature) will be measured as per protocol schedule of events.

All vital signs data will be listed and descriptive statistics will be presented vital signs measurements by assessment time point and treatment. Change from baseline will be summarized in a similar manner. Blood pressure and heart rate only will be summarized for Part 1. Blood pressure, heart rate, and temperature will be summarized for Part 2.

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The number and percentage of participants experiencing abnormal post-baseline blood pressure results (as per categories defined below) will be provided by assessment time point and treatment. The categories of interest are as follows:

Vital Sign (unit)	Abnormality Categories
Systolic Blood Pressure (mmHg)	140 - < 160 ≥ 160 - < 180 ≥ 180
Diastolic Blood Pressure (mmHg)	90 - < 100 ≥ 100 - < 110 ≥ 110

Vital signs abnormalities reported as AEs will be graded in severity as per protocol and will be summarized along with the TEAEs.

6.7 Electrocardiogram

Twelve-lead safety ECGs (QTcF, QT, QRS, RR, PR, HR) will be measured as per protocol schedule of events.

ECGs will be collected in triplicate. The triplicate measures will be averaged and rounded to the nearest tenth. The averages will be used in all summaries. For summaries of investigator ECG interpretation (normal; abnormal not clinically significant; abnormal clinically significant), the worst result of the triplicate at each triplicate time point will be used in the analysis.

Only valid ECGs will be used to calculate average ECG values for each parameter that will be used in the analysis. Valid ECGs do not include records of questionable quality. These include, but are not limited to, records with an associated comment indicating an artifact, lead reversal, wandering lead, etc. ECGs collected in error will also not be classified as valid ECGs. After excluding these ECGs, the remaining ECGs for the respective triplicate set will be assessed against a time window of 10 minutes. A triplicate ECG set is expected to be performed within a 5-minute window but a 10-minute window is selected to increase the likelihood of having a full triplicate ECG set for the calculation of the average ECG value; the specific time window will be defined in the protocol. ECGs that fall outside of the 10-minute window will not be considered valid ECGs. At a given time point, if it is not possible to form a complete ECG triplicate set of valid results, the average will be calculated using the available valid results, i.e., the average of 2 valid ECGs or the single valid ECG result will be used in the analysis. Averaged ECG values will be displayed to the nearest tenth and used in the analysis.

Descriptive statistics will be presented for the averages of triplicates of each ECG parameter by assessment time point and treatment. Change from baseline will be summarized in a similar manner. Baseline is defined as the average of the valid ECG set closest and prior to

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dosing (or first dosing, or dosing in the respective period, as applicable) which may include unscheduled assessments. At post-baseline time points, the average of the first valid ECG set will be used in the analysis. Post-baseline unscheduled and early termination measurements will not be included in summaries.

The number and percentage of participants with Normal, Abnormal not clinically significant, and Abnormal clinically significant ECGs will be presented by assessment time point and treatment.

All ECG data will be listed by participant and QTcF values > 450 msec will be flagged. A separate by participant listing will be provided to display the ECG average values to be used during analysis where QTcF average values > 450 msec and increase from baseline > 30 msec will be flagged.

ECG abnormalities reported as AEs will be graded in severity as per protocol and will be summarized along with the TEAEs.

6.8 Prior and Concomitant Medications

Prior and concomitant medications recorded during the trial will be coded with the World Health Organization (WHO) Drug Dictionary Version 01-Mar-2023 b3 and listed.

6.9 Physical Examination

Abnormal physical examination findings will be reported as medical history or AEs. All data found in the CRF will be listed.

6.10 Medical History

All medical history will be coded using MedDRA®, Version 26.0 and listed.

6.11 Ophthalmologic Assessments

A visual assessment (visual acuity and color vision) will be conducted during the treatment period for Part 2 participants per protocol schedule of assessments to assess for possible signs of optic neuropathy toxicity from repeat dosing. Visual acuity will be assessed on each eye separately by means of a Snellen chart and Rosenbaum pocket chart. Color vision will be assessed on each eye separately using the Ishihara color plates. An overall assessment (normal/abnormal) will also be provided for each test (i.e, Snellen, Rosembaum, and by eye for Ishihara).

All visual assessment results collected on the CRF will be listed by part, participant, and assessment time point. Visual assessment data will be summarized for Part 2 only. Summaries will be provided for the Per Protocol Population in addition to the Safety Population.

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For each visual acuity test (Snellen and Rosembaum) and eye, a shift table will be developed to compare the frequency of the results at baseline compared to the worst post-baseline score. For the purpose of this analysis, Snellen and Rosembaum scores will be categorized as follows:

- 0 = Normal (20/25 or better)
- 1 = Worse than 20/25 but better than or equals to 20/40
- 2 = Worse than 20/40 but better than or equals to 20/200
- 3 = Worse than 20/200

For each visual acuity test (Snellen and Rosembaum), the number and percentage of participants with a post-baseline visual acuity score worse than 20/25 in either eye at each time point and overall (i.e., at least once across post-baseline time points) will be provided by treatment. A score worse than 20/25 in either eye is equivalent to an abnormal overall assessment on the CRF, therefore the CRF overall assessment will be used for this analysis.

For color vision, the number and percentage of participants with a post-baseline color vision abnormality in either eye at each time point and overall (i.e., at least once across post-baseline time points) will be provided by treatment. The CRF overall assessment will be used to conduct this analysis. At each time point, participants will be counted if they experience an abnormal result in the right or left eye.

Abnormalities of vision reported as AEs will be graded in severity as per protocol and will be summarized along with the TEAEs. The proportion of participants experiencing an eye symptom in either eye will be assessed in the TEAE summaries under the 'Eye Disorders' system organ class.

Separate TEAE summaries by severity grades will be provided for visual acuity decreased and color vision change related TEAEs as described in [Section 6.4](#).

6.12 Brief Peripheral Neuropathy Screen (BPNS)

Peripheral sensory neuropathy screening will be conducted using the BPNS test during the treatment period for Part 2 participants per protocol schedule of assessments to assess for signs of peripheral neuropathy toxicity from repeat dosing. The non-invasive BPNS test combines questions regarding neuropathic symptoms in the feet and lower legs with objective testing of ankle reflexes and vibration sensation in the big toes. Specifically, the following neuropathic symptoms will be assessed on each lower extremity (i.e., right and left):

- Pain, Aching, or Burning
- Pins and Needles
- Numbness (lack of feeling)

Each symptom will be scored on a 01 to 10 scale where 01 = Mild and 10 = Severe. An overall subjective peripheral grade (defined as the highest score of the individual symptoms)

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is also available on the CRF. This CRF overall grade will be listed but will not be used in the analysis.

Objective testing of vibration sensation in the big toe (right and left) will be recorded on the following scale:

- 0 = Vibration Felt For Greater Than 10 Seconds [Normal]
- 1 = Vibrations Felt For 6-10 Seconds [Mild Loss]
- 2 = Vibrations Felt For 5 Seconds Or Less [Moderate Loss]
- 3 = No Feeling Of Vibrations [Severe Loss]

Objective testing of tendon reflexes (right and left) will be recorded on the following scale:

- 0 = Absent
- 1 = Hypoactive
- 2 = Normal Deep Tendon Reflexes
- 3 = Hyperactive Deep Tendon Reflexes, e.g With Prominent Spread
- 4 = Clonus

All BPNS results recorded on the CRF will be listed by part, participant, and assessment time point. BPNS results will be summarized for Part 2 only. Summaries will be provided for the Per Protocol Population in addition to the Safety Population.

For each treatment, the following summaries will be provided by time point and overall:

- The number and percentage of participants with a reported new post-baseline peripheral neuropathy symptom (defined as a score within 01-10) in either extremity on BPNS will be provided. This summary will be provided by symptom and overall (i.e, any symptoms). For participants meeting the criteria, frequency counts of the post-baseline grade will be provided using the following grading classifications:
 - Grade of 1 = Score 01-03
 - Grade of 2 = Score 04-06
 - Grade of 3 = Score 07-10

The worst grade across extremities or over all time points (for overall time point summary) will be used for summaries.

- For each objective testing (vibration in big toes or tendon reflexes) and overall, the number and percentage of participants with a reported new post-baseline peripheral objective physical finding (defined as scores within 1-3 for vibration or scores of 1-4 for tendon reflexes) in either extremity on BPNS will be provided. For summaries by objective testing, frequency counts of the post-baseline results for participants with at least one reported new post-baseline objective physical finding will also be included. The worst score across extremities or over all time points (for overall time point summary) will be used for summaries.

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- The number and percentage of participants with new post-baseline peripheral neuropathy symptom and at least one objective physical finding on BPNS will be provided.

A reported new (treatment-emergent) post-baseline event is an event that is worse than the baseline value. The comparison to baseline will take into consideration the extremity side – e.g., if a participant presents a baseline abnormality on the left leg and develops a new or worsening post-baseline abnormality on the right leg, it will be considered treatment-emergent.

7. SUMMARY OF CHANGES FROM PROTOCOL-PLANNED ANALYSIS

The protocol outlined that descriptive statistics would be provided for participants who met specific criteria for platelet count, ANC, WBC count, reticulocyte count, RBC count, and hemoglobin. During generation of the SAP, it was determined that the tabulation of results meeting these criteria would be sufficient and the descriptive statistics for the specific values meeting these criteria would not be calculated.

All other analyses described in this SAP are aligned with those analyses described in the protocol.

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8. REFERENCES

Brookmeyer R, Crowley J. A confidence interval for the median survival time. Biometrics 1982;38:29-41.

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SAFETY SHELLS

A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose and Multiple Ascending Dose Trial in Healthy Adult Participants to Evaluate the Safety, Tolerability, and Pharmacokinetics of MK-7762 with an Open Label (Single Dose) Food Effect Panel

Protocol No: Gates MRI-TBD09-101
Final Protocol Date: 27 September 2022
Amendment No. 1 Date: 19 December 2022
Amendment No. 2: 04 April 2023
Compound Name: MK-7762

Celerion Project CA35747
Final Version 1.0
Date: 02 June 2023

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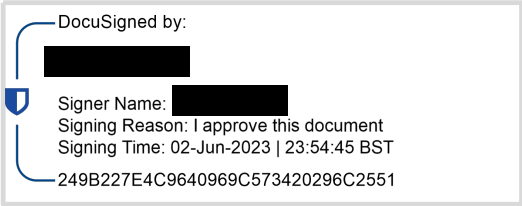
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Compound Name: MK-7762

Protocol: Gates MRI-TBD09-101

Study Title: A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose and Multiple Ascending Dose Trial in Healthy Adult Participants to Evaluate the Safety, Tolerability, and Pharmacokinetics of MK-7762 with an Open Label (Single Dose) Food Effect Panel

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[Redacted]
Signer Name: [Redacted]
Signing Reason: I approve this document
Signing Time: 02-Jun-2023 | 23:54:45 BST
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Date: _____

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Senior Biostatistician II, Data Management and Biometrics
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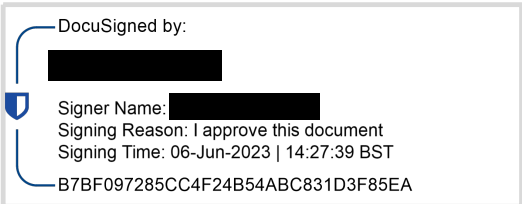
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Protocol: Gates MRI-TBD09-101

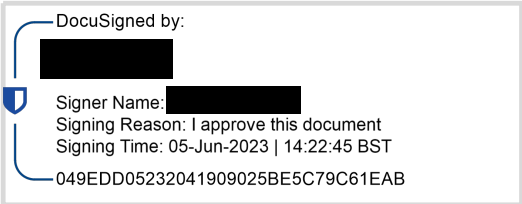
Study Title: A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose and Multiple Ascending Dose Trial in Healthy Adult Participants to Evaluate the Safety, Tolerability, and Pharmacokinetics of MK-7762 with an Open Label (Single Dose) Food Effect Panel

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Portfolio Statistics Leader
Gates Medical Research Institute

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Signer Name: [Redacted]
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[Redacted], M.D. MSc
Clinical Development Leader
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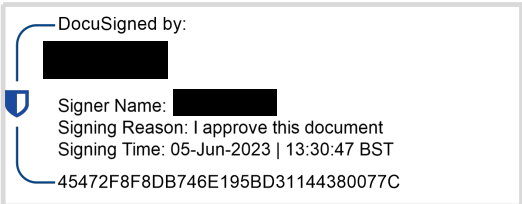
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Protocol: Gates MRI-TBD09-101

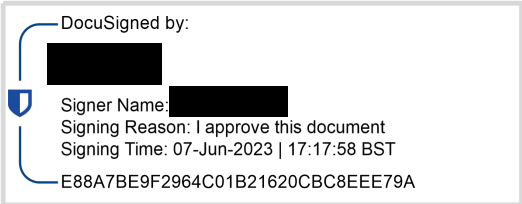
Study Title: A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Single Ascending Dose and Multiple Ascending Dose Trial in Healthy Adult Participants to Evaluate the Safety, Tolerability, and Pharmacokinetics of MK-7762 with an Open Label (Single Dose) Food Effect Panel

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Date: _____

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[Redacted], MD
Head of Therapeutics Development
Gates Medical Research Institute

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1. SUMMARY TABLES, FIGURES, AND LISTINGS

Summary tables and figures are numbered following the International Council on Harmonization (ICH) structure but may be renumbered as appropriate during the compilation of the tables and figures for the CSR. Note that all safety summary tables and figures will be generated using SAS® Version 9.4 or higher, as appropriate.

In-text tables and figures will be generated as RTF and all other tables and listings will be generated as SAS® LST format and converted to MS Word for inclusion in the CSR. In compliance with Celerion SOP/PG, SAS® outputs will not be manually edited.

1.1 In-text Summary Tables and Figures

The following is a list of table and figure titles that will be included in the text of the CSR. Tables and figures will be numbered appropriately during compilation of the CSR.

Section 10:

Number	Title	Shell
Table 10-1	Disposition Summary – Part 1 (Safety Population)	IDS
Table 10-2	Disposition Summary – Part 2 (Safety Population)	IDS

Section 11:

Number	Title	Shell
Table 11-1	Demographic Summary – Part 1 (Safety Population)	IDEM
Table 11-2	Demographic Summary – Part 2 (Safety Population)	IDEM

Section 12:

Number	Title	Shell
Table 12-1	Treatment-Emergent Adverse Event Frequency by Treatment - Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)	IAES
Table 12-2	Treatment-Emergent Adverse Event Frequency by Treatment - Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Safety Population)	IAES

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1.2 Section 14 Summary Tables and Figures

The following is a list of table and figure titles that will be included in Section 14 of the report. Table and figure titles may be renumbered as appropriate during the compilation of the report.

Note: Per Protocol Population summaries will only be generated if the population differs from the Safety Population.

14.1 Demographic Data Summary Tables

Number	Title	Shell
Table 14.1.1.1	Disposition Summary – Part 1 (Safety Population)	CDS
Table 14.1.1.2	Participant Dosing Status and Trial Disposition – Part 1, FE (Safety Population)	SDS
Table 14.1.1.3	Demographic Summary – Part 1 (Safety Population)	CDEM
Table 14.1.2.1	Disposition Summary – Part 2 (Safety Population)	CDS
Table 14.1.2.2	Demographic Summary – Part 2 (Safety Population)	CDEM

14.2 Pharmacokinetic Data Summary Tables and Figures

Not applicable.

14.3 Safety Data Summary Tables

14.3.1 Displays of Adverse Events

Number	Title	Shell
Part 1		
Table 14.3.1.1.1	Treatment-Emergent Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)	CAES
Table 14.3.1.1.2	Treatment-Emergent Study Drug Related Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)	CAES
Table 14.3.1.1.3	Treatment-Emergent Adverse Event Frequency by Treatment, Severity, and Relationship to Study Drug – Number of Adverse Events – Part 1 (Safety Population)	CAESR

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Number	Title	Shell
Table 14.3.1.1.4	Treatment-Emergent Serious Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)	CAES
Table 14.3.1.1.5	Treatment-Emergent Study Drug Related Serious Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)	CAES
Table 14.3.1.1.6	Treatment-Emergent Adverse Event Leading to Drug Discontinuation Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)	CAES
Table 14.3.1.1.7	Treatment-Emergent Study Drug Related Adverse Event Leading to Drug Discontinuation Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)	CAES
Table 14.3.1.1.8	Treatment-Emergent Adverse Event of Special Interest Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)	CAES
Table 14.3.1.1.9	Treatment-Emergent Study Drug Related Adverse Event of Special Interest Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)	CAES
Part 2		
Table 14.3.1.2.1	Treatment-Emergent Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Safety Population)	CAES
Table 14.3.1.2.2	Treatment-Emergent Study Drug Related Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Safety Population)	CAES
Table 14.3.1.2.3	Treatment-Emergent Adverse Event Frequency by Treatment, Severity, and Relationship to Study Drug – Number of Adverse Events – Part 2 (Safety Population)	CAESR

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Number	Title	Shell
Table 14.3.1.2.4	Treatment-Emergent Serious Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Safety Population)	CAES
Table 14.3.1.2.5	Treatment-Emergent Study Drug Related Serious Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Safety Population)	CAES
Table 14.3.1.2.6	Treatment-Emergent Adverse Event Leading to Drug Discontinuation Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Safety Population)	CAES
Table 14.3.1.2.7	Treatment-Emergent Study Drug Related Adverse Event Leading to Drug Discontinuation Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Safety Population)	CAES
Table 14.3.1.2.8	Treatment-Emergent Adverse Event of Special Interest Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Safety Population)	CAES
Table 14.3.1.2.9	Treatment-Emergent Study Drug Related Adverse Event of Special Interest Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Safety Population)	CAES
Table 14.3.1.2.10	Treatment-Emergent Visual Acuity and Color Vision Adverse Event (Subset of TEAEs) Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Safety Population) <i>Note: This table will include visual acuity and color vision TEAEs programmatically flagged from all TEAEs as per Section 6.4 of the SAP.</i>	CAES

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Number	Title	Shell
Table 14.3.1.2.11	Treatment-Emergent Study Drug Related Visual Acuity and Color Vision Adverse Event (Subset of TEAEs) Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Safety Population) <i>Note: This table will include visual acuity and color vision TEAEs programmatically flagged from all TEAEs as per Section 6.4 of the SAP.</i>	CAES
Table 14.3.1.2.12	Summary of Time to Adverse Event Resolution in Participants With Ongoing Neurologic or Hematologic Adverse Event of Special Interest at Time of Treatment Discontinuation – Part 2 (Safety Population)	CAEKM
Table 14.3.1.2.13	Treatment-Emergent Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Per Protocol Population)	CAES
Table 14.3.1.2.14	Treatment-Emergent Study Drug Related Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Per Protocol Population)	CAES
Table 14.3.1.2.15	Treatment-Emergent Adverse Event Frequency by Treatment, Severity, and Relationship to Study Drug – Number of Adverse Events – Part 2 (Per Protocol Population)	CAESR
Table 14.3.1.2.16	Treatment-Emergent Serious Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Per Protocol Population)	CAES
Table 14.3.1.2.17	Treatment-Emergent Study Drug Related Serious Adverse Event Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Per Protocol Population)	CAES
Table 14.3.1.2.18	Treatment-Emergent Adverse Event Leading to Drug Discontinuation Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Per Protocol Population)	CAES

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Number	Title	Shell
Table 14.3.1.2.19	Treatment-Emergent Study Drug Related Adverse Event Leading to Drug Discontinuation Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Per Protocol Population)	CAES
Table 14.3.1.2.20	Treatment-Emergent Adverse Event of Special Interest Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Per Protocol Population)	CAES
Table 14.3.1.2.21	Treatment-Emergent Study Drug Related Adverse Event of Special Interest Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Per Protocol Population)	CAES
Table 14.3.1.2.22	Treatment-Emergent Visual Acuity and Color Vision Adverse Event (Subset of TEAEs) Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Per Protocol Population) <i>Note: This table will include visual acuity and color vision TEAEs programmatically flagged from all TEAEs as per Section 6.4 of the SAP.</i>	CAES
Table 14.3.1.2.23	Treatment-Emergent Study Drug Related Visual Acuity and Color Vision Adverse Event (Subset of TEAEs) Frequency by Treatment and Severity – Number of Participants Reporting the Event (% of Participants Dosed) – Part 2 (Per Protocol Population) <i>Note: This table will include visual acuity and color vision TEAEs programmatically flagged from all TEAEs as per Section 6.4 of the SAP.</i>	CAES
Table 14.3.1.2.24	Summary of Time to Adverse Event Resolution in Participants With Ongoing Neurologic or Hematologic Adverse Event of Special Interest at Time of Treatment Discontinuation – Part 2 (Per Protocol Population)	CAEKM

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14.3.2 Listings of Deaths, other Serious and Significant Adverse Events

Number	Title	Shell
Table 14.3.2.1.1	Serious Adverse Events – Part 1 (Safety Population)	16.2.7
Table 14.3.2.1.2	Adverse Events of Special Interest – Part 1 (Safety Population)	16.2.7
Table 14.3.2.2.1	Serious Adverse Events – Part 2 (Safety Population)	16.2.7
Table 14.3.2.2.2	Adverse Events of Special Interest – Part 2 (Safety Population)	16.2.7

14.3.3 Narratives of Deaths, other Serious and Certain other Significant Adverse Events

14.3.4 Abnormal Laboratory Value Listing (each participant)

Number	Title	Shell
Part 1		
Table 14.3.4.1.1	Out-of-Range Values and Recheck Results – Chemistry – Part 1 (Safety Population)	CLBO
Table 14.3.4.1.2	Out-of-Range Values and Recheck Results – Hematology – Part 1 (Safety Population)	
Table 14.3.4.1.3	Out-of-Range Values and Recheck Results – Coagulation – Part 1 (Safety Population)	
Table 14.3.4.1.4	Out-of-Range Values and Recheck Results – Urinalysis – Part 1 (Safety Population)	
Part 2		
Table 14.3.4.2.1	Out-of-Range Values and Recheck Results – Chemistry – Part 2 (Safety Population)	
Table 14.3.4.2.2	Out-of-Range Values and Recheck Results – Hematology – Part 2 (Safety Population)	
Table 14.3.4.2.3	Out-of-Range Values and Recheck Results – Coagulation – Part 2 (Safety Population)	
Table 14.3.4.2.4	Out-of-Range Values and Recheck Results – Urinalysis – Part 2 (Safety Population)	

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14.3.5 Displays of Other Laboratory, Vital Signs, Electrocardiogram, Physical Examination, and Other Safety Data

Number	Title	Shell
Part 1		
Table 14.3.5.1.1	Clinical Laboratory Summary and Change From Baseline – Chemistry – Part 1 (Safety Population)	CLBD
Table 14.3.5.1.2.1	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Pooled Placebo – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.2.2	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Single Dose <i>50 mg</i> MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.2.3	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Single Dose <i>150 mg</i> MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.2.4	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Single Dose <i>300 mg</i> MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.2.5	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Single Dose <i>600 mg</i> MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.2.6	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Single Dose <i>TBD mg</i> MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.2.7	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Single Dose <i>TBD mg</i> MK-7762 Fasted (Cohort 6) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.2.8	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Single Dose <i>TBD mg</i> MK-7762 Fed (Cohort 6) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.2.9	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Single Dose MK-7762 Fasted (All Cohorts) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.3	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Chemistry – Part 1 (Safety Population)	CLBS

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Number	Title	Shell
Table 14.3.5.1.4	Clinical Laboratory Summary and Change From Baseline – Hematology – Part 1 (Safety Population)	CLBD
Table 14.3.5.1.5.1	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Pooled Placebo – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.5.2	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Single Dose 50 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.5.3	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Single Dose 150 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.5.4	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Single Dose 300 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.5.5	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Single Dose 600 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.5.6	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Single Dose TBD mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.5.7	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Single Dose TBD mg MK-7762 Fasted (Cohort 6) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.5.8	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Single Dose TBD mg MK-7762 Fed (Cohort 6) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.5.9	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Single Dose MK-7762 Fasted (All Cohorts) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.6	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Hematology – Part 1 (Safety Population)	CLBS
Table 14.3.5.1.7	Hematological Classifications Frequency by Treatment and Time Point – Part 1 (Safety Population)	CLBH

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Number	Title	Shell
Table 14.3.5.1.8	Clinical Laboratory Summary and Change From Baseline – Coagulation – Part 1 (Safety Population)	CLBD
Table 14.3.5.1.9.1	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Pooled Placebo – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.9.2	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Single Dose 50 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.9.3	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Single Dose 150 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.9.4	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Single Dose 300 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.9.5	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Single Dose 600 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.9.6	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Single Dose TBD mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.9.7	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Single Dose TBD mg MK-7762 Fasted (Cohort 6) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.9.8	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Single Dose TBD mg MK-7762 Fed (Cohort 6) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.9.9	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Single Dose MK-7762 Fasted (All Cohorts) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.10	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Coagulation – Part 1 (Safety Population)	CLBS
Table 14.3.5.1.11	Clinical Laboratory Summary and Change From Baseline – Urinalysis – Part 1 (Safety Population)	CLBD

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Number	Title	Shell
Table 14.3.5.1.12.1	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Pooled Placebo – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.12.2	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Single Dose 50 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.12.3	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Single Dose 150 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.12.4	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Single Dose 300 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.12.5	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Single Dose 600 mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.12.6	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Single Dose TBD mg MK-7762 Fasted – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.12.7	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Single Dose TBD mg MK-7762 Fasted (Cohort 6) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.12.8	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Single Dose TBD mg MK-7762 Fed (Cohort 6) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.12.9	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Single Dose MK-7762 Fasted (All Cohorts) – Part 1 (Safety Population)	CLBSD
Table 14.3.5.1.13	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Urinalysis – Part 1 (Safety Population)	CLBS
Table 14.3.5.1.14	Vital Sign Summary and Change From Baseline – Part 1 (Safety Population)	CVS
Table 14.3.5.1.15	Categorical Summary of Abnormal Vital Signs – Part 1 (Safety Population)	CVSC

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Number	Title	Shell
Table 14.3.5.1.16	Average of Safety Triplicate 12-Lead Electrocardiogram Summary and Change From Baseline – Part 1 (Safety Population)	CEG
Table 14.3.5.1.17	Categorical Summary of Abnormal Safety 12-Lead Electrocardiogram – Part 1 (Safety Population)	CEGC
Part 2		
Table 14.3.5.2.1	Clinical Laboratory Summary and Change From Baseline – Chemistry – Part 2 (Safety Population)	CLBD
Table 14.3.5.2.2.1	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Pooled Placebo – Part 2 (Safety Population)	CLBSD
Table 14.3.5.2.2.2	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSD
Table 14.3.5.2.2.3	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSD
Table 14.3.5.2.2.4	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSD
Table 14.3.5.2.2.5	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Chemistry – Multiple Dose MK-7762 (All Cohorts) – Part 2 (Safety Population)	CLBSD
Table 14.3.5.2.3.1	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Chemistry – Pooled Placebo – Part 2 (Safety Population)	CLBSM
Table 14.3.5.2.3.2	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Chemistry – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSM
Table 14.3.5.2.3.3	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Chemistry – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSM
Table 14.3.5.2.3.4	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Chemistry – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSM

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Number	Title	Shell
Table 14.3.5.2.3.5	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Chemistry – Multiple Dose MK-7762 (All Cohorts) – Part 2 (Safety Population)	CLBSM
Table 14.3.5.2.4	Clinical Laboratory Summary and Change From Baseline – Hematology – Part 2 (Safety Population)	CLBD
Table 14.3.5.2.5.1	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Pooled Placebo – Part 2 (Safety Population)	CLBSD
Table 14.3.5.2.5.2	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSD
Table 14.3.5.2.5.3	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSD
Table 14.3.5.2.5.4	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSD
Table 14.3.5.2.5.5	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Hematology – Multiple Dose MK-7762 (All Cohorts) – Part 2 (Safety Population)	CLBSD
Table 14.3.5.2.6.1	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Hematology – Pooled Placebo – Part 2 (Safety Population)	CLBSM
Table 14.3.5.2.6.2	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Hematology – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSM
Table 14.3.5.2.6.3	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Hematology – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSM
Table 14.3.5.2.6.4	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Hematology – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSM
Table 14.3.5.2.6.5	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Hematology – Multiple Dose MK-7762 (All Cohorts) – Part 2 (Safety Population)	CLBSM

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Number	Title	Shell
Table 14.3.5.2.7	Hematological Classifications Frequency by Treatment and Time Point – Part 2 (Safety Population)	CLBH
Table 14.3.5.2.8	Clinical Laboratory Summary and Change From Baseline – Coagulation – Part 2 (Safety Population)	CLBD
Table 14.3.5.2.9.1	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Pooled Placebo – Part 2 (Safety Population)	CLBSD
Table 14.3.5.2.9.2	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSD
Table 14.3.5.2.9.3	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSD
Table 14.3.5.2.9.4	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSD
Table 14.3.5.2.9.5	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Coagulation – Multiple Dose MK-7762 (All Cohorts) – Part 2 (Safety Population)	CLBSD
Table 14.3.5.2.10.1	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Coagulation – Pooled Placebo – Part 2 (Safety Population)	CLBSM
Table 14.3.5.2.10.2	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Coagulation – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSM
Table 14.3.5.2.10.3	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Coagulation – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSM
Table 14.3.5.2.10.4	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Coagulation – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSM
Table 14.3.5.2.10.5	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Coagulation – Multiple Dose MK-7762 (All Cohorts) – Part 2 (Safety Population)	CLBSM
Table 14.3.5.2.11	Clinical Laboratory Summary and Change From Baseline – Urinalysis – Part 2 (Safety Population)	CLBD

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Number	Title	Shell
Table 14.3.5.2.12.1	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Pooled Placebo – Part 2 (Safety Population)	CLBSD
Table 14.3.5.2.12.2	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSD
Table 14.3.5.2.12.3	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSD
Table 14.3.5.2.12.4	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSD
Table 14.3.5.2.12.5	Clinical Laboratory Shift From Baseline Based on DAIDS Grades – Urinalysis – Multiple Dose MK-7762 (All Cohorts) – Part 2 (Safety Population)	CLBSD
Table 14.3.5.2.13.1	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Urinalysis – Pooled Placebo – Part 2 (Safety Population)	CLBSM
Table 14.3.5.2.13.2	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Urinalysis – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSM
Table 14.3.5.2.13.3	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Urinalysis – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSM
Table 14.3.5.2.13.4	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Urinalysis – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	CLBSM
Table 14.3.5.2.13.5	Clinical Laboratory Shift From Baseline for Non-Graded Tests – Urinalysis – Multiple Dose MK-7762 (All Cohorts) – Part 2 (Safety Population)	CLBSM
Table 14.3.5.2.14	Vital Sign Summary and Change From Baseline – Part 2 (Safety Population)	CVS
Table 14.3.5.2.15	Categorical Summary of Abnormal Vital Signs – Part 2 (Safety Population)	CVSC
Table 14.3.5.2.16	Average of Safety Triplicate 12-Lead Electrocardiogram Summary and Change From Baseline – Part 2 (Safety Population)	CEG

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Number	Title	Shell
Table 14.3.5.2.17	Categorical Summary of Abnormal Safety 12-Lead Electrocardiogram – Part 2 (Safety Population)	CEGC
Table 14.3.5.2.18	Shifts to Worst Post-Baseline Visual Acuity by Treatment – Part 2 (Safety Population)	CVISS
Table 14.3.5.2.19	Frequency of Abnormalities in Visual Acuity and Color Vision Assessments by Treatment and Time Point– Part 2 (Safety Population)	CVISC
Table 14.3.5.2.20	Frequency of New Post-Baseline Abnormalities in Peripheral Neuropathy Assessments by Treatment, Time Point, and Severity – Part 2 (Safety Population)	CBPNS
Table 14.3.5.2.21	Hematological Classifications Frequency by Treatment and Time Point – Part 2 (Per Protocol Population)	CLBH
Table 14.3.5.2.22	Frequency of Abnormalities in Visual Acuity and Color Vision Assessments by Treatment and Time Point– Part 2 (Per Protocol Population)	CVISC
Table 14.3.5.2.23	Frequency of New Post-Baseline Abnormalities in Peripheral Neuropathy Assessments by Treatment, Time Point, and Severity – Part 2 (Per Protocol Population)	CBPNS

14.4 Safety Figures

Number	Title	Shell
Part 1		
Figure 14.4.1.1	Boxplot of Platelet Count by Treatment and Time Point – Part 1 (Safety Population)	BOXP
Figure 14.4.1.2	Boxplot of Absolute Neutrophil Count by Treatment and Time Point – Part 1 (Safety Population)	BOXP
Figure 14.4.1.3	Boxplot of White Blood Cell Count by Treatment and Time Point – Part 1 (Safety Population)	BOXP
Figure 14.4.1.4	Boxplot of Reticulocyte Count by Treatment and Time Point – Part 1 (Safety Population)	BOXP
Figure 14.4.1.5	Boxplot of Red Blood Cell Count by Treatment and Time Point – Part 1 (Safety Population)	BOXP
Figure 14.4.1.6	Boxplot of Hemoglobin by Treatment and Time Point – Part 1 (Safety Population)	BOXP

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Figure 14.4.1.7	E-DISH Scatter Plot of Maximum Total Bilirubin Versus Maximum Aspartate Aminotransferase Post-Baseline – Part 1 (Safety Population)	EDISH
Figure 14.4.1.8	E-DISH Scatter Plot of Maximum Total Bilirubin Versus Maximum Alanine Aminotransferase Post-Baseline – Part 1 (Safety Population)	EDISH
Part 2		
Figure 14.4.2.1*	Kaplan-Meier Cumulative Incidence Plot – Time to Adverse Event Resolution in Participants With Ongoing Neurologic or Hematologic Adverse Event of Special Interest at Time of Treatment Discontinuation – Pooled Placebo – Part 2 (Safety Population)	KMPLOT
Figure 14.4.2.2*	Kaplan-Meier Cumulative Incidence Plot – Time to Adverse Event Resolution in Participants With Ongoing Neurologic or Hematologic Adverse Event of Special Interest at Time of Treatment Discontinuation – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	KMPLOT
Figure 14.4.2.3*	Kaplan-Meier Cumulative Incidence Plot – Time to Adverse Event Resolution in Participants With Ongoing Neurologic or Hematologic Adverse Event of Special Interest at Time of Treatment Discontinuation – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	KMPLOT
Figure 14.4.2.4*	Kaplan-Meier Cumulative Incidence Plot – Time to Adverse Event Resolution in Participants With Ongoing Neurologic or Hematologic Adverse Event of Special Interest at Time of Treatment Discontinuation – Multiple Dose <i>TBD mg</i> MK-7762 – Part 2 (Safety Population)	KMPLOT
Figure 14.4.2.5*	Kaplan-Meier Cumulative Incidence Plot – Time to Adverse Event Resolution in Participants With Ongoing Neurologic or Hematologic Adverse Event of Special Interest at Time of Treatment Discontinuation – Multiple Dose MK-7762 (All Cohorts) – Part 2 (Safety Population)	KMPLOT
Figure 14.4.2.6	Boxplot of Platelet Count by Treatment and Time Point – Part 2 (Safety Population)	BOXP

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Figure 14.4.2.7	Boxplot of Absolute Neutrophil Count by Treatment and Time Point – Part 2 (Safety Population)	BOXP
Figure 14.4.2.8	Boxplot of White Blood Cell Count by Treatment and Time Point – Part 2 (Safety Population)	BOXP
Figure 14.4.2.9	Boxplot of Reticulocyte Count by Treatment and Time Point – Part 2 (Safety Population)	BOXP
Figure 14.4.2.10	Boxplot of Red Blood Cell Count by Treatment and Time Point – Part 2 (Safety Population)	BOXP
Figure 14.4.2.11	Boxplot of Hemoglobin by Treatment and Time Point – Part 2 (Safety Population)	BOXP
Figure 14.4.2.12	E-DISH Scatter Plot of Maximum Total Bilirubin Versus Maximum Aspartate Aminotransferase Post-Baseline – Part 2 (Safety Population)	EDISH
Figure 14.4.2.13	E-DISH Scatter Plot of Maximum Total Bilirubin Versus Maximum Alanine Aminotransferase Post-Baseline – Part 2 (Safety Population)	EDISH
* Figures will only be generated if there are more than 5 participants with ongoing neurologic or hematologic adverse events of special interest at the time of treatment discontinuation.		

1.3 Section 16 Data Listings

Note: Hepatitis and HIV serology results that are provided by the clinical laboratory will not be presented in Participant data listings and will not be included in any database transfer. All data will be presented as outlined in the CRF (i.e., time point information will be consistent with the CRF data).

Data listings are numbered following the ICH structure but may be renumbered as appropriate during the compilation of the TFLs for the CSR. The following is a list of appendix numbers and titles that will be included as data listings:

16.1 Study Information

16.1.9 Statistical Methods

Number	Title
Appendix 16.1.9.1	Statistical Analysis Plan

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16.1.10 Clinical Laboratory Reference Ranges

Number	Title
Appendix 16.1.10.1	Clinical Laboratory Reference Ranges

16.2 Participant Data Listings

16.2.1 Participant Discontinuation

Number	Title
Appendix 16.2.1.1	Participant Disposition – Part 1 (Safety Population)
Appendix 16.2.1.2	Participant Disposition – Part 2 (Safety Population)
Appendix 16.2.1.3	Participant Disposition – Screen Failures

16.2.2 Protocol Deviations

Number	Title
Appendix 16.2.2.1	Protocol Deviations

16.2.3 Participants Excluded From the Pharmacokinetic Analysis

Not Applicable.

16.2.4 Demographic Data

Number	Title
Appendix 16.2.4.1.1	Demographics – Part 1 (Safety Population)
Appendix 16.2.4.1.2	Demographics – Part 2 (Safety Population)
Appendix 16.2.4.1.3	Demographics – Screen Failures (Safety Population)
Appendix 16.2.4.2.1	Physical Examination – Part 1 (Safety Population)
Appendix 16.2.4.2.2	Physical Examination – Part 2 (Safety Population)
Appendix 16.2.4.3.1	Medical History – Part 1 (Safety Population)
Appendix 16.2.4.3.2	Medical History – Part 2 (Safety Population)
Appendix 16.2.4.4.1	Substance Use – Part 1 (Safety Population)
Appendix 16.2.4.4.2	Substance Use – Part 2 (Safety Population)

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16.2.5 Compliance and/or Drug Concentration Data

Number	Title
Appendix 16.2.5.1.1	Participant Eligibility – Part 1 (Safety Population)
Appendix 16.2.5.1.2	Participant Eligibility – Part 2 (Safety Population)
Appendix 16.2.5.1.3	Participant Eligibility – Screen Failures
Appendix 16.2.5.2.1.1	Test Compound Description – Part 1
Appendix 16.2.5.2.1.2	Test Compound Administration Times – Part 1 (Safety Population)
Appendix 16.2.5.2.2.1	Test Compound Description – Part 2
Appendix 16.2.5.2.2.2	Test Compound Administration Times – Part 2 (Safety Population)
Appendix 16.2.5.3	Meal Times – Part 1 (Safety Population)
Appendix 16.2.5.4.1	Prior and Concomitant Medications – Part 1 (Safety Population)
Appendix 16.2.5.4.2	Prior and Concomitant Medications – Part 2 (Safety Population)

16.2.6 Individual Pharmacokinetic Response Data

Not applicable.

16.2.7 Adverse Events Listings

Number	Title
Appendix 16.2.7.1.1	Adverse Events – Part 1 (Safety Population)
Appendix 16.2.7.1.2	Details for Serious Adverse Events – Part 1 (Safety Population) <i>This listing will be removed if no serious adverse events are reported.</i>
Appendix 16.2.7.2.1	Adverse Events – Part 2 (Safety Population)
Appendix 16.2.7.2.2	Details for Serious Adverse Events – Part 2 (Safety Population) <i>This listing will be removed if no serious adverse events are reported.</i>
Appendix 16.2.7.2.3	Ongoing Neurologic and Hematologic Adverse Events of Special Interest at Time of Treatment Discontinuation – Part 2 (Safety Population)
Appendix 16.2.7.3.1	Adverse Events – Screen Failures

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Number	Title
Appendix 16.2.7.3.2	Details for Serious Adverse Events – Screen Failures <i>This listing will be removed if no serious adverse events are reported.</i>

16.2.8 Clinical Laboratory Reports

Number	Title
Appendix 16.2.8.1.1	Clinical Laboratory Report – Chemistry – Part 1 (Safety Population)
Appendix 16.2.8.1.2	Clinical Laboratory Report – Hematology – Part 1 (Safety Population)
Appendix 16.2.8.1.3	Clinical Laboratory Report – Coagulation – Part 1 (Safety Population)
Appendix 16.2.8.1.4	Clinical Laboratory Report – Urinalysis – Part 1 (Safety Population)
Appendix 16.2.8.1.5	Clinical Laboratory Report – Urine Drug Screening – Part 1 (Safety Population)
Appendix 16.2.8.1.6	Clinical Laboratory Report – Virology – Part 1 (Safety Population)
Appendix 16.2.8.1.7	Vital Signs – Part 1 (Safety Population)
Appendix 16.2.8.1.8	Safety 12-Lead Electrocardiogram – Part 1 (Safety Population)
Appendix 16.2.8.1.9	Safety 12-Lead Electrocardiogram – Average of Triplicates – Part 1 (Safety Population)
Appendix 16.2.8.1.10	Visual Assessment – Part 1 (Safety Population)
Appendix 16.2.8.1.11	Brief Peripheral Neuropathy Assessment – Part 1 (Safety Population)
Appendix 16.2.8.2.1	Clinical Laboratory Report – Chemistry – Part 2 (Safety Population)
Appendix 16.2.8.2.2	Clinical Laboratory Report – Hematology – Part 2 (Safety Population)
Appendix 16.2.8.2.3	Clinical Laboratory Report – Coagulation – Part 2 (Safety Population)
Appendix 16.2.8.2.4	Clinical Laboratory Report – Urinalysis – Part 2 (Safety Population)
Appendix 16.2.8.2.5	Clinical Laboratory Report – Urine Drug Screening – Part 2 (Safety Population)

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Number	Title
Appendix 16.2.8.2.6	Clinical Laboratory Report – Virology – Part 2 (Safety Population)
Appendix 16.2.8.2.7	Vital Signs – Part 2 (Safety Population)
Appendix 16.2.8.2.8	Safety 12-Lead Electrocardiogram – Part 2 (Safety Population)
Appendix 16.2.8.2.9	Safety 12-Lead Electrocardiogram – Average of Triplicates – Part 2 (Safety Population)
Appendix 16.2.8.2.10	Visual Assessment – Part 2 (Safety Population)
Appendix 16.2.8.2.11	Brief Peripheral Neuropathy Assessment – Part 2 (Safety Population)
Appendix 16.2.8.2.12	New Post-Baseline Abnormalities in Neuropathy Symptom and Objective Physical Findings Assessments – Part 2 (Safety Population)

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2. TABLE, FIGURE, AND LISTING SHELLS

The following table shells provide a framework for the display of data from this trial. The shells may change due to unforeseen circumstances. These shells may not be reflective of every aspect of this trial but are intended to show the general layout of the tables that will be presented and included in the final report. Unless otherwise noted, all in-text tables will be presented in Times New Roman font size 9 and post-text tables will be presented in Courier New font size 9. In-text tables and figures will be generated as RTF and all other tables and listings will be generated as SAS® LST format and converted to MS Word for inclusion in the CSR. In compliance with Celerion SOP/PG, SAS® outputs will not be manually edited. Tables will be generated from ADaM datasets created in accordance with CDISC guidance (ADaM Model 2.1 and ADaM implementation Guide 1.1)

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2.1 In-text Summary Tables Shells

In-text Shell IDS will be in the following RTF format:

Table 10-1 Disposition Summary (Part 1) (Safety Population)

	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6) Treatment Sequence		
Disposition	Pooled Placebo	50 mg	150 mg	300 mg	600 mg	TBD mg	TBD mg Fasted/Fed	TBD mg Fed/Fasted	Part 1 Overall
Dosed	X (100%)	X (100%)	X (100%)	X (100%)	X (100%)	X (100%)	X (100%)	X (100%)	X (100%)
Replaced	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Completed Trial	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Discontinued From Trial	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Reason	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Completed Treatment	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Discontinued From Treatment	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Reason	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)	X (X%)
Source: Table 14.1.X Program: /CAXXXXX/sas_prg/stsas/intexttest/t_disp.sas 08OCT2015 16:36									

Programmer note: Participants with participant number greater than or equals to 1100 for Part 1 or 2100 for Part 2 are replacement participants and will be counted in the ‘Replaced’ summary of this table. ‘Single Dose MK-7762 or Placebo Fasted (Cohorts 1–5)’ will be replaced by ‘Multiple Doses MK-7762 or Placebo QD’ for the Part 2 table. The food effect columns will be removed for the Part 2 table. ‘Part 1 Overall’ will be replaced with an ‘Overall’ column presented under ‘Multiple Doses MK-7762 or Placebo QD’ for the Part 2 table.

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In-text Shell IDEM will be in the following RTF format:

Table 11-1 Demographic Summary – Part 1 (Safety Population)

		Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6) Treatment Sequence		
Trait	Category/ Statistics	Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	TBD mg (N=X)	TBD mg Fasted/Fed (N=X)	TBD mg Fed/Fasted (N=X)	Part 1 Overall (N=X)
Sex	Male	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Female	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Race	Asian	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Black or African American	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	White	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Ethnicity	Not Hispanic or Latino	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Age (yr)	n	X	X	X	X	X	X	X	X	X
	Mean	XX.X	XX.X	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	XX.X	XX.X
	Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
	Median	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX
Weight (kg)	n	X	X	X	X	X	X	X	X	X
	Mean	XX.X	XX.X	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	XX.X	XX.X
	Minimum	XX.X	XX.X	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	XX.X	XX.X
	Maximum	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Height (cm)	n	X	X	X	X	X	X	X	X	X
	Mean	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X
	SD	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
	Minimum	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX
	Median	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X	XXX.X
	Maximum	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX	XXX

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Trait	Category/ Statistics	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6) Treatment Sequence		Part 1 Overall (N=X)
		Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	TBD mg (N=X)	TBD mg Fasted/Fed (N=X)	TBD mg Fed/Fasted (N=X)	
BMI (kg/m ²)	n	X	X	X	X	X	X	X	X	X
	Mean	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
	SD	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
	Minimum	XX.X	XX.X	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	XX.X	XX.X
	Maximum	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X	XX.X
Descriptive statistics for body mass index, height, and weight are calculated using Screening measurements.										
Source: Table 14.1.X.X Program: /CAXXXXX/sas_prg/stmts/intexttest/t_dem.sas 08OCT2015 16:36										

Programmer note: ‘Single Dose MK-7762 or Placebo Fasted (Cohorts 1–5)’ will be replaced by ‘Multiple Doses MK-7762 or Placebo QD’ for the Part 2 table. The food effect columns will be removed for the Part 2 table. ‘Part 1 Overall’ will be replaced with an ‘Overall’ column presented under ‘Multiple Doses MK-7762 or Placebo QD’ for the Part 2 table.

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In-text Shell IAES will be in the following RTF format:

Table IAES Treatment-Emergent Adverse Event Frequency by Treatment- Number of Participants Reporting the Event (% of Participants Dosed) – Part 1 (Safety Population)

	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6)		All Part 1 Cohorts*	
System Organ Class Preferred Term	Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	TBD mg (N=X)	TBD mg Fasted (N=X)	TBD mg Fed (N=X)	All MK-7762 Fasted (N=X)	All MK-7762 (N = X)
Number of Participants With TEAEs	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Eye disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Visual blurred	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Gastrointestinal disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Dyspepsia	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Nausea	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Musculoskeletal and connective tissue disorders	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Back pain	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Muscle cramps	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Musculoskeletal pain	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)

Although a participant may have had 2 or more adverse events, the participant is counted only once within a category. The same participant may appear in different categories.
Adverse events are classified according to MedDRA Version 26.0.
*‘All MK-7762 Fasted’ summary includes participants who received MK-7762 under fasting conditions only. The ‘All MK-7762’ summary includes participants who received MK-7762 regardless of fasting conditions.
TEAEs = Treatment-emergent adverse events

Source: Table 14.3.1.X
Program: /CAXXXXX/sas_prg/stsas/intext/t_ae.sas DDMMYYYY HH:MM

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Programmer notes:

- The table may be split across 2 pages if it is not possible to fit all columns on 1 page. Additional pooled treatments may be added as outlined in the notes of Section 5 of the SAP.
- For Part 2 tables:
 - ‘Single Dose MK-7762 or Placebo Fasted (Cohorts 1–5)’ will be replaced by ‘Multiple Doses MK-7762 or Placebo QD’
 - The food effect columns will be removed.
 - ‘All Part 1 Cohorts’ columns will be replaced by the ‘All MK-7762 QD’ column.
 - The following footnote will be deleted: *The ‘All MK-7762 Fasted’ summary includes participants who received MK-7762 under fasting conditions only. The ‘All MK-7762’ summary includes participants who received MK-7762 regardless of fasting conditions.

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2.2 Section 14 Summary Tables Shells

Shell CDS will be in the following LST format:

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Table CDS Disposition Summary - Part 1 (Safety Population)

Category	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food effect MK-7762 (Cohort 6) Treatment Sequence		Part 1 Overall
	Pooled Placebo	50 mg	150 mg	300 mg	600 mg	TBD mg	TBD mg Fasted/Fed	TBD mg Fed/Fasted	
Dosed	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Replaced	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Completed Trial	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Discontinued From Trial	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
<Reason>	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Completed Treatment	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
Discontinued From Treatment	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)
<Reason>	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)	XX (XX%)

Programmer note: Participants with participant number greater than or equals to 1100 for Part 1 or 2100 for Part 2 are replacement participants and will be counted in the 'Replaced' summary of this table. 'Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)' will be replaced by 'Multiple Doses MK-7762 or Placebo QD' for the Part 2 table. The food effect columns will be removed for the Part 2 table. 'Part 1 Overall' will be replaced with an 'Overall' column presented under 'Multiple Doses MK-7762 or Placebo QD' for the Part 2 table.

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1programname2022Q1.sas DDMMYYYY HH:MM

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Shell SDS will be in the following LST format:

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Table SDS Participant Dosing Status and Trial Disposition - Part 1, FE (Safety Population)						
Participant Number	TBD mg MK-7762 Treatment Sequence	TBD mg MK-7762 Dosed Treatment		Trial Completion		
		Fasted	Fed	Status	Date	
X	Fasted/Fed	Yes	No	Discontinued From Trial: <Reason>	DDMONYYYY	
X	Fed/Fasted	Yes	Yes	Completed Trial	DDMONYYYY	
X	Fed/Fasted	Yes	Yes	Completed Trial	DDMONYYYY	
X	Fasted/Fed	Yes	Yes	Completed Trial	DDMONYYYY	
		-----	-----			
		XX	XX			

Source: < >
Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

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Shell CDEM will be in the following LST format:

Page 1 of X

Table CDEM Demographic Summary - Part 1 (Safety Population)										
Trait	Category/ Statistic	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6) Treatment Sequence		Part 1 Overall (N=X)
		Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	TBD mg (N=X)	TBD mg Fasted/Fed (N=X)	TBD mg Fed/Fasted (N=X)	
Sex	Male	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Female	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Race	Asian	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Black	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	White	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Age (yr)	n	X	X	X	X	X	X	X	X	X
	Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
	SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
	Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
	Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
	Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX
Weight (kg)	n	X	X	X	X	X	X	X	X	X
	Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
	SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
	Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
	Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
	Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX

Descriptive statistics for body mass index, height, and weight are calculated using Screening measurements.

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDDMMYYYY HH:MM

Programmer note: Height and BMI measurements collected at Screening will also be included in this table. 'Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)' will be replaced by 'Multiple Doses MK-7762 or Placebo QD' for the Part 2 table. The food effect columns will be removed for the Part 2 table. 'Part 1 Overall' will be replaced with an 'Overall' column presented under 'Multiple Doses MK-7762 or Placebo QD' for the Part 2 table.

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Shell CAES will be in the following LST format:

Page 1 of X

Table CAES Treatment-Emergent Adverse Event Frequency by Treatment and Severity -
Number of Participants Reporting the Event (% of Participants Dosed) - Part 1 (Safety Population)

System Organ Class Preferred Term Severity Grade	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6)		All Part 1 Cohorts*	
	Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	TBD mg (N=X)	TBD mg Fasted (N=X)	TBD mg Fed (N=X)	All MK-7762 Fasted (N=X)	All MK-7762 (N=X)
Number of Participants With TEAEs	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Mild	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Moderate	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Severe	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
< >	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Respiratory, thoracic and mediastinal disorders	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Mild	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Moderate	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Severe	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
< >	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Dry throat	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Mild	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Moderate	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Severe	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
< >	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Oropharyngeal pain	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Mild	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Moderate	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Severe	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
< >	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)

Adverse events are classified according to MedDRA Version 26.0.

Although a participant may have had 2 or more adverse events, the participant is counted only once within a category. The same participant may appear in different categories.

When a participant experienced the same AE at more than one level of severity during a treatment period, the AE with the worst severity is counted.

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*The 'All MK-7762 Fasted' summary includes participants who received MK-7762 under fasting conditions only. The 'All MK-7762' summary includes participants who received MK-7762 regardless of fasting conditions.
TEAEs = Treatment-emergent adverse events

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab_PROGRAMNAME.sas DDMMYYYY HH:MM

Programmer notes:

- o For all AE tables:
 - o These tables will only include TEAEs captured during the analysis window described in Section 6.4.
 - o The table may be split across 2 pages if it is not possible to fit all columns on 1 page. Additional pooled treatments may be added as outlined in the notes of Section 5 of the SAP.
 - o Only present severity grades that are populated in the CRF for the system organ class and/or preferred term.
- o For all Part 2 tables:
 - o 'Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)' will be replaced by 'Multiple Doses MK-7762 or Placebo QD'
 - o The food effect columns will be removed.
 - o 'All Part 1 Cohorts' columns will be replaced by the 'All MK-7762 QD' column.
 - o The following footnote will be deleted: **The 'All MK-7762 Fasted' summary includes participants who received MK-7762 under fasting conditions only. The 'All MK-7762' summary includes participants who received MK-7762 regardless of fasting conditions.*
- o For Part 2 visual acuity and color vision related AE tables:
 - o These tables will only include participants with visual acuity or color vision related TEAEs. These will be flagged programmatically as outlined in Section 6.4 of the SAP.
 - o The following footnote will be added: 'Visual acuity and color vision TEAEs were determined from the adverse events recorded during the study using the algorithm defined in the SAP.'
- o For all Study Drug Related TEAE tables:
 - o These tables will only include participants with TEAEs marked as related to study product on the AE CRF.
 - o 'Number of Participants With TEAEs' will be replaced with 'Number of Participants With Study Drug Related TEAEs'
- o For all SAE tables:
 - o These tables will only include participants with serious TEAEs.
 - o 'Number of Participants With TEAEs' will be replaced with 'Number of Participants With Serious TEAEs'
- o For all Study Drug Related Serious TEAE tables:
 - o These tables will only include participants with serious TEAEs marked as related to study product on the AE CRF.
 - o 'Number of Participants With TEAEs' will be replaced with 'Number of Participants With Study Drug Related Serious TEAEs'

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- For all TEAE leading to drug discontinuation tables:
 - These tables will only include participants with TEAEs leading to drug discontinuation.
 - 'Number of Participants With TEAEs' will be replaced with 'Number of Participants With TEAEs Leading to Drug Discontinuation'
- For all Study Drug Related TEAE leading to drug discontinuation tables:
 - These tables will only include participants with TEAEs leading to drug discontinuation marked as related to study product on the AE CRF.
 - 'Number of Participants With TEAEs' will be replaced with 'Number of Participants With Study Drug Related TEAEs Leading to Drug Discontinuation'
- For all AESI tables:
 - These tables will only include participants with AESIs as flagged in the CRF.
 - 'Number of Participants With TEAEs' will be replaced with 'Number of Participants With AESIs'
 - The following footnote will be added: 'This table is based on AESIs identified in the AE page of the CRF (i.e., AESI flag = Yes in CRF).'
- For all Study Drug Related AESI tables:
 - These tables will only include participants with AESIs marked as related to study product on the AE CRF.
 - 'Number of Participants With TEAEs' will be replaced with 'Number of Participants With Study Drug Related AESIs'
 - The following footnote will be added: 'This table is based on AESIs identified in the AE page of the CRF (i.e., AESI flag = Yes in CRF).'

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Shell CAESR will be in the following LST format:

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Table CAESR Treatment-Emergent Adverse Event Frequency by Treatment and Severity, and Relationship to Study Drug -
Number of Adverse Events - Part 1 (Safety Population)

System Organ Class Preferred Term	Treat- ment	Number of Participants With TEAEs	Number of TEAEs	Severity Grade					Relationship to Study Drug	
				1	2	3	4	5	Not Related	Related
Eye disorders	Pooled Placebo	X	X	X	X	X	X	X	X	X
	50 mg Fasted	X	X	X	X	X	X	X	X	X
	150 mg Fasted	X	X	X	X	X	X	X	X	X
	300 mg Fasted	X	X	X	X	X	X	X	X	X
Vision blurred	Pooled Placebo	X	X	X	X	X	X	X	X	X
	50 mg Fasted	X	X	X	X	X	X	X	X	X
	150 mg Fasted	X	X	X	X	X	X	X	X	X
	300 mg Fasted	X	X	X	X	X	X	X	X	X
< >		< >								
		Pooled Placebo	X	X	X	X	X	X	X	X
		50 mg Fasted	X	X	X	X	X	X	X	X
		150 mg Fasted	X	X	X	X	X	X	X	X
		300 mg Fasted	X	X	X	X	X	X	X	X
		< >								

All participants received a single oral dose of MK-7762 or matching placebo under fasting conditions with exception of Cohort 6 which was designed as a cross-over food effect cohort with one fasted trial period and one fed trial period.

Adverse events are classified according to MedDRA Version 26.0.

Severity Grade: 1 = Mild; 2 = Moderate; 3 = Severe; 4 = Potentially life-threatening; 5 = Fatal

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab PROGRAMNAME.sas DMMYYYY HH:MM

Programmer note: These tables will only include TEAEs captured during the analysis window described in Section 6.4. The appropriate treatments will be included for each trial part. Similar treatment footnote for Part 2: All participants received multiple oral doses of MK-7762 or matching placebo QD for 28 days. Pooled MK-7762 treatment summaries will not be included in this table.

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Shell CAEKM will be in the following LST format:

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Table CAEKM Summary of Time to Adverse Event Resolution in Participants With Ongoing Neurologic or Hematologic Adverse Event of Special Interest at Time of Treatment Discontinuation - Part 2 (Safety Population)

		Multiple Doses MK-7762 or Placebo QD				
Statistic		Pooled Placebo (N=X)	TBD mg (N=X)	TBD mg (N=X)	TBD mg (N=X)	All MK-7762 (N=X)
1. Number (%) of Participants with Ongoing AESI at Treatment Discontinuation		X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
2. Number (%) of Participants with AESI Resolved Within 5 Days of Treatment Discontinuation		X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
3. Time to AESI Resolution (Days)	n	XX	XX	XX	XX	XX
	Mean	X.X	X.X	X.X	X.X	X.X
	SD	X.XX	X.XX	X.XX	X.XX	X.XX
	Minimum	X	X	X	X	X
	Median	X.X	X.X	X.X	X.X	X.X
	Maximum	X	X	X	X	X
	Kaplan-Meier	XX.X	XX.X	XX.X	XX.X	XX.X
	Median Time (hr)					
	95% CI	X.XX-X.XX	X.XX-X.XX	X.XX-X.XX	X.XX-X.XX	X.XX-X.XX
	Censored	XX	XX	XX	XX	XX

Time to AE resolution is calculated as the difference between the date of treatment discontinuation and the AE resolution date.
Criterion 1: Any participant with at least one ongoing neurologic or hematologic AESI at the time of treatment discontinuation is included.
Criterion 2: Any participant meeting Criterion 1 and with at least one AESI which resolved within 5 days of treatment discontinuation.
For both criterion 1 and 2, percentages are based on the number of participants dosed.
Kaplan-Meier median time (product-limit median estimate) to AE resolution is presented along with the two-sided 95% confidence intervals.
For participants with multiple ongoing AESIs, the worst time to AE resolution is summarized.
Censored = Number of participants with ongoing AESI (right censored to last date of AE assessment).
AE = Adverse event; AESI = Adverse event of special interest; CI = Confidence interval

Programmer note: Please refer to section 6.4 of the SAP for details on the analysis. 95% confidence intervals will be presented with 2 decimal places. For each treatment, Kaplan-Meier median time, confidence interval, and number censored will only be presented if there are more than 5 participants experiencing an event.

Program: /CAXXXX/sas_prg/stsas/tab_PROGRAMNAME.sas DMMYYYY HH:MM

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Table 14.3.2.1.1 Serious Adverse Events - Part 1 (Safety Population)

Tables 14.3.2.1.1 and 14.3.2.2.1 will match the format of Appendix 16.2.7.

Or contain statement as follows:

"There were no events that met this criteria."

Source: < >
Program: /CAXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

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Table 14.3.2.1.2 Adverse Events of Special Interest - Part 1 (Safety Population)

Tables 14.3.2.1.2 and 14.3.2.2.2 will match the format of Appendix 16.2.7.

Or contain statement as follows:

"There were no events that met this criteria."

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

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Shell CLBO will be in the following LST format:

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Table CLBO Out-of-Range Values and Recheck Results - <Clinical Laboratory Panel> - Part 1 (Safety Population)

Cohort	Participant Number	Age/ Sex	Trial Period	Treatment	Day	Date	Time	Parameter1 <Range> (Unit)	Parameter2 <Range> (Unit)	Parameter3 <Range> (Unit)	Parameter4 <Range> (Unit)
X	X	XX/X	Screen 1	50 mg Fasted	-X	DDMMYYYY DDMMYYYY	HH:MM:SS HH:MM:SS	XX H XX L		XX L	XX H G1 XX L

Programmer Note: Replace Parameter1, 2 etc. with actual lab tests in the trial. Sort unscheduled assessment and early termination chronologically with other scheduled assessments and rechecks. Recheck should be sorted with the scheduled time point the recheck is for. Unscheduled and Early Termination records should only be included if they are out of range or recheck results. Derived DAIDS grades will be presented along with the abnormality flags.

F = Female; M = Male

H = Above reference range; L = Below reference range

DAIDS Grade: G1 = Grade 1; G2 = Grade 2; G3 = Grade 3; G4 = Grade 4

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

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Shell CLBD will be in the following LST format:

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Table CLBD Clinical Laboratory Summary and Change From Baseline - < Clinical Laboratory > - Part 1 (Safety Population)

Laboratory Test (units)	Reference Range	Time Point	Statistic	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6)		All Part 1 Cohorts\$
				Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	TBD mg (N=X)	TBD mg Fasted (N=X)	TBD mg Fed (N=X)	
Testname (unit)	< - >#	Baseline	n	X	X	X	X	X	X	X	X	X
			Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX
		Day 2	Absolute	n	X	X	X	X	X	X	X	X
			Mean	X.X*	X.X	X.X^	X.X	X.X	X.X	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX
		Change	n	X	X	X	X	X	X	X	X	X
			Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX

Baseline is the last measurement collected prior to dosing in each treatment period.

= Lowest of the lower ranges and highest of the higher ranges are used. Refer to Appendix 16.1.10.1 for the breakdown.

\$The 'All MK-7762 Fasted' summary includes data from participants who received MK-7762 under fasting conditions only.

* = Above reference range; ^ = Below reference range

EOT = End of trial

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

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Programmer Note:

- o For all tables:
 - o The table may be split across 2 pages if it is not possible to fit all columns on 1 page. Additional pooled treatments may be added as outlined in the notes of Section 5 of the SAP.
 - o Treatment means at specific time points will be flagged (with a *) if they are above or below the reference range. This only applies to the clinical laboratory treatment results (i.e., not the change from baseline or any other endpoints).
- o For all Part 1 tables:
 - o Time points will be Baseline, Day 2, Day 4 and EOT (Day 7). The sample size at EOT for the Cohort 6 summaries will be 4 or less.
- o For all Part 2 tables:
 - o 'Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)' will be replaced by 'Multiple Doses MK-7762 or Placebo QD'
 - o The food effect columns will be removed.
 - o 'All Part 1 Cohorts' column will be replaced by the 'All MK-7762 QD' column.
 - o The following footnote will be deleted: *\$The 'All MK-7762 Fasted' summary includes data from participants who received MK-7762 under fasting conditions only.*
 - o Time points will be Baseline, Day 2, Day 4, Day 7, Day 10, Day 14, Day 17, Day 21, Day 24, Day 29, and EOT (Day 33).
 - o The baseline footnote will be: Baseline is the last measurement collected prior to first dosing.

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Shell CLBSD will be in the following LST format:

Table CLBSD Clinical Laboratory Shift From Baseline Based on DAIDS Grades - < Clinical Laboratory > - Pooled Placebo - Part 1 (Safety Population) Page 1 of X

Laboratory Test (units)	Time Point	Baseline Grade	Post-baseline Grade				
			0	1	2	3	4
Testname (unit)	Day 2	0	XX	X	X	X	X
		1	X	X	X	X	X
		2	X	X	X	X	X
		3	X	X	X	X	X
		4	X	X	X	X	X
	Day 4	0	XX	X	X	X	X
		1	X	X	X	X	X
		2	X	X	X	X	X
		3	X	X	X	X	X
		4	X	X	X	X	X
< >							

All participants received a single oral dose of MK-7762 or matching placebo under fasting conditions with exception of Cohort 6 which was designed as a cross-over food effect cohort with one fasted trial period and one fed trial period.
Baseline is the last measurement collected prior to dosing in each treatment period.
DAIDS Grade: G1 = Grade 1; G2 = Grade 2; G3 = Grade 3; G4 = Grade 4
Grade 0 refers to ungraded (i.e., normal) results.
EOT = End of trial

Source: < >
Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DMMMYYYY HH:MM

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Programmer Note:

- o For all Part 1 tables:
 - o Time points will be Day 2, Day 4 and EOT (Day 7). The sample size at EOT for the Cohort 6 summaries will be 4 or less.
 - o The following footnote will be added for the 'Single Dose MK-77662 Fasted (All Cohorts)' table: '\$This summary includes data from participants who received MK-7762 under fasting conditions only.'
- o For all Part 2 tables:
 - o The first footnote will be replaced by: All participants received multiple oral doses of MK-7762 or matching placebo QD for 28 days.
 - o Time points will be Day 2, Day 4, Day 7, Day 10, Day 14, Day 17, Day 21, Day 24, Day 29, and EOT (Day 33).
 - o The baseline footnote will be: Baseline is the last measurement collected prior to first dosing.

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Shell CLBS will be in the following LST format:

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Table CLBS Clinical Laboratory Shift From Baseline for Non-Graded Tests - < Clinical Laboratory > - Part 1 (Safety Population)

Laboratory Test (units)	Treatment	Time Point	Baseline L			Baseline N			Baseline H		
			Postdose			Postdose			Postdose		
			L	N	H	L	N	H	L	N	H
Testname (unit)	Pooled Placebo	Day 2	X	XX	X	X	XX	X	X	XX	X
		Day 4	X	XX	X	X	XX	X	X	XX	X
		EOT	X	XX	X	X	XX	X	X	XX	X
	50 mg MK-7762 Fasted	Day 2	X	XX	X	X	XX	X	X	XX	X
		Day 4	X	XX	X	X	XX	X	X	XX	X
		EOT	X	XX	X	X	XX	X	X	XX	X
	150 mg MK-7762 Fasted	Day 2	X	XX	X	X	XX	X	X	XX	X
		Day 4	X	XX	X	X	XX	X	X	XX	X
		EOT	X	XX	X	X	XX	X	X	XX	X
	300 mg MK-7762 Fasted	Day 2	X	XX	X	X	XX	X	X	XX	X
		Day 4	X	XX	X	X	XX	X	X	XX	X
		EOT	X	XX	X	X	XX	X	X	XX	X

< >

All participants received a single oral dose of MK-7762 or matching placebo under fasting conditions with exception of Cohort 6 which was designed as a cross-over food effect cohort with one fasted trial period and one fed trial period.

Baseline is the last measurement collected prior to dosing in each treatment period.

\$The 'All MK-7762 Fasted' summary includes data from participants who received MK-7762 under fasting conditions only.

EOT = End of trial

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

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Programmer Note:

- o This table only includes laboratory tests with no grading criteria available in DAIDS.
- o For urinalysis, the following footnote is used since the categories of N and O will be used instead of L, N, H: N = Within reference range; O = Outside reference range
- o Time points will be Day 2, Day 4 and EOT (Day 7). The sample size at EOT for the Cohort 6 summaries will be 4 or less.
- o Treatments will be the same as those presented in Shell CLBD for Part 1. Short treatment descriptions in Section 5 of the SAP can be used for treatment labels.

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Shell CLBSM will be in the following LST format:

Table CLBSM Clinical Laboratory Shift From Baseline for Non-Graded Tests - < Clinical Laboratory > - Pooled Placebo - Part 2 (Safety Population)

Laboratory Test (units)	Time Point	Baseline L			Baseline N			Baseline H		
		Postdose			Postdose			Postdose		
		L	N	H	L	N	H	L	N	H
Testname (unit)	Day 2	X	XX	X	X	XX	X	X	XX	X
	Day 4	X	XX	X	X	XX	X	X	XX	X
	Day 7	X	XX	X	X	XX	X	X	XX	X
	Day 10	X	XX	X	X	XX	X	X	XX	X
	Day 14	X	XX	X	X	XX	X	X	XX	X
	Day 17	X	XX	X	X	XX	X	X	XX	X
	Day 21	X	XX	X	X	XX	X	X	XX	X
	Day 24	X	XX	X	X	XX	X	X	XX	X
	Day 29	X	XX	X	X	XX	X	X	XX	X
	EOT	X	XX	X	X	XX	X	X	XX	X

< >

All participants received multiple oral doses of MK-7762 or matching placebo QD for 28 days.
Baseline is the last measurement collected prior to first dosing.
EOT = End of trial

Source: < >
Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

Programmer Note:

- o This table only includes laboratory tests with no grading criteria available in DAIDS.
- o For urinalysis, the following footnote is used since the categories of N and O will be used instead of L, N, H: N = Within reference range; O = Outside reference range
- o Time points will be Day 2, Day 4, Day 7, Day 10, Day 14, Day 17, Day 21, Day 24, Day 29, and EOT (Day 33).

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Shell CLBH will be in the following LST format:

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Table CLBH Hematological Classifications Frequency by Treatment and Time Point - Part 1 (Safety Population)

Lab. Test Point	Time	Result Abnormality Category	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6)		All Part 1 Cohorts*
			Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	TBD mg (N=X)	TBD mg Fasted (N=X)	TBD mg Fed (N=X)	All MK-7762 Fasted (N=X)
Platelet Count (unit)	Day 2	Abs. <LLN	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Abs. <50% of LLN	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 20% decrease	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	< >	≥ 50% decrease	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Overall		Abs. <LLN	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Abs. <50% of LLN	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 20% decrease	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 50% decrease	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)

The number of participants with a post-baseline result meeting the abnormality criteria is presented at each time point. The overall time point summary presents the number of participants meeting the abnormality criteria at any post-baseline time point. Decrease refers to a percent decrease from baseline where baseline is the last measurement collected prior to dosing in each treatment period.

Percentages are based on the number of participants dosed with available assessments at each time point. For the overall time point summary, percentages are based on the number of participants dosed and with at least one available post-baseline assessment.

*The 'All MK-7762 Fasted' summary includes data from participants who received MK-7762 under fasting conditions only.

Abs. = Observed value; ANC = Absolute neutrophil count; EOT = End of trial; Lab. = Laboratory; LLN = Lower limit of normal; RBC = Red blood cell count; WBC = White blood cell count

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

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Programmer notes:

- o For all tables:
 - o The table may be split across 2 pages if it is not possible to fit all columns on 1 page. Additional pooled treatments may be added as outlined in the notes of Section 5 of the SAP.
 - o Laboratory tests will be platelet count, absolute neutrophil count (ANC), white blood cell (WBC) count, reticulocyte count, red blood cell (RBC) count, and hemoglobin. Abbreviations may be used for laboratory test names with corresponding footnotes included.
 - o Abnormality criteria (a. through d.) are outlined in Section 6.5 of the SAP.
- o For all Part 1 tables:
 - o Time points will be Day 2, Day 4, EOT (Day 7) and Overall. The sample size at EOT for the Cohort 6 summaries will be 4 or less. Overall will show the proportion of participants with at least one result meeting the abnormality criteria at any post-baseline time point.
- o For all Part 2 tables:
 - o 'Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)' will be replaced by 'Multiple Doses MK-7762 or Placebo QD'
 - o The food effect columns will be removed.
 - o 'All Part 1 Cohorts' columns will be replaced by the 'All MK-7762 QD' column.
 - o The following footnote will be deleted: **The 'All MK-7762 Fasted' summary includes data from participants who received MK-7762 under fasting conditions only.*
 - o Time points will be Day 2, Day 4, Day 7, Day 10, Day 14, Day 17, Day 21, Day 24, Day 29, EOT (Day 33), and Overall. Overall will show the proportion of participants with at least one result meeting the abnormality criteria at any post-baseline time point.
 - o The baseline footnote will be: Baseline is the last measurement collected prior to first dosing.

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Shell CVS will be in the following LST format:

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Table CVS Vital Sign Summary and Change From Baseline - Part 1 (Safety Population)

		Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)							Food Effect MK-7762 (Cohort 6)		All Part 1 Cohorts*
		Statistic	Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	TBD mg (N=X)	TBD mg Fasted (N=X)	TBD mg Fed (N=X)	All MK-7762 Fasted (N=X)
Vital Sign (units)	Time Point										
Testname (unit)	Baseline	n	X	X	X	X	X	X	X	X	X
		Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
		SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
		Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
		Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
		Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX
	Day 1 Hour 0.5	Absolute	n	X	X	X	X	X	X	X	X
			Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX
		Change	n	X	X	X	X	X	X	X	X
			Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX

Baseline is the last measurement collected prior to dosing in each treatment period.

*The 'All MK-7762 Fasted' summary includes data from participants who received MK-7762 under fasting conditions only.

EOT = End of trial

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

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Programmer Note:

- o For all tables:
 - o The table may be split across 2 pages if it is not possible to fit all columns on 1 page. Additional pooled treatments may be added as outlined in the notes of Section 5 of the SAP.
- o For all Part 1 tables:
 - o Blood pressure and heart rate only will be summarized.
 - o Time points will be Baseline, Day 1 Hour 0.5, Day 1 Hour 1, Day 1 Hour 2, Day 1 Hour 3, Day 1 Hour 4, Day 1 Hour 5, Day 1 Hour 6, Day 1 Hour 8, Day 1 Hour 12, Day 2 Hour 24, Day 2 Hour 36, Day 3, Day 4 and EOT (Day 7). The sample size at EOT for the Cohort 6 summaries will be 4 or less.
- o For all Part 2 tables:
 - o Blood pressure, heart rate, and temperature will be summarized.
 - o 'Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)' will be replaced by 'Multiple Doses MK-7762 or Placebo QD'
 - o The food effect columns will be removed.
 - o 'All Part 1 Cohorts' column will be replaced by the 'All MK-7762 QD' column.
 - o The following footnote will be deleted: **The 'All MK-7762 Fasted' summary includes data from participants who received MK-7762 under fasting conditions only.*
 - o Time points will be Baseline, Day 1 Hour 0.5, Day 1 Hour 1, Day 1 Hour 2, Day 1 Hour 3, Day 1 Hour 4, Day 1 Hour 5, Day 1 Hour 6, Day 1 Hour 8, Day 1 Hour 12, Day 2 Predose, Day 2 Hour 12, Day 3 Predose, Day 3 Hour 12, Day 7 Predose, Day 14 Predose, Day 21 Predose, Day 28 Predose, Day 28 Hour 12, Day 29, and EOT (Day 33).
 - o The baseline footnote will be: Baseline is the last measurement collected prior to first dosing.

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Shell CVSC will be in the following LST format:

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Table CVSC Categorical Summary of Abnormal Vital Signs - Part 1 (Safety Population)

Vital Sign Sign (units)	Time Point	Abnormality Category	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6)		All Part 1 Cohorts*
			Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	TBD mg (N=X)	TBD mg Fasted (N=X)	TBD mg Fed (N=X)	All MK-7762 Fasted (N=X)
SBP (unit)	D1H0.5	140-<160	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 160-<180	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 180	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		< >	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
DBP (unit)	D1H0.5	90-<100	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 100-<110	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		≥ 110	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		< >	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)

*The 'All MK-7762 Fasted' summary includes data from participants who received MK-7762 under fasting conditions only.

Time point Day X Hour X is presented as DXHX.

DBP = Diastolic blood pressure; EOT = End of trial; SBP = Systolic blood pressure

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

Programmer Note:

- o For all tables:
 - o The table may be split across 2 pages if it is not possible to fit all columns on 1 page. Additional pooled treatments may be added as outlined in the notes of Section 5 of the SAP.
 - o Systolic and diastolic blood pressure will be included in this table.
 - o In order to save space, time point Day X Hour X may be presented as DXHX.
 - o At each time point, all abnormality categories will be presented even if no participants meet the criteria.
- o For all Part 1 tables:
 - o Time points will be Day 1 Hour 0.5, Day 1 Hour 1, Day 1 Hour 2, Day 1 Hour 3, Day 1 Hour 4, Day 1 Hour 5, Day 1 Hour 6, Day 1 Hour 8, Day 1 Hour 12, Day 2 Hour 24, Day 2 Hour 36, Day 3, Day 4 and EOT (Day 7). The sample size at EOT for the Cohort 6 summaries will be 4 or less.

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- o For all Part 2 tables:
 - o 'Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)' will be replaced by 'Multiple Doses MK-7762 or Placebo QD'
 - o The food effect columns will be removed.
 - o 'All Part 1 Cohorts' column will be replaced by the 'All MK-7762 QD' column.
 - o The following footnote will be deleted: **The 'All MK-7762 Fasted' summary includes data from participants who received MK-7762 under fasting conditions only.*
 - o Time points will be Day 1 Hour 0.5, Day 1 Hour 1, Day 1 Hour 2, Day 1 Hour 3, Day 1 Hour 4, Day 1 Hour 5, Day 1 Hour 6, Day 1 Hour 8, Day 1 Hour 12, Day 2 Predose, Day 2 Hour 12, Day 3 Predose, Day 3 Hour 12, Day 7 Predose, Day 14 Predose, Day 21 Predose, Day 28 Predose, Day 28 Hour 12, Day 29, and EOT (Day 33).
 - o The baseline footnote will be: Baseline is the last measurement collected prior to first dosing.

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Shell CEG will be in the following LST format:

Table CEG Average of Safety Triplicate 12-Lead Electrocardiogram Summary and Change From Baseline - Part 1 (Safety Population) Page 1 of X

Measurement (units)	Time Point	Statistic	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6)		All Part 1 Cohorts*
			Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	TBD mg (N=X)	TBD mg Fasted (N=X)	TBD mg Fed (N=X)	All MK-7762 Fasted (N=X)
Testname (unit)	Baseline	n	X	X	X	X	X	X	X	X	X
		Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
		SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
		Minimum	XX	XX	XX	XX	XX	XX	XX	XX	XX
		Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
		Maximum	XX	XX	XX	XX	XX	XX	XX	XX	XX
	Day 1 Hour 2	Absolute	n	X	X	X	X	X	X	X	X
			Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX
		Change	n	X	X	X	X	X	X	X	X
			Mean	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			SD	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX	X.XX
			Minimum	XX	XX	XX	XX	XX	XX	XX	XX
			Median	X.X	X.X	X.X	X.X	X.X	X.X	X.X	X.X
			Maximum	XX	XX	XX	XX	XX	XX	XX	XX

Average of triplicates are used in the analysis.

Baseline is the last triplicate measurement collected prior to dosing in each treatment period.

*The 'All MK-7762 Fasted' summary includes data from participants who received MK-7762 under fasting conditions only.

EOT = End of trial

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Programmer Note:

- o For all tables:
 - o The table may be split across 2 pages if it is not possible to fit all columns on 1 page. Additional pooled treatments may be added as outlined in the notes of Section 5 of the SAP.
- o For all Part 1 tables:
 - o Time points will be Baseline, Day 1 Hour 2, Day 1 Hour 6, Day 1 Hour 12, Day 2, and EOT (Day 7). The sample size at EOT for the Cohort 6 summaries will be 4 or less.
- o For all Part 2 tables:
 - o 'Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)' will be replaced by 'Multiple Doses MK-7762 or Placebo QD'
 - o The food effect columns will be removed.
 - o 'All Part 1 Cohorts' column will be replaced by the 'All MK-7762 QD' column.
 - o The following footnote will be deleted: **The 'All MK-7762 Fasted' summary includes data from participants who received MK-7762 under fasting conditions only.*
 - o Time points will be Baseline, Day 1 Hour 2, Day 1 Hour 6, Day 1 Hour 12, Day 2 Predose, Day 3 Predose, Day 7 Predose, Day 14 Predose, Day 21 Predose, Day 28 Predose, Day 28 Hour 2, Day 28 Hour 6, Day 28 Hour 12, Day 29, and EOT (Day 33).
 - o The baseline footnote will be: Baseline is the last triplicate measurement collected prior to first dosing.

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Shell CEGC will be in the following LST format:

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Table CEGC Categorical Summary of Abnormal Safety 12-Lead Electrocardiogram - Part 1 (Safety Population)

Time Point	Result	Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)						Food Effect MK-7762 (Cohort 6)		All Part 1 Cohorts*
		Pooled Placebo (N=X)	50 mg (N=X)	150 mg (N=X)	300 mg (N=X)	600 mg (N=X)	TBD mg (N=X)	TBD mg Fasted (N=X)	TBD mg Fed (N=X)	All MK-7762 Fasted (N=X)
Baseline	Normal	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	ANCS	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	ACS	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Day 1 Hour 2	Normal	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	ANCS	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	ACS	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Day 1 Hour 6	Normal	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	ANCS	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	ACS	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)

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At each time point, the worst assessment of the triplicates is considered.

Baseline is the last triplicate measurement collected prior to dosing in each treatment period.

Percentages are based on the number of participants dosed with available assessments at the time point of interest.

*The 'All MK-7762 Fasted' summary includes data from participants who received MK-7762 under fasting conditions only.

ACS = Abnormal clinically significant; ANCS = Abnormal not clinically significant; EOT = End of trial

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

Programmer Note:

- o For all tables:

- o At each time point, all abnormality categories will be presented even if no participants meet the criteria.

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- For all Part 1 tables:
 - Time points will be Baseline, Day 1 Hour 2, Day 1 Hour 6, Day 1 Hour 12, Day 2, and EOT (Day 7). The sample size at EOT for the Cohort 6 summaries will be 4 or less.
- For all Part 2 tables:
 - 'Single Dose MK-7762 or Placebo Fasted (Cohorts 1-5)' will be replaced by 'Multiple Doses MK-7762 or Placebo QD'
 - The food effect columns will be removed.
 - 'All Part 1 Cohorts' column will be replaced by the 'All MK-7762 QD' column.
 - The following footnote will be deleted: **The 'All MK-7762 Fasted' summary includes data from participants who received MK-7762 under fasting conditions only.*
 - Time points will be Baseline, Day 1 Hour 2, Day 1 Hour 6, Day 1 Hour 12, Day 2 Predose, Day 3 Predose, Day 7 Predose, Day 14 Predose, Day 21 Predose, Day 28 Predose, Day 28 Hour 2, Day 28 Hour 6, Day 28 Hour 12, Day 29, and EOT (Day 33).
 - The baseline footnote will be: Baseline is the last triplicate measurement collected prior to first dosing.

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Shell CUISS will be in the following LST format:

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Table CUISS Shifts to Worst Post-Baseline Visual Acuity Results by Treatment- Part 2 (Safety Population)

Test Name	Treatment	Eye	Baseline Category	Post-baseline Category			
				0	1	2	3
Snellen	Pooled Placebo	Right	0	XX	X	X	X
			1	X	X	X	X
			2	X	X	X	X
			3	X	X	X	X
		Left	0	XX	X	X	X
			1	X	X	X	X
			2	X	X	X	X
			3	X	X	X	X
		<similar for all treatment and test (i.e., Rosebaum) >					

All participants received multiple oral doses of MK-7762 or matching placebo QD for 28 days.

Baseline is the last measurement collected prior to first dosing.

Result categories are as follows: 0= Normal (20/25 or better); 1= Worse than 20/25 but better than or equals to 20/40; 2 = Worse than 20/40 but better than or equals to 20/200; 3 = Worse than 20/200

EOT = End of trial

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

Programmer notes:

- o Treatments will be the same as those presented in Shell CUISS for Part 2 with the exception of the 'All MK-7762 QD' summary which will be excluded.
- o The worst post-baseline result is summarized in this table.

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Shell CVISC will be in the following LST format:

Table CVISC Frequency of Abnormalities in Visual Acuity and Color Vision Assessments by Treatment and Time Point - Part 2 (Safety Population) Page 1 of X

		Multiple Doses MK-7762 or Placebo QD				
Visual Test Abnormality	Time Point	Pooled Placebo (N=X)	TBD mg (N=X)	TBD mg (N=X)	TBD mg (N=X)	All MK-7762 (N=X)
Snellen - Abnormal result in either eye	Day 7	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 14	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 21	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 29	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	EOT	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Overall	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Rosebaum - Abnormal result in either eye	Day 7	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 14	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 21	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 29	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	EOT	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Overall	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
Ishihara - Abnormal result in either eye	Day 7	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 14	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 21	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Day 29	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	EOT	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
	Overall	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)

For Snellen and Rosebaum tests, an abnormal result is a score worse than 20/25 in either eye. For Ishihara color vision test, an abnormal result is a score less than 10 in either eye.

Percentages are based on the number of participants dosed with available assessments at the time point of interest. The overall time point summary presents the number of participants with an abnormal result in either eye at any post-baseline time point.

Baseline is the last measurement collected prior to first dosing.

EOT = End of trial

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Programmer Note:

- o Time points will be Day 7, Day 14, Day 21, Day 29, EOT (Day 33), and Overall. Overall will show the proportion of participants with at least one abnormal result in either eye at any post-baseline time point.
- o The Visual Assessment CRF Normal/Abnormal flags will be used to flag abnormal results. For Ishihara, a participant will be counted if they have an abnormal result in either eye.

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Shell CBPNS will be in the following LST format:

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Table CBPNS Frequency of New Post-Baseline Abnormalities in Peripheral Neuropathy Assessments by Treatment, Time Point, and Severity - Part 2
(Safety Population)

Neuropathy Assessment	Time Point	Abnormality in either Extremity/ Score or Graded Score	Multiple Doses MK-7762 or Placebo QD				
			Pooled Placebo (N=X)	TBD mg (N=X)	TBD mg (N=X)	TBD mg (N=X)	All MK-7762 (N=X)
Symptoms	Day 7	Any Neuropathy Symptom	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 1	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 2	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 3	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Pain, Aching or Burning	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 1	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 2	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 3	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Pins and Needles	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 1	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 2	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 3	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Numbness (Lack of feeling)	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 1	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 2	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Grade 3	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		<similar for all time points>					
Physical Objective Finding	Day 7	Any Objective Finding	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Vibration in Big Toes	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Score 1	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Score 2	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Score 3	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Tendon Reflexes	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Score 1	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Score 2	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		Score 3	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)
		<similar for all time points>					
Both	Day 7	Any Objective Finding and Symptom	X (XX%)	X (XX%)	X (XX%)	X (XX%)	X (XX%)

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At each time point, the table presents the number of participants with a post-baseline result which meets the abnormality criteria and which was not present at baseline. The overall time point summary presents the number of participants meeting the abnormality criteria at any post-baseline time point.

Percentages are based on the number of participants dosed with available assessments at the time point of interest. For the overall time point summary, percentages are based on the number of participants dosed and with at least one available post-baseline assessment.

Baseline is the last measurement collected prior to first dosing.

When participants experience multiple events meeting the criteria, the worst grade/score is summarized.

For neuropathy symptom assessments, scores are graded as follows: Grade 1 = Scores 01-03; Grade 2 = Scores 04-06; Grade 3 = Scores 07-10, where scores are on a 01 to 10 scale with 01 = Mild and 10 = Severe.

For vibration in big toes: Score 1 = Mild loss; Score 2 = Moderate loss; Score 3 = Severe loss

For tendon reflexes: Score 1 = Hypoactive; Score 2 = Normal deep tendon reflexes; Score 3 = Hyperactive deep tendon reflex; Score 4 = Clonus
EOT = End of Trial

Source: < >

Program: /CAXXXXX/sas_prg/stsas/tab/programname2022Q1.sas DDMMYYYY HH:MM

Programmer Note:

- o Time points will be Day 7, Day 14, Day 21, Day 29, EOT (Day 33), and Overall. Overall will show the proportion of participants with meeting the criteria in either extremity at any post-baseline time point.
- o Please refer to Section 6.12 of the SAP for details on the analysis and definitions of abnormal results.
- o Neuropathy symptoms are Pain, Aching, or Burning in Feet, Legs; Pins and Needles in Feet, Legs; Numbness [Lack of Feeling] in Feet, Legs. Physical objective findings are CRF Great Toe Distal Interphalangeal (labelled as Vibration in Big Toes) and Ankle Reflexes (labelled as Tendon Reflexes).
- o The following steps will be followed to distinguish a new post-baseline event at each time point:
 1. For each extremity and symptom/objective finding, compare baseline score to the post-baseline score and only select those worse than the baseline value and abnormal. For neuropathy symptom, abnormality refers to a score within 01-10 and for physical objective testing, abnormality is defined as scores within 1-3 for vibration or scores of 1-4 for tendon reflexes.
 2. For each type of event (each symptom or each objective physical finding), select the worst grade of both extremities from the values selected in step 1.
 3. For symptoms, Grade scores selected from step 2 according to the following classification: Grade 1 = Scores 01-03; Grade 2 = Scores 04-06; Grade 3 = Scores 07-10.
 4. Scores selected in step 2 for objective physical findings and step 3 for symptoms will be used in the summaries.
- o The summary of 'Any Neuropathy Symptom' will include participants with a score of Grade 1 or higher (Step 3 above) in at least one symptom. The worse grade across all symptoms will be presented for grade frequency counts for this summary.

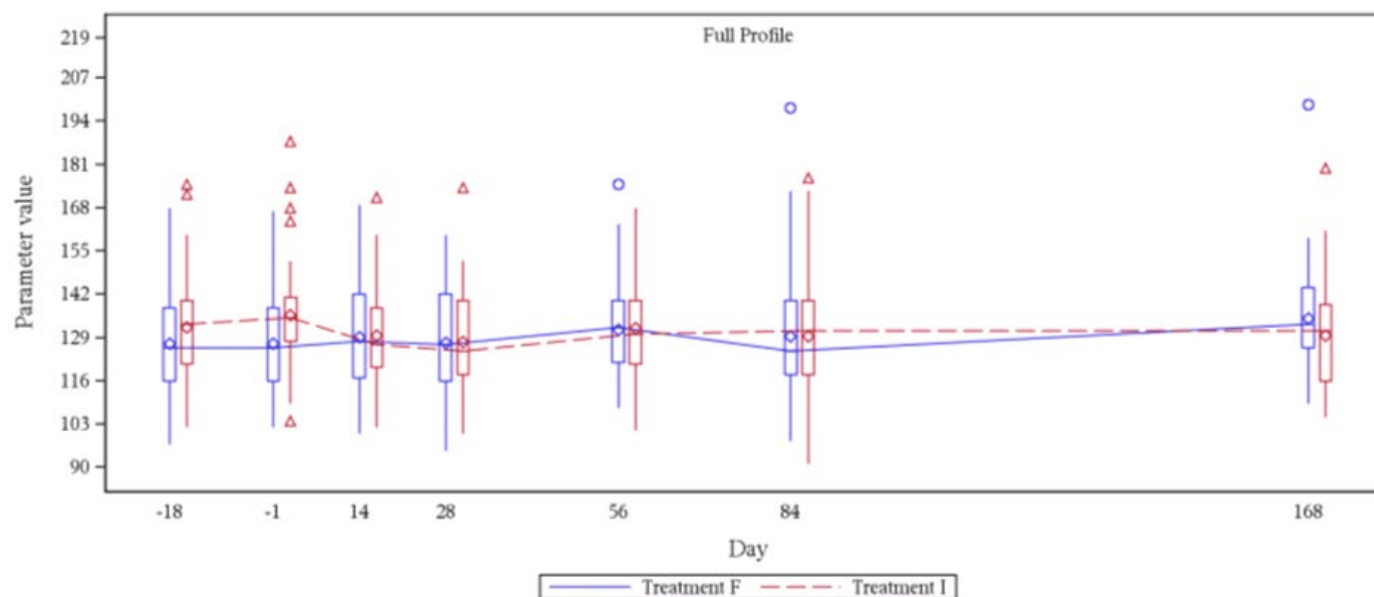
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- o The summary of 'Any Objective Finding' will include participants with scores 1 through 3 for vibration in big toes or scores 1-4 for tendon reflexes in either extremities.
- o The summary of 'Any Objective Finding and Symptom' will include participants who experience at least one symptom and at least one objective finding at each time point or overall.
- o Frequency counts of scores will not be presented for the following abnormality criteria/time point:
 1. 'Any Objective Finding' summary at all time points
 2. 'Any Objective Finding and Symptom' summary at all time points
 3. 'Vibration in Big Toes' and 'Tendon Reflexes' summaries at the 'Overall' time point.

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Figures BOXP will be in the following format:

Figure BOXP Boxplot of <Clinical Laboratory Test Name> by Treatment and Time Point - Part 1 (Safety Population)



Programmer notes:

- Time points & treatments (with corresponding Treatment description legend) applicable for each part will be presented in consistency with the summary table, with the exception of the pooled summary.
- The y-axis label will be the parameter name (unit)

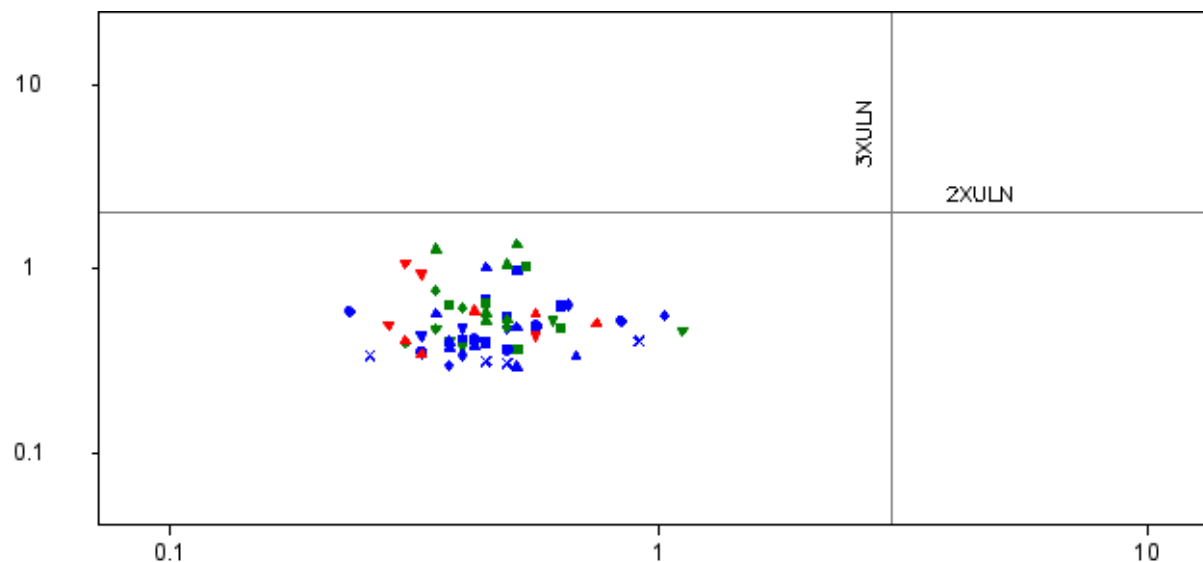
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- The x-axis label will be Time Point (Days).
- The following footnote will be added to explain the features of the boxplot, e.g., *The horizontal line in the box interior represents the median. The symbol in the box interior represents the mean. Values outside the whiskers are identified with symbols. The upper (lower) edge of the box represents the 75th (25th) percentile. A whisker is drawn from the upper (lower) edge of the box to the largest (smallest) value within 1.5× interquartile range above (below) the edge of the box.*

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Figures EDISH will be in the following format:

Figure EDISH E-DISH Scatter Plot of Maximum Total Bilirubin Versus Maximum <Aspartate Aminotransferase or Alanine Aminotransferase> Post-Baseline - Part 1 (Safety Population)



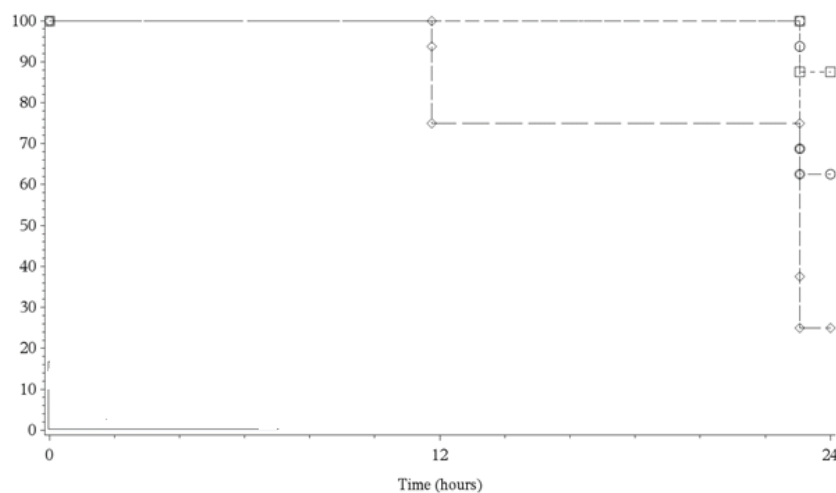
Programmer notes:

- Treatments (with corresponding Treatment description legend) will be identified with different symbols.
- The y-axis label will be 'Maximum Total Bilirubin (value/ULN)'
- The x-axis label will be 'Maximum <Aspartate Aminotransferase or Alanine Aminotransferase>(value/ULN)'

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Figures KMPLLOT will be generated as follows:

Figure KMPLLOT Kaplan-Meier Cumulative Incidence Plot - Time to Adverse Event Resolution in Participants With Ongoing Neurologic or Hematologic Adverse Event of Special Interest at Time of Treatment Discontinuation - Pooled Placebo - Part 2 (Safety Population)



Programmer notes:

- These figures will only be generated if there are more than 5 participants with ongoing AESIs at the time of treatment discontinuation.
- There will be a separate figure for each treatment.
- The y-axis label will be 'Percent of Participants With Resolved AESI'
- The x-axis label will be 'Time (Days)'
- 95% confidence bands will also be presented in the figures as outlined in the SAP.

DocuSign Envelope ID: 5135543D-B495-416D-9C71-4D33D78F7EC4

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3. LISTING SHELLS

The following listing shells provide a framework for the display of data from this trial. The shells may change due to unforeseen circumstances. These shells may not be reflective of every aspect of this trial, but are intended to show the general layout of the listings that will be presented and included in the final report. Listings will be generated from data created in accordance with SDTM Model 1.4 with Implementation Guide 3.3. Listings with derived data (i.e., triplicate ECGs) may be created from the ADaM data. All listings will be presented in Courier New size font 9. Time point information (period, day, hour) will match that found in the CRF. Part 2 listings will follow the same format as Part 1 listing shells.

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Appendix 16.1.10.1 Clinical Laboratory Reference Ranges

Laboratory Group	Test Name	Sex	Age Category	Reference Range	Unit
Chemistry	Testname1	MALE		XX - XXX	mEq/L
	Testname2	MALE	0-25	XX - XXX	U/L
			26-99	XX - XXX	U/L
<similar for all other tests, note that age will only be presented when different reference range exists>					
Hematology	<similar to chemistry>				
Urinalysis	Testname	MALE		NEGATIVE	
Urine Drug Screening	Amphetamines	MALE		NOT DETECTED	

Source: SDTM.LB; SDTM.MB
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.1.1 Participant Disposition - Part 1 (Safety Population)

			Study Drug Discontinuation				End of Trial			
Cohort	Participant Number	Treatment/ Treatment Sequence	Did Participant	Treatment	Primary Treatment		Did Participant	Date of	Primary	
			Prematurely Discontinue?	Discontinuation Date	Discontinuation Reason	Specify	Complete the Trial?	Completion/Discontinuation	Discontinuation Reason	Specify
1	1001	50 mg Fasted	No				Yes	DDMMYYYY		
	1002	Placebo	No				No	DDMMYYYY	Personal Reason	XXXXX
	1003	Placebo	Yes	DDMMYYYY	Adverse Event	XXXXXXX	No	DDMMYYYY	Other	XXXX

Programmer note: For participants in Cohort 6, treatment sequence will be TBD mg Fasted/Fed or TBD mg Fed/Fasted.

Following footnotes will be included in all listings that contain treatment column:

All participants received a single oral dose of MK-7762 or matching placebo under fasting conditions with exception of Cohort 6 which was designed as a cross-over food effect cohort with one fasted trial period and one fed trial period.

Similar footnote for MAD (only shown on first listing):

All participants received multiple oral doses of MK-7762 or matching placebo QD for 28 days.

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMMYYYY HH:MM

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Appendix 16.2.1.3 Participant Disposition - Screen Failures

Screening ID	Discontinuation Date	Primary Reason for Discontinuation	Specify
X			
X			
XX	DDMMYYYY	Adverse Event	XXXXXXX

Source: < >

Program: /CAXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMMYYYY HH:MM

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Appendix 16.2.2.1 Protocol Deviations

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Cohort	Participant Number	Trial Period	Treat- ment	Day	Hour	Deviation Date	Deviation Category	Deviation	Severity
1	XXX	X	X	X	XX.XX	DDMONYYYY	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX
				X	XX.XX	DDMONYYYY	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX
				X	XX.XX	DDMONYYYY	XXXXXXXXXX	XXXXXXXXXX	XXXXXXXXXX

Include treatment note seen on 16.2.1.

Programmer Note: A spreadsheet containing protocol deviations will be provided by the Clinical Study Manager to the SDTM programmer for incorporation in the SDTM. This listing will be generated off the SDTM dataset. If there are more variables or less collected in the spreadsheet, they will be presented or removed from this listing, accordingly.

Program: /CAXXXXX/sas_prg/stsas/lis_PROGRAMNAME.sas DDMMYYYY HH:MM

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Appendix 16.2.4.1.1 Demographics - Part 1 (Safety Population)

Cohort	Participant Number	Birth MMYYYY	Age (yr)	Sex	Race	Ethnicity	Height (cm)	Weight (kg)	Body Mass Index (kg/m ²)	Protocol Version	Consent		
											Informed?	PG?	Withdrawn?
1	1001	Feb2023	47	Male	< >	Hispanic or Latino	XXX	XX.X	XX.XX	< >	DDMMYYYY	Yes	DDMONYYY
	1002	<similar to above>										No	

Age is approximated by subtracting the date of birth (day is not collected so the first day of the month is used) from the date of informed consent. If calculated difference is one more than the protocol maximum age then the age approximation will be the calculated difference - 1.

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYY HH:MM

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Appendix 16.2.4.1.3 Demographics - Screen Failures

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Screening ID	Birth YYYY	Sex	Race	Ethnicity	Informed Consent Date
< >	XXXX	Male	< >	Hispanic or Latino	DDMMYYYY
< >	<similar to above>				

Source: < >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.4.2.1 Physical Examination – Part 1 (Safety Population)

Cohort	Participant Number	Trial Period	Treatment	Day	Hour	Date	Type	Question	Answer
1	1001	Screen				DDMONYYYY	Complete	Was PE performed? (Yes/No)	YES
		1	50 mg Fasted	-1	-17.75	DDMONYYYY	Complete	Was PE performed? (Yes/No)	NO
				3	51.53	DDMONYYYY	Complete	Was PE performed? (Yes/No)	NO

<similar for all participants>

Include treatment note seen on 16.2.1.
PE = Physical examination

Source: < >
Program: /CAXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.4.3.1 Medical History - Part 1 (Safety Population)

Cohort	Participant Number	Any History?	System Organ Class Preferred Term (Verbatim)	Date		Ongoing?
				Start	End	
1	1001	No				
	1002	Yes				

<note date can be YYYY, MONYYYY, or DDMONYYYY based on individual participant data>

Include treatment note seen on 16.2.1.
History Events are classified according to MedDRA Version 26.0.

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.4.4.1 Substance Use - Part 1 (Safety Population)

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Cohort	Participant Number	Substance	Description of Use	Start Date	End Date
1	1001 1002	Tobacco Use NON-SMOKER	0-4 CIGARETTES WEEK	DDMONYYYY DDMONYYYY	DDMONYYYY

Include treatment note seen on 16.2.1.

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.5.1.1 Participant Eligibility - Part 1 (Safety Population)

Cohort	Participant Number	Did participant meet all eligibility criteria?	Criterion Not Met	Specify
1	1001 1002	YES NO	Exclusion 5	<specify and criterion not met will only be presented if populated>
<similar for all participants>				

Source: < >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

Programmer note: Screen failure listing will be identical to this one with the exception of removing the cohort and specify columns and participant number will be replaced with Screening ID.

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Appendix 16.2.5.2.1.1 Test Compound Description - Part 1

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CRF Treatment Description	Form	Route
< >	SOLUTION	ORAL

Source: < >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.5.2.1.2 Test Compound Administration Times - Part 1 (Safety Population)

Cohort	Participant Number	Trial Period	Treatment	Day	Hour	Dose Date	Dose Time	Dosing Compliance Met?	Compound	Planned Dosage	Comments
1	1	1	50 mg Fasted	1	0.00	DDMONYYYY	HH:MM:SS	Yes	< >	500 NCI	<This column prints only if data is

Include treatment note seen on 16.2.1.

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.5.3 Meal Times - Part 1 (Safety Population)

Participant Number	Trial Period	Treatment	Day	Hour	Interval	Event	Start		Stop	
							Date	Time	Date	Time
X	X	XXXXXX	-1	-15.0		DINNER	DDMONYYYY	HH:MM:SS	DDMONYYYY	HH:MM:SS
				-11.0		SNACK	DDMONYYYY	HH:MM:SS	DDMONYYYY	HH:MM:SS
			1	4.1		LUNCH	DDMONYYYY	HH:MM:SS	DDMONYYYY	HH:MM:SS

Include treatment note seen on 16.2.1.

Source: < >

Program: /CAXXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.5.4.1 Prior and Concomitant Medications - Part 1 (Safety Population)

Cohort	Participant Number	Treatment	Prior?	Medication (WHO DD)	Dosage	Route	Start Date (Study Day)	Start Time	End Date (Study Day)	End Time	Frequency	Indication	Ongoing?
1	1001		None										
	1002		None										
	1003		Yes	CETIRIZINE (CETIRIZINE)	X MG	BY MOUTH	DDMONYYYY		DDMONYYYY	HH:MM	XXXXXXX	XXXXXXX	NO
		50 mg Fasted	No	PARACETAMOL (PARACETAMOL)	X MG	XXXXXXXXX	DDMONYYYY	HH:MM	XXXXXXXXX	HH:MM	XXXXXXXXX	XXXXXXXXX	XX

Include treatment note seen on 16.2.1.

Concomitant medications are coded with WHO Drug Dictionary Version 01-Mar-2023 b3.

WHO DD = World Health Organization Drug Dictionary

Prior is defined as a medication administered prior to the first study drug administration.

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.7.1.1 Adverse Events - Part 1 (Safety Population)

Cohort	Participant Number	Age/ Sex	Treatment	TEAE?	AESI?	System Organ Class/ Preferred Term (Verbatim)	Time From Last Dose (DD:HH:MM)	Study Day: Date:Time Start/ End Duration (DD:HH:MM)	Serious/ Outcome	Severity/ Frequency	Study Product Relationship/ Action
1	1001	30/F				None					
	1002	24/M				None					
	1003	52/M	50 mg Fasted	Yes	No	XXXXXXXXXXXXX/ XXXXXXXXXXXXX (XXXXXXXXXXXXX)	XX:XX:XX	X:DDMONYYYY:HH:MM/ X:DDMONYYYY:HH:MM 00:23:15	No/ Resolved	Moderate/ Intermittent	Related/ Drug Withdrawn
			50 mg Fasted	Yes	Yes	<similar to above>					

Include treatment note seen on 16.2.1.

Adverse events are classified according to MedDRA Version 26.0.

TEAE = Abbreviation for treatment-emergent adverse event; AESI = Adverse Event Special Interest

F = Female; M = Male

Programmer Note:

For all listings:

- AEs should be presented start date/time order for each participant.

For Part 2 listings:

- A 'VC?' flag will be added after the 'AESI?' flag. This will be populated as 'Yes' for AEs related to visual acuity decrease or color vision change as outlined in Section 6.4 of the SAP.
- A '#' symbol will also be tied to the AESI response (i.e., Yes#) when the AESI is an ongoing neurologic and hematologic AESI as outlined in Section 6.4 of the SAP.
- Screen Failure listing will resemble this listing; however, the cohort and treatment will not be included and participant number will be replaced by Screening ID.

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.7.1.2 Details for Serious Adverse Events - Part 1 (Safety Population)

Cohort	Participant Number	Age/ Sex	Treatment	System Organ Class/ Preferred Term	Class/ TE? (Verbatim)	Study Day: Date:Time Start/ End Duration*	Serious Event	Persistent/ Congenital Anomaly/ Birth Defect	Significant Disability/ Incapacity	Hospital- ization	Life- Threat	Important Medical Event	Death
1	1001	52/M	50 mg Fasted	Yes^	XXXXXXXXXXXX/ XXXXXXXXXXXXXXX (XXXXXXXXXXXXX)	X:DDMONYYYY:HH:MM/ X:DDMONYYYY:HH:MM 00:23:15	Yes	No	No	Yes	No	Yes: < >	No

Programmer Note: If Serious = Yes then present AEs in this listing otherwise please do not include this listing. Screen Failure listing will resemble this listing; however, the cohort and treatment columns will not be included and participant number will be replaced by Screening ID.

Include treatment note seen on 16.2.1.
Adverse events are classified according to MedDRA Version 26.0.
* Duration is represented by DD:HH:MM; TE = Abbreviation for treatment-emergent
^ Adverse Event is of Special Interest
F = Female; M = Male

Source: < >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.7.2.3 Ongoing Neurologic and Hematologic Adverse Events of Special Interest at Time of Treatment Discontinuation - Part 2
(Safety Population)

Cohort	Participant Number	Age/ Sex	Treatment	TE?	System Organ Class/ Preferred Term (Verbatim)	Study Day: Date:Time Start/ End Duration (DD:HH:MM)	Outcome/ Action	Date of Treatment Discontinuation	Time to AE Resolution (Days)
X	XXXX	XX/X	TBD mg	Yes	XXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX (XXXXXXXXXXXXX)	X:DDMONYYYY:HH:MM/ X:DDMONYYYY:HH:MM 00:23:15	Resolved/ Drug Withdrawn	DDMONYYYY	X
	XXXX	XX/X	TBD mg	Yes	XXXXXXXXXXXXX/ XXXXXXXXXXXXXXXXXXXX (XXXXXXXXXXXXX)	DDMONYYYY:HH:MM/ UNK	Not Resolved/ Not Recovered/ Drug Withdrawn	DDMONYYYY	X*
<similar to above>									

Programmer Note: AEs should be presented start date/time order for each participant. This listing will only presents ongoing hematologic and neurologic AESIs at time of treatment discontinuation. These will be flagged using the criteria outlined in Section 6.4 of the SAP. Time to AE Resolution will be derived as described in Section 6.4 of the SAP. Censored events will be flagged with a '*'.

Include treatment note seen on 16.2.1.
Adverse events are classified according to MedDRA Version 26.0.
TE = Abbreviation for treatment-emergent
F = Female; M = Male
* Time is censored in the analysis.

Source: < >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Clinical Laboratory listings will resemble Appendix 16.2.8.1.

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Appendix 16.2.8.1 Clinical Laboratory Report - Chemistry - Part 1 (Safety Population)

Cohort	Participant Number	Age/ Sex	Trial Period	Treatment	Day	Hour	Date	Time	Chloride M: 97-105 (mEq/L)	Potassium M: 3.7-5.2 (mEq/L)	Phosphorus M: 2.4-4.4 (mg/dL)	Sodium M: 135-143 (mEq/L)
1	1001	XX/M	Screen				DDMONYYYY	HH:MM:SS	XXX	X.X	X.X	XXX H
			1	50 mg Fasted	1	-17.00	DDMONYYYY	HH:MM:SS	XXX H	X.X	X.X	XXX H G1
			Recheck				DDMONYYYY	HH:MM:SS	XXX	X.X	X.X	XXX

<similar to above for all participants/time points>

Programmer note: Derived DAIDs grades will be presented along with the abnormality flags.

Include treatment note seen on 16.2.1.

F = Female; M = Male

H = Above reference range

DAIDS Grade: G1 = Grade 1; G2 = Grade 2; G3 = Grade 3; G4 = Grade 4

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.8.1.7 Vital Signs - Part 1 (Safety Population)

Cohort	Participant Number	Age/ Sex	Trial Period	Treatment	Day	Hour	Date	Time	Blood Pressure (mmHg)	Pulse (bpm)	Respir- ation (brpm)	Temper- ature (°C)	Weight (kg)
									Sys/Dia				
1	1001	30/F	Screen				DDMONYYYY	HH:MM:SS	XXX/ XX	XX	XX	XX.X	XX.X
							R	HH:MM:SS	XXX/ XX*				
							R	HH:MM:SS	XXX^/ XX				
			1	50 mg Fasted	-1	-17.00	DDMONYYYY	HH:MM:SS	XXX/ XX				

Include treatment note seen on 16.2.1.
F = Female; M = Male
R = Recheck value; brpm = breaths/min
^ = Systolic > 140 mmHg; * = Diastolic > 90 mmHg

Source: < >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.8.1.8 Safety 12-Lead Electrocardiogram - Part 1 (Safety Population)

Cohort	Participant Number	Age/ Sex	Trial Period	Treatment	Day	Hour	Date	Time	Result	Heart Rate (bpm)	RR (msec)	PR (msec)	QRS (msec)	QT (msec)	QTcF (msec)	Specify/Comments
1	1001	30/F	Screen				DDMONYYYY	X:XX:XX	WNL	XX	XXX	XX	XX	XXX	XXX	EARLY REPOLARIZATION; LEFT AXIS DEVIATION
			1	50 mg Fasted	-1	X.XX	DDMONYYYY	XX:XX:XX	ANCS	XX	XXX	XX	XX	XXX	410	LEFT AXIS DEVIATION
						X	X.XX	DDMONYYYY	XX:XX:XX	< >	XX	XXX	XX	XXX	441	SINUS BRADYCARDIA
						X	X.XX	DDMONYYYY	XX:XX:XX	< >	XX	XXX	XX	XXX	451#	

Include treatment note seen on 16.2.1.

F = Female; M = Male

WNL = Within normal limits; ANCS = Abnormal, not clinically significant

QTcF = QT corrected for heart rate using Fridericia's correction

= QTc value greater than 450 msec

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.8.1.9 Safety 12-Lead Electrocardiogram - Average of Triplicates - Part 1 (Safety Population)

Cohort	Participant Number	Age/ Sex	Trial Period	Treatment	Day	Hour	Result	Heart Rate (bpm)	RR (msec)	PR (msec)	QRS (msec)	QT (msec)	QTcF (msec)
1	1001	30/F	1	50 mg Fasted	Baseline		Normal	XX.X	XX.X	XX.X	XX.X	XX.X	410.2
					X X.XX		Normal	XX.X	XX.X	XX.X	XX.X	XX.X	451.4 # @

Programmer Note: Averaged triplicate values will be displayed to the nearest tenth.

Include treatment note seen on 16.2.1.

This listing only presents average triplicate 12-lead electrocardiogram results used during analysis. Result is the worst assessment of the triplicate records.

Baseline is the last triplicate measurement collected prior to dosing in each treatment period.

F = Female; M = Male

QTcF = QT corrected for heart rate using Fridericia's correction

= QTc value greater than 450 msec; @ = QTc change from baseline greater than 30 msec

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMYYYYY HH:MM

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Appendix 16.2.8.1.10 Visual Assessment - Part 1 (Safety Population)

Cohort	Participant Number	Trial Period	Treatment	Day	Hour	Date	Time	Corrective Lenses?	Snellen			Rosenbaum			
									Right	Left	Overall	Right	Left	Overall	
1	1001	Screen				DDMONYYYY	HH:MM	No	XXXX	#	XXXX	XXXX	XXX	XXXX	XXXX
<similar for all participants/time points>															

Programmer note: For Part 1, treatment, day, and hour columns may be removed from the listing. A score worse than 20/25 is a score with a denominator that is greater than 25.

Include treatment note seen on 16.2.1.

= Shellen/Rosenbaum score worse than 20/25

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.8.1.10 Visual Assessment - Part 1 (Safety Population)

Cohort	Participant Number	Trial Period	Treatment	Day	Hour	Date	Time	Corrective Lenses?	Ishihara Right		Ishihara Left	
									Correct/14	Overall	Correct/14	Overall
1	1001	Screen				DDMONYYYY	HH:MM	No	< > *	Normal	< >	Normal
<similar for all participants/time points>												

Programmer note: For Part 1, treatment, day, and hour columns may be removed from the listing. A 'Derived Overall' column will be included in the Part 2 listing and will be populated as *Normal* if the participant has a normal result in both eyes or *Abnormal* if the participant has an abnormal result in either eye.

Include treatment note seen on 16.2.1.

* = Ishihara score less than 10

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.8.1.11 Brief Peripheral Neuropathy Assessment - Part 1 (Safety Population)

Cohort	Participant Number	Trial Period	Treatment	Day	Hour	Date	Completed?	Pain, Ache, Burn		Pins, Needles		Numbness		Peripheral Neuropathy Grade
								Right	Left	Right	Left	Right	Left	
1	1001	Screen				DDMONYYYY	No: Subject Declined	XXXX	XXXX	XXXX	XXX	XXXX	XXXX	XXX
<similar for all participants/time points>														

Programmer note: For Part 1, treatment, day, and hour columns may be removed from the listing.

Include treatment note seen on 16.2.1.

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.8.1.11 Brief Peripheral Neuropathy Assessment - Part 1 (Safety Population)

Cohort	Participant Number	Trial Period	Treatment	Day	Hour	Date	Perception of Vibration Completed?	Great Toe Distal Interphalangeal		Deep Tendon Reflexes Completed?	Ankle Reflexes	
								Right	Left		Right	Left
1	1001	Screen				DDMONYYYY	No: Subject Declined	XXXX	XXXX	XXXX	XXX	XXXX
	<similar for all participants/time points>											

Programmer note: For Part 1, treatment, day, and hour columns may be removed from the listing.

Include treatment note seen on 16.2.1.

Source: < >

Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM

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Appendix 16.2.8.2.12 New Post-Baseline Abnormalities in Neuropathy Symptom and Objective Physical Finding Assessments - Part 2 (Safety Population)

Cohort	Participant Number	Trial Period	Treatment	Day	Hour	Date	Symptom or Objective Finding	Symptom or Finding	Worst Grade or Score
1	XXXX	1	TBD mg QD	X	XX.XX	DDMONYYYY	Symptom	Pain, Ache, Burn Pins, Needles	Grade 1 (Score 01-03) Grade 2 (Score 04-06)
<similar for all participants/time points>							Objective Finding	GTDI Ankle Reflexes	2 (Moderate) 1 (Mild)

Programmer note: This listing will only present treatment-emergent results which will be considered for analysis as described in Section 6.12 of the SAP and in the corresponding summary table notes.

Include treatment note seen on 16.2.1.
This listing is based on the neuropathy assessment data from the CRF.

Source: < >
Program: /CAXXXXX/sas_prg/stsas/lis/programname2022Q1.sas DDMONYYYY HH:MM