Official Protocol Title:	A Phase 2a, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of MK-6194 in Adult Participants with Non-Segmental Vitiligo
NCT number:	NCT06113328
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TITLE PAGE

STATISTICAL ANALYSIS PLAN

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Protocol Title: A Phase 2a, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of MK-6194 in Adult Participants with Non-Segmental Vitiligo

Protocol Number: 007-02

Compound Number: MK-6194

Sponsor Name:
Merck Sharp & Dohme LLC (hereafter called the Sponsor or MSD)
Legal Registered Address:
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1 INTRODUCTION

This SAP is a companion document to the protocol. While Section 9 of the protocol provides the principal features of the confirmatory analyses for this trial, this SAP provides additional statistical analysis details/data derivations and may document modifications or additions to the protocol-specified analysis plan that are not principal in nature and/or result from information that was not available at the time of protocol finalization.

2 SUMMARY OF CHANGES

SAP Version #	SAP Section # and Name	Description of Change	Brief Rationale
01	3.3.1 Efficacy endpoint	Adding the exploratory endpoints	This update adds analysis details about the exploratory endpoints for completeness
01	3.3.3 Derivation of the Efficacy endpoints	Adding the derivation details of exploratory endpoints	Same above
01	3.3.3 Derivation of the Efficacy endpoints	Adding details of baseline and analysis window definition	ensuring consistency of baseline derivation between sap and analysis specification finalized after previous sap version
01	3.5.2 Statistical Methods for Efficacy Analyses	Add analysis details for the exploratory endpoints	This update adds analysis details before the database lock to ensure they are finalized before unblinding the data. This step is essential to maintain the integrity and unbiased nature of the analysis.
01	3.7 Multiplicity	CCI [redacted]	[redacted]

SAP Version #	SAP Section # and Name	Description of Change	Brief Rationale
01	3.8 Sample Size	CCI [redacted]	[redacted]
01	3.9 Subgroup analysis	Subgroup information update	The subgroup, Skin type (Fitzpatrick scale Type I and II, Type III to VI), is removed because its data is not collected

3 ANALYTICAL AND METHODOLOGICAL DETAILS

This section outlines the statistical analysis strategy and procedures for the study. If, after the study has begun, but prior to any unblinding, there are changes made to the primary hypothesis, or the statistical methods related, then the protocol will be amended (consistent with ICH Guidance for Industry E9). Changes to non-confirmatory analyses made after the protocol has been finalized, but prior to unblinding will be documented in a SAP and referenced in the CSR for the study. Post-hoc exploratory analyses will be clearly identified in the CSR. Separate analysis plans (ie, separate documents from the SAP) will be developed to detail other planned analyses including those specific to the analysis of PK data.

3.1 Responsibility for Analyses/In-house Blinding

The statistical analysis of the data obtained from this study will be the responsibility of the Sponsor.

This study will be conducted as a double-blind study under in-house blinding procedures. The official, final database for the Double-Blind Treatment Period (at Week 24) will not be unblinded until medical/scientific review has been performed, protocol deviations have been identified, and data have been declared final and complete. Only the clinical database and sponsor personnel directly involved in the Week 24 analysis and reporting will become unblinded at the time of the Week 24 database lock.

The extension period of this study will also be conducted as a blinded study. The database of the extension period will be unblinded after the end of the Blinded Extension Period (Week 52). Additional efficacy and safety analyses will be performed based on the data acquired from the completion of the extension period.

The Biostatistics and Research Decision Sciences department will generate the randomized allocation schedule(s) for study treatment assignment.

3.2 Hypotheses/Estimation

Objectives and hypotheses of the study are stated in Section 3 of the protocol.

3.3 Analysis Endpoints

Efficacy and safety endpoints that will be evaluated for within- and/or between-treatment differences are listed below.

3.3.1 Efficacy Endpoints

Primary Efficacy Endpoint

- Percent change from baseline in F-VASI at Week 24

Secondary Efficacy Endpoint

- Percent change from baseline in T-VASI at Week 24

Exploratory Efficacy Endpoints

- Change from baseline in VitiQoL score at all timepoints assessed
- VNS score at all timepoint accessed
- VNS responder status at all timepoints assessed
- PGI-S and PGIC/M measurement at all timepoints assessed
- PGI-S and PGIC/M responder status at all timepoints assessed
- CGI-S and CGI-C measurement at all timepoints assessed
- CGI-S and CGI-C responder status at all timepoints assessed
- CCI [redacted]

3.3.2 Safety Endpoints

Safety endpoints are stated in Section 3 of the protocol.

Safety and tolerability will be assessed by clinical review of all relevant parameters including adverse events, laboratory values, and vital signs.

3.3.3 Derivations of Efficacy Endpoints

Baseline for efficacy variables is defined as the last non-missing value measured on or before the first study intervention.

CCI [redacted]

CCI [redacted]

Percent change from baseline is defined as the value at a specific visit minus the baseline value, divided by baseline value and multiplied by 100%, ie,

$$\%Change\ from\ Baseline\ in\ F\text{-}VASI = \frac{Post\ Baseline\ F\text{-}VASI - Baseline\ F\text{-}VASI}{Baseline\ F\text{-}VASI} \times 100\%$$

A negative percent change from baseline signifies an improvement.

The extent of depigmentation is expressed by the following 6 percentages: 10%, 25%, 50%, 75%, 90%, or 100%. Area with no depigmentation will be 0% and will not be considered for VASI calculation.

- 100% depigmentation: no pigment is present;
- 90% depigmentation: specks of pigment are present;
- 75% depigmentation: the depigmented area exceeds the pigmented area;
- 50% depigmentation: the depigmented and pigmented areas are equal;
- 25% depigmentation: the pigmented area exceeds the depigmented area;
- 10% depigmentation: only specks of depigmentation are present.

3.3.3.1 F-VASI

The F-VASI is calculated using a formula that includes contribution of affected facial surface areas showing six different depigmentation rates (above) with a modified method described below

$$F\text{-}VASI = \sum_{all\ face\ area*} [Fingertip\ Units] \times 0.03 \times [Depigmentation\ Rates]$$

*Scalp, neck, eyebrows, eyelashes, and vermilion will be excluded from this calculation

The percentage of vitiligo involvement is estimated in fingertip units by the same investigator if possible, during the entire course of the study. The FACE is defined as the area between the hairline, chin, and up to the ears. The area of the face is divided into 4 quadrants. The investigator uses his/her finger to mimic the participant's finger size to

evaluate vitiligo involvement. Since one fingertip unit is approximately 0.03% of the body surface area (BSA), the coefficient 0.03 was applied to the calculation.

3.3.3.2 T-VASI

The T-VASI is calculated using a similar formula as F-VASI, however all body regions will be included in the formula. The body is divided into the following 6 mutually exclusive areas 1) Head/Neck (Including the Face), 2) Hands, 3) Upper extremities (Excluding the hands), 4) Trunk (Including genitalia; Excluding buttocks), 5) Lower extremities (Including buttocks, Excluding the feet), and 6) Feet. The percentage of vitiligo involvement is estimated in hand units (% of BSA) by the same investigator if possible, during the entire course of the study. The investigator uses his/her hand to mimic the participant's hand size to evaluate % BSA vitiligo involvement.

$$T\text{-}VASI = \sum_{all\ body\ sites} [Hand\ Units] \times [Depigmentation\ Rates]$$

3.3.3.3 F-VASI-(25/50/75/90)

F-VASI-(25/50/75/90) represents greater than 25/50/75/90% improvement (a negative value in percent change from baseline indicates improvement) from baseline (ie, % change in F-VASI score from baseline ≤ -25/-50/-75/-90%), *eg,* the binary variable F-VASI-25 = 1 if percent improvement from baseline ≥ 25% (% change from baseline ≤ -25%); F-VASI-25 = 0 otherwise,

$$F\text{-}VASI\text{-}25\ Responder: \frac{Post\ Baseline\ F\text{-}VASI\ -\ Baseline\ F\text{-}VASI}{Baseline\ F\text{-}VASI} \times 100\% \leq -25\%$$

3.3.3.4 T-VASI-(25/50/75/90)

T-VASI-(25/50/75/90) represents greater than 25/50/75/90% improvement from baseline (ie, % change in T-VASI score from baseline ≤ -25/-50/-75/-90%).

3.3.3.5 VitiQoL

The VitiQoL is a 16-item validated, disease-specific instrument that measures the impact of vitiligo on patients' social, emotional and physical functioning. Items are scored using a 7-point Likert scale (0 – 6), the final score could range from 0 to 96, with lower scores indicating better quality of life. Percent change from baseline is defined as the value at a specific visit minus the baseline value, divided by baseline value and multiplied by 100%.

3.3.3.6 VNS

The VNS is a single-item measure that asks patients to rate the noticeability of their vitiligo compared with before they started treatment on a 5-point scale ranging from 1 (more noticeable) to 5 (no longer noticeable).

Participants with scores ranging from 4 to 5 are classified as responders.

3.3.3.7 PGI-S

The PGI-S is a 2-item measure asking the participant to rate the severity of their vitiligo on their facial area and on their total body area right now, with response options of "none", "mild", "moderate", "severe", and "very severe".

Participants with measurements of "none" or "mild" are classified as responders.

3.3.3.8 PGIC/M

The PGIC/M is a 2-part measure asking the participant to rate the change in their vitiligo since they started taking the study medication. Participants can choose from the following response options: "much better", "a little better", "no change", "a little worse" and "much worse".

Participants with measurements of "much better" or "a little better" are classified as responders.

3.3.3.9 CGI-S

The CGI-S is a 2-item measure asking the investigator to rate the severity of participant's vitiligo on their facial area and on the total body area right now, with response options of "none", "mild", "moderate", "severe", and "very severe".

Participants with measurements of "none" or "mild" are classified as responders.

3.3.3.10 CGI-C

The CGI-C is a 2-item measure asking the investigator to rate the change in the participant's vitiligo on their facial area and on the total body area since they started taking the study medication. Participants can choose from the following response options: "much better," "a little better," "no change," "a little worse," and "much worse".

Participants with measurements of "much better" or "a little better" are classified as responders.

CCI [redacted]

3.4 Analysis Populations

3.4.1 Efficacy Analysis Population

The FAS population will serve as the primary population for the efficacy data analysis. The FAS population consists of all randomized participants who received at least one injection of study intervention. Participants will be analyzed by the treatment group assigned at randomization.

3.4.2 Safety Analysis Population

The APaT population will be used for the safety data analysis. The APaT population consists of all randomized/allocated participants who received at least one injection of study intervention. Participants will be analyzed in the treatment arm actually received.

3.4.3 Pharmacokinetic Analysis Population

The population for PK data analysis will include all participants with at least 1 measurable PK sample after treatment with MK-6194.

3.4.4 Pharmacodynamic Analysis Population

The population for the PD endpoints will be the FAS population. All randomized participants who have at least 1 injection (including partial injection) of study intervention and have at least 1 assessment for those analyses for which this is required will be included in this population.

3.4.5 Immunogenicity Analysis Population

The population for immunogenicity analysis will include all participants with at least 1 ADA assay result after treatment with MK-6194.

3.5 Statistical Methods

Efficacy results that will be deemed to be statistically significant after consideration of the Type-I error control strategy are described in Section 3.7 of the SAP.

3.5.1 Estimand(s)

Estimand for the Primary Efficacy Analysis

The estimand for the primary objective of this study contains 5 attributes:

- Treatment Regimen: MK-6194 or matching placebo
- Target population: Adult with Non-Segmental Vitiligo
- Endpoint: The percent change from baseline in F-VASI at Week 24
- Population-level summary: the difference in the mean percent change from baseline in F-VASI at Week 24 between the treatment group and placebo

- Intercurrent events: Detailed below:

Number	Intercurrent Events	Handling Strategy
Intercurrent Event #1	Discontinuation of MK-6194 or placebo	Treatment Policy Strategy
Intercurrent Event #2	Usage of any medication for the treatment of Vitiligo as listed in Protocol Section 5.2 # 19	Treatment Policy Strategy

3.5.2 Statistical Methods for Efficacy Analyses

All efficacy endpoints will be analyzed based on the FAS population. Unless otherwise specified, all efficacy data will be included in efficacy analyses. A Hochberg testing procedure will be implemented in this study for multiplicity adjustment. LDA method will be used for the analysis of the continuous endpoints, and stratified M&N method will be used for the analysis of the binary endpoints.

Primary Efficacy Analysis

The primary endpoint, the percent change from baseline in F-VASI score at Week 24, will be analyzed using a LDA model for repeated measures. This model will use all available data on F-VASI at baseline and all post-baseline timepoints up to Week 24. In this model, time will be treated as a categorical variable so that no restriction is imposed on the trajectory of the means over time. The analysis model will adjust for treatment, visit, treatment by visit, and baseline vitiligo status (stable, active) and previous JAK inhibitor use (yes, no) based on IRT values. The treatment difference in terms of the mean percent change from baseline at Week 24 will be estimated and tested from this model. Point estimates, 95% CI and p-value for the treatment differences will be provided. An unstructured covariance matrix will be used to model the correlation among repeated measurements. If the unstructured covariance structure fails to converge with the default algorithm, an autoregressive AR(1) or compound symmetric (CS) structure will be used.The LDA method assumes that the mechanism for missing data is MAR. In this study, it is expected that MAR/MCAR mechanisms will underlie most of the missingness, and the proportion of data that are MNAR, driven solely by unobserved values of the study endpoints, will be small. Reasons for discontinuation from the study may include lack of efficacy, AEs, relocation, withdrawal of consent and protocol deviations. Missing data caused by a participant's relocation or data processing issues are likely to be MCAR. Missing data caused by discontinuations due to lack of efficacy may belong to MAR because this type of discontinuation may depend on the observed efficacy outcomes. The MAR or MNAR mechanisms might each underlie the other reasons to some extent. If the assigned study intervention in large part determines the loss of data for these other reasons (such as AEs), the mechanism may be close to MAR since the intervention assignment is an observed variable and included in the analysis model.

Sensitivity Analyses

In addition to the analysis approach specified above for the primary endpoint analysis section, the following sensitivity analyses will be used to assess the robustness of the primary analysis approach.

Multiple-imputation Analysis

For all participants who are missing baseline F-VASI assessment, single imputation (only once) will be implemented based on baseline vitiligo status (stable, active) and previous JAK inhibitor use (yes, no). All post-baseline missing F-VASI assessments will be handled using MI under the missing-at-random assumption.

A fully conditional specification method that assumes the existence of a joint distribution for all variables will be used. A regression model including treatment group, stratification factor(s) and percent change from baseline in F-VASI scores at all post-baseline visits up to Week 24 will be specified for the fully conditional specification method. The randomization seed will be set to 6194007. The MI procedure will be repeated 50 times and the imputed endpoint will be analyzed using the same analysis model as the primary analysis based on each of the datasets. SAS PROC MIANALYZE will be used to generate the final treatment differences between MK-6194 treatment group and placebo group and the statistical inferences, including hypothesis testing, and 95% CI will be combined using Rubin's rule.

Tipping-point Multiple-imputation Analysis

Tipping point analyses as described in Ratitch et al. (2013) [Ratitch, B., et al 2013] will be conducted. In this approach, missing data are first imputed for all visits under the MAR assumption, and then the worsening/shift is applied. This is repeated with increasing the delta-shift (worsening) until the result is no longer statistically significant. Specifically, after generating 50 datasets using MI procedure and before analyzing each of the imputed datasets, add a constant c from each of the imputed values of the active arm (to the detriment of active) and a constant d from each of the imputed values of the placebo arm. SAS PROC MIANALYZE will be used to combine results using Rubin's rule.

Secondary Efficacy Analysis

The secondary efficacy endpoint, the percent change from baseline in T-VASI at Week 24, will be analyzed similarly as the primary endpoint.

Table 2 summarizes the analysis strategy of the primary and secondary efficacy endpoints.

Table 2 Analysis Strategy for Key Efficacy Variables

Endpoint/Variable (Description, Time Point)	Primary vs Supportive Approach	Statistical Method	Analysis Population	Missing Data Approach
Primary Endpoint/Hypothesis 1				
Percent change from baseline in F-VASI at Week 24	P	LDA	FAS	Model based
	S	LDA	FAS	Multiple Imputation
	S	LDA	FAS	Tipping Point Multiple Imputation
Secondary Endpoint 2				
Percent change from baseline in T-VASI at Week 24	P	LDA	FAS	Model based

FAS=Full Analysis Set; F-VASI= Facial Vitiligo Area Scoring Index; LDA=longitudinal data analysis; T-VASI= Total Vitiligo Area Scoring Index
P=Primary approach; S=Supportive approach.

The efficacy analysis mentioned above will be performed at the end of the Double-Blind Treatment Period (Week 24). Additional descriptive analyses will be performed at the end of the Blinded Extension Period (Week 52). No comparison between treatment groups will be involved in any of the analyses for blinded extension. Details of the analysis plan will be finalized in the SAP before the final database lock.

Exploratory Efficacy Analysis

Descriptive statistics will be provided for time points with measurements from at least three different participants for the following continuous F-VASI and T-VASI endpoints. The analysis will utilize all observed data, with no imputation for missing values. The derivation details of the following endpoints are in Section 3.3.3:

- Percent change from baseline in F-VASI at all timepoints
- Percent change from baseline in T-VASI at all timepoints

The proportion of participants achieving 25%, 50%, 75%, and 90% improvement in F-VASI and T-VASI will be provided across time points for the following binary endpoint. The derivation details of the binary endpoints are in Section 3.3.3.

The proportion of participants achieving 50%, 75%, and 90% improvement in F-VASI and T-VASI at Week 24 will be analyzed using the stratified M&N method with the following stratification factors: vitiligo status (stable, active) and previous JAK inhibitor use (yes, no) based on IRT values. The estimated treatment difference along with the corresponding 95% CIs will be presented. The post-baseline missing F-VASI assessments will be handled using MI under the missing-at-random assumption. The derivation details of the binary endpoints are in Section 3.3.3.

Descriptive statistics for change from baseline of the VitiQoL score will be provided for time points with measurements from at least three different participants. The analysis will utilize all observed data, with no imputation for missing values. The derivation details of the binary endpoints are in Section 3.3.3.

The proportion of participants in each level for the following categorical endpoints will be provided across time points. The analysis will utilize all observed data, with no imputation for missing values. The derivation details of the binary endpoints are in Section 3.3.3.

VNS

- PGI-S on facial area and PGI-S on total body area
- PGIC/M on facial area and PGIC/M on total body area
- CGI-S on facial area and CGI-S on total body area
- CGI-C on facial area and CGI-C on total body area
- CCI

In addition, the proportion of participants achieving treatment success as defined below for the following categorical endpoints will be provided across time points.

- VNS of 4 (A lot less noticeable) or 5 (No longer noticeable)
- PGI-S on facial area of None or Mild
- PGI-S on total body area of None or Mild
- PGIC/M on facial area of Better or Much Better
- PGIC/M on total body area of Better or Much Better
- CGI-S on facial area of None or Mild
- CGI-S on total body area of None or Mild
- CGI-C on facial area of Better or Much Better
- CGI-C on total body area of Better or Much Better

3.5.3 Statistical Methods for Safety Analyses

Safety and tolerability will be assessed by clinical review of AEs and other relevant parameters, including laboratory tests, and vital signs.

3.5.3.1 Overall Safety Assessment

The overall safety evaluation will include a summary (ie, frequency and percentage) by treatment group of participants with at least one AE, drug-related AE, serious AE, serious drug-related AE, discontinuation from study intervention due to an AE, and AE resulting in death.

Point estimates and 95% CIs for the differences between treatment groups in the percentages of participants with events will be provided for AEs that occur in at least 4 participants in any treatment group using the M&N method [Miettinen, O. and Nurminen, M. 1985]. This threshold for the number of participants with AEs was chosen because the 95% CI for the between-group difference in percent incidence will always include zero when fewer

participants per group have events and thus would add little to the interpretation of potentially meaningful differences. CIs that are not adjusted for multiplicity should only be regarded as helpful descriptive measures for the review of the safety profile and not as a formal method for assessing statistical significance of between-group differences. Figures and/or plots will be provided as needed.

For continuous safety measures, such as laboratory, and vital signs, summary statistics for baseline, on-treatment, and change from baseline values will be provided by treatment group.

Table 3 summarizes analysis strategy for safety endpoints in this study.

Table 3 Analysis Strategy for Safety Parameters

Safety Endpoint	**Descriptive Statistics**	**95% Between-group CI**	**Graphical Display**
Any AE	X	X	
Any serious AE	X	X	
Any drug-related AE	X	X	
Any serious drug-related AE	X	X	
Discontinued study treatment due to AE	X	X	
AE that resulted in death	X		
Specific AEs or SOCs (incidence ≥ 4 participants in any treatment group)	X	X[a]	X[a]
Change from Baseline Results (Labs, Vital Signs)	X		
AE=adverse event; CI=Confidence Interval; SOC=System Organ Class. [a]: Threshold for incidence will be applied for CI and Graphical Display.			

The safety analysis mentioned above will be performed at the end of the Double-Blind Treatment Period (Week 24). Additional descriptive analyses will be performed at the end of the Blinded Extension Period (Week 52). No comparison between treatment groups will be involved in any of the analyses for Blinded Extension Period. Details of the analysis plan will be finalized in the SAP before the final database lock.

3.5.3.2 Assessment of Safety Topics of Special Interest

There are no safety topics of special interest in this study.

3.5.4 Demographic and Baseline Characteristics

The number and percentage of participants randomized, completed, discontinued, and the primary reasons for discontinuation will be displayed. Demographic variables (including age, gender, race, height, weight), baseline characteristics, medical history, prior and concomitant therapies will be summarized by treatment group either by descriptive statistics or categorical tables. The comparability of the treatment group for each relevant characteristic will be assessed by the summary tables. No statistical hypothesis tests will be performed on these characteristics.

Safety Interim Analyses

The eDMC will be responsible for periodic interim safety reviews. Additional details will be specified in the eDMC charter.

3.7 Multiplicity

If the interim analysis for futility is conducted, an α-spending of 0.0001 will be applied to the 2-sided Type I error rate of 5% for the primary hypothesis based on the Haybittle-Peto method [Haybittle, J. L. 1971] [Peto, R., et al 1976]. Multiplicity adjustment will be made for testing 2 doses on the primary endpoint for the analysis, i.e., for testing a family of the following hypotheses:

- H1(1): 3 mg MK-6194 Q4W dose is superior to placebo in the percent change from baseline in F-VASI at Week 24.
- H1(2): 3 mg MK-6194 Q2W dose is superior to placebo in the percent change from baseline in F-VASI at Week 24.

To strongly control the Type-I error rate for this family, the Hochberg procedure [Hochberg, Y. 1988] will be applied.

3.8 Sample Size and Power Calculations

This study will randomize 55 participants in each treatment group and has >80% power to demonstrate the superiority of at least 1 dose of MK-6194 over placebo at an overall 2-sided 0.05 PPD alpha-level, if the underlying treatment difference in percent change from baseline at Week 24 in F-VASI score is -20%. The power and sample size are based on the following assumptions: 1) a 15% drop out rate, 2) a standard deviation of 33%, pooled across treatment groups.

3.9 Subgroup Analyses

To assess whether the treatment effect with respect to the primary endpoint is consistent across various subgroups of the study population, the between-treatment group effect (with a nominal 95% CI) will be estimated/summarized within each subgroup of the following classification variables. For stratification factors: vitiligo status and previous JAK inhibitor use, participants will be analyzed based on the IRT values at randomization.

- Vitiligo status (active, stable)
- Baseline F-VASI (<1, ≥1)
- Gender (male, female)
- Age, years (≥18 to ≤40, >40 to ≤64, > 64)
- Race (American Indian or Alaska Native, Asian, Black or African American, Multiple, White)
- Baseline F-BSA (<1, ≥1)
- Previous JAK inhibitor use (yes, no)

To ensure a sufficient number of participants for the subgroup analysis, summary statistics including mean, SD, and 95% CI will only be provided when there are >5 participants in each subgroup level for each treatment group.

3.10 Compliance (Medication Adherence)

For each participant, percent compliance will then be calculated using the following formula:

$$Percent\ Compliance = \frac{Number\ of\ Injections\ Received}{Number\ of\ Injections\ Should\ Have\ Received} \times 100$$

Summary statistics will be provided on percent compliance by treatment group for the FAS population.

3.11 Extent of Exposure

Extent of exposure will be summarized by the actual dose/intervention received. Each dose will be counted as 2 weeks of exposure.

Participants who took more than one treatment (MK-6194 and placebo) will be counted according to the time spent on each intervention.

The extent of exposure will be summarized using descriptive statistics for all participants as treated.

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5 SUPPORTING DOCUMENTATION

5.1 Appendix 1: Abbreviations

Abbreviation	Expanded Term
APaT	All-Participants-as-Treated
AE	adverse event
CI	confidence interval
CGI-C	Clinical Global Impression of Change
CGI-S	Clinical Global Impression of Severity
DMC	Data Monitoring Committee
F-VASI	Facial Vitiligo Area Scoring Index
FAS	Full Analysis Set
LDA	longitudinal data analysis
MCAR	missing completely at random
MI	multiple imputation
M&N	Miettinen and Nurminen
MAR	missing at random
MNAR	missing not at random
PGIC/M	Patient Global Impression of Change/Meaningfulness
PGI-S	Patient Global Impression of Severity
T-VASI	Total Vitiligo Area Scoring Index
VitiQoL	Vitiligo-Specific Quality of Life Instrument
CCI	[redacted]
VNS	Vitiligo Noticeability Scale

5.2 Appendix 2: Approval Information

The SAP Amendment 01 of Protocol MK-6194-007-02 was approved by the BARDS TA head, PPD

Date: 24-April-2025