Statistical Analysis Plan

A Phase 1b/2a Study to Evaluate the Safety, Pharmacokinetics, and Efficacy of IMG-007 in Adult Alopecia Areata Participants with 50% or Greater Scalp Hair Loss

Investigational Product:	IMG-007
Protocol Number:	IMG-007-202
Statistical Analysis Plan Version:	Version 1.0
Version Release Date:	25 Oct 2024
Sponsor:	Inmagene LLC

Signature Page

Declaration

The undersigned have reviewed and agreed to the statistical analysis and procedures of this clinical study, as presented in this document.

Statistical Analysis Plan Version: 1.0

Statistical Analysis Plan Date: 25 Oct 2024

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Inmagene Biopharmaceuticals

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Version History

SAP Version	Date	Change	Rationale
1.0	25Oct2024	Not applicable	First version

List of Abbreviations

AA	Alopecia Areata
AAPPO	Alopecia Areata Patient Priority Outcome
AD	Atopic Dermatitis
ADA	Anti-drug Antibody
ADCC	Antibody-dependent Cellular Cytotoxicity
AE	Adverse Event
ALT	Alanine Aminotransferase
AST	Aspartate Aminotransferase
AT	Alopecia Totalis
ATC	Anatomical Therapeutic Chemical
AU	Alopecia Universalis
BMI	Body Mass Index
CTCAE	Common Terminology Criteria for Adverse Event
DPCP	Diphenylcyclopropenone
ECG	Electrocardiogram
EOI	End of Infusion
EOS	End of Study
EOT	End of Treatment
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HADS	Hospital Anxiety and Depression Scale
HBcAb	antibody to hepatitis B core antibody
HBsAb	Hepatitis B Surface Antibody
HBsAg	Hepatitis B Surface Antigen
hCG	Human Chorionic Gonadotropin
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HMG-CoA	Hydroxymethylglutaryl Coenzyme A
IA	Interim Analysis
IATS	Investigator's Assessment of a Target Scalp Lesion
ICF	Informed Consent Form
ICH	International Council for Harmonization
IEC	Independent Ethics Committee
Ig	Immunoglobulin
IGA	Investigator's Global Assessment
IGA-EB	Investigator's Global Assessment of Eyebrows
IGA-EL	Investigator's Global Assessment of Eyelashes
IGA-FN	Investigator's Global Assessment of Fingernails
IMP	Investigational Medicinal Product
IV	Intravenous

JAK	Janus Kinase
mAb	Monoclonal Antibody
MedDRA	Medical Dictionary for Regulatory Activities
MMF	Mycophenolate Mofetil
NCI	National Cancer Institute
OX40L	OX40 Ligand
PD	Pharmacodynamics
PGIC	Patient Global Impression of Change
PGIC-AA	Patient Global Impression of Change of Overall Alopecia Areata
PGIC-EB	Patient Global Impression of Change of Alopecia Areata on the Eyebrows
PGIC-EL	Patient Global Impression of Change of Alopecia Areata on the Eyelashes
PGIC-FN	Patient Global Impression of Change of Alopecia Areata on the Fingernails
PGIC-S	Patient Global Impression of Change of Alopecia Areata on the Scalp
PGIS	Patient Global Impression of Severity
PGIS-AA	Patient Global Impression of Severity of Overall Alopecia Areata
PGIS-EB	Patient Global Impression of Severity of Alopecia Areata on the Eyebrows
PGIS-EL	Patient Global Impression of Severity of Alopecia Areata on the Eyelashes
PGIS-FN	Patient Global Impression of Severity of Alopecia Areata on the Fingernails
PGIS-S	Patient Global Impression of Severity of Alopecia Areata on the Scalp
PK	Pharmacokinetics
PT	Preferred Term
SAE	Serious Adverse Event
SALT	Severity of Alopecia Tool
SAP	Statistical Analysis Plan
SD	Standard Deviation
SoA	Schedule of Assessments
SOC	System Organ Class
SRC	Safety Review Committee
TB	Tuberculosis
TEAE	Treatment-emergent Adverse Event
Th	T-helper
US	United States
UV	Ultraviolet
VS	Vital Sign
WHODrug	World Health Organization Drug Dictionary

1. OVERVIEW

The purpose of the statistical analysis plan (SAP) is to ensure the credibility of the study results by pre-specifying statistical approaches for the analysis of this study. The SAP is intended to be a comprehensive and detailed description of strategy and statistical techniques to be used to realize the analysis of data for IMG-007-202. This SAP was written and finalized prior to the database lock, based on study protocol IMG-007-202 version 4 and 4.1(Canada only) (02 August 2024). Any methodological deviations from the protocol are documented. The analyses laid out in this SAP will be implemented by MeDaStats LLC for Inmagene Biopharmaceuticals.

1.1 Background and Rationale

Alopecia areata (AA) is a chronic relapsing and remitting autoimmune disease characterized by nonscarring hair loss involving the scalp, face, and/or body. It can affect children and adults of all ages, races and genders but more commonly in females and non-whites especially Asians. Approximately 2% of the general population can be affected by AA during their lifetime. The point prevalence rates of AA based on recent studies using electronic healthcare records were approximately 0.22% in the United States (US) and 0.58% in the United Kingdom.

AA typically presents with well-demarcated patches of hair loss, most commonly on the scalp, but it may also involve the beard, eyebrows, eyelashes, and nails. In severe cases, AA involves the full scalp (alopecia totalis [AT]) or even full body (alopecia universalis [AU]). AA involving 50% or greater scalp hair loss, including AT and AU, is considered an advanced form. AA is associated with other inflammatory and autoimmune diseases including atopic diseases (e.g., atopic dermatitis [AD] and allergic rhinitis), autoimmune diseases (e.g., thyroiditis, lupus erythematosus), metabolic syndrome, and psychiatric disorders. AA significantly impacts patients' daily life and often leads to profound psychological distress, social isolation, anxiety, and depression.

The exact pathogenesis of AA is not fully understood. It involves a complex interplay between genetics, environmental factors, and adaptive immune response to unknown antigens. It is thought that the collapse of follicular immune privilege leads to activation and infiltration of immune cells, primarily $CD4^+$ and $CD8^+$ T cells, and also natural killer cells, mast cells, and dendritic cells, which swam and attack the hair bulbs. Hair follicle cells in turn release more cytokines and chemokines that further recruit T cells and other immune cells forming positive feedback loops that shorten and distort the hair cycle. Activation of T cell subsets including T-helper (Th) type 1 (Th1) and Th2 cells in AA patients is associated with disease severity or chronicity.

Current treatment options for AA are limited. They include topical, intralesional, and systemic agents. Topical treatments (e.g., topical corticosteroids, calcineurin inhibitors, diphenylcyclopropenone [DPCP], squaric acid, and minoxidil) have limited efficacy and are not suitable for large areas or long-term use. Intralesional corticosteroids are also not applicable for large areas and chronic use. Oral corticosteroids and conventional immunosuppressants (e.g., cyclosporine A, mycophenolate mofetil [MMF], and azathioprine) are used off-label, with limited evidence from randomized controlled trials regarding their benefit/risk profiles in AA patients. These immunosuppressive agents are often associated with adverse events (AEs)

that prevent their long-term use. Although oral Janus kinase (JAK) inhibitor baricitinib was recently approved by the US Food and Drug Administration (FDA) for severe and very severe AA, potential serious safety risks would limit its use for chronic management of AA. There remain significant unmet needs for safe and effective novel targeted systemic therapies for long-term treatment of AA.

Emerging evidence supports an important role of OX40– OX40 ligand (OX40L) signaling in promoting the proliferation and survival of T cells and augmenting the clonal expansion and function of effector and memory T cells, thereby mediating the pathogenesis of a spectrum of inflammatory and autoimmune diseases including AD and AA.

A genetic mapping study in AA patients revealed that an OX40L genetic locus is associated with susceptibility to AA. OX40L/OX40 interaction is required for the activation of $CD4^+$ and $CD8^+$ T cell as well as recruitment of other immune cells. In AA, activated T cells interact with other immune cells such as mast cells in amplifying follicular inflammation. Aggregation of peri- and intrafollicular $OX40^+$ T cells and their physical contacts with $OX40L^+$ mast cells were observed in AA hair follicles. Separately, elevated OX40 gene expression has been shown in AA lesional scalp.

AA and AD coexist in many patients. Based on a systemic review and meta-analysis, 9.6% of AA patients have comorbid AD. The two diseases share overlapping molecular profiles including important roles of OX40–OX40L interactions in the disease pathogenesis. monoclonal sntibody (mAbs) targeting OX40 rocatinlimab (KHK4083) and telazorlimab (GBR 830) have shown remarkable clinical effect in improving skin signs in AD patients. The clinical evidence of OX40 antagonists in AD supports a similar role of OX40–OX40L signaling in AA.

The above evidence suggests that OX40 is a promising target for AA. IMG-007 is a humanized IgG1 subclass mAb that specifically targets human OX40 with high affinity and inhibits OX40L-induced signaling. Modifications in the Fc region were made to remove glycosylation and abolish antibody-dependent cellular cytotoxicity (ADCC). IMG-007 represents a promising therapeutic candidate for the treatment of AA.

1.2 Study Objectives

1.2.1 Primary Objective

To evaluate adverse events (AEs) emergent from multiple doses of IMG-007 in adult participants with alopecia areata (AA)

1.2.2 Secondary Objectives

To evaluate the efficacy of multiple doses of IMG-007 in AA participants as measured by severity of alopecia tool (SALT) at Week 24

1.2.3 Exploratory Objectives

- To further evaluate the efficacy of multiple doses of IMG-007 in AA participants as measured by SALT and other investigator's assessment and patient reported outcomes
- To further characterize the safety and tolerability of multiple doses of IMG-007 in AA participants

- To characterize the pharmacokinetic (PK) profile of multiple doses of IMG-007 in AA participants
- To evaluate the pharmacodynamic (PD) effect of IMG-007 on biomarkers in AA participants
- To evaluate the immunogenicity of IMG-007 in AA participants

2. INVESTIGATIONAL PLAN

2.1 Study Design

This is a phase 1b/2a, open label, dose escalation study to assess the safety, efficacy, PK, and PD of IMG-007 in alopecia areata (AA) participants. Approximately 30 participants will be enrolled. The study will consist of two dose cohorts to be initiated sequentially in ascending dose order: Cohort 1 with six participants receiving three Intravenous (IV) infusions of IMG-007 [redacted] over 4 weeks and Cohort 2 with 24 participants receiving three IV infusions of IMG-007 [redacted] over 4 weeks. [redacted]

Dose escalation decision would be made when all six participants in Cohort 1 have completed the Week 2/Day 15 visit, and all the safety and laboratory data have been reviewed by the Safety Review Committee (SRC). Adverse event (AE) severity will be evaluated according to the National Cancer Institute's (NCI) Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0.

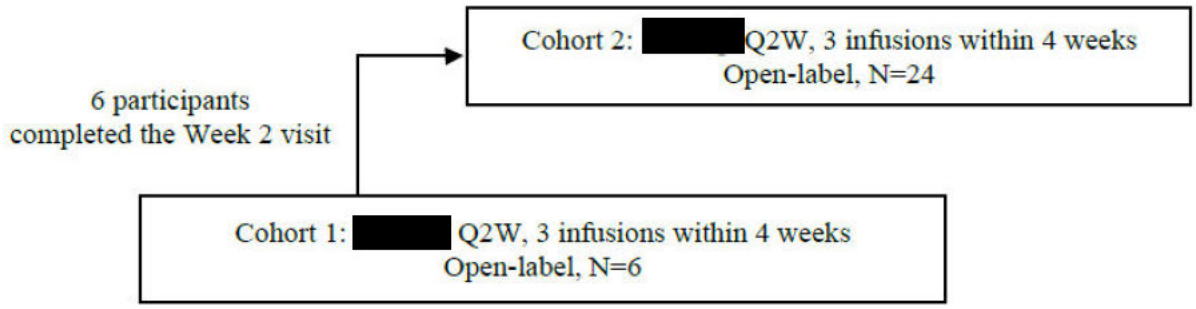


Figure 1 Study Schema

2.2 Sample Size Determination

A key secondary objective of the study is to explore the efficacy of IMG-007 treatment based on the percent change from baseline in SALT score at Week 24. [redacted]

[redacted]

2.3 Study Plan

The study consists of a screening period, a treatment period, a follow-up period, and an extended follow-up period.

Screening Period: Day -35 to Day -1 (up to 5 weeks)

After providing informed consent, participants will be assessed for compliance with protocol requirements and study eligibility. Only in exceptional circumstances, when information concerning eligibility is outstanding (e.g., delayed laboratory results), will a longer screening period be permitted for up to three business days. Upon consultation with the medical monitor, a participant may be rescreened one time. Circumstances that may permit rescreening include, but are not limited to, a laboratory test result that does not meet eligibility requirements.

Treatment Period: Day 1 (Baseline) to Day 113 (16 weeks)

Participants who meet all eligibility criteria will be enrolled and will receive three IV infusions of IMG-007 [redacted] or [redacted] administered 2 weeks apart at the Baseline (Day 1), Week 2 (Day 15), and Week 4 (Day 29) visits. The study site will contact participants by telephone approximately 24 hours after each infusion for assessment of AEs and/or concomitant medications.

On dosing days, study treatment will be administered as an IV infusion over approximately 60 minutes with a slower rate during the first 15 minutes. Participants will be closely monitored at the study site for a minimum of 1 hour after completion of each infusion or until any AEs observed during the observation have resolved or stabilized, whichever is longer. For diagnostic purposes, any participant who experiences any systemic infusion-related event should have a blood sample taken ideally 30–60 minutes after the onset for tryptase testing, and samples should be analyzed by a local laboratory if feasible. Study sites should have access to equipment or facilities for the management of potential hypersensitivity reactions.

Beyond dosing visits, participants will complete visits at Week 1 (Day 8), Week 6 (Day 43), Week 8 (Day 57), Week 12 (Day 85) and Week 16 (Day 113)/end of treatment (EOT).

Follow-up Period: Day 113 to Day 169 (8 weeks)

The follow-up period consists of two visits: Week 20 (Day 141) and end of study (EOS; Week 24 [Day 169]) Visits.

Extended Follow-up Period Post EOS: Day 169 to 253 (12 weeks)

The extended follow-up period after EOS consists of two visits: Week 30 (Day 211) and Week 36 (Day 253).

3. ANALYSIS SETS

The following analysis sets will be used for all statistical analyses covered within the scope of this analysis plan. There could be other analysis sets outside the scope of this SAP for dedicated purposes, such as population PK analysis.

The analysis sets defined below are based on guidance from the International Conference of Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guideline ICH E9 Statistical Principles for Clinical Trials (1998).

3.1 Safety analysis set

The safety analysis set includes all participants who received at least one dose of study treatment.

Safety analysis set will be used for analyses demographic and baseline characteristics, and safety data.

3.2 Modified full analysis set

The modified full analysis set includes all participants who received at least one dose of study treatment.
Modified full analysis set will be used for all efficacy analyses.

3.3 Pharmacokinetic analysis set

PK analysis set includes all participants in the safety analysis set and have baseline and at least one post-baseline evaluable data point. PK analysis set will be used for PK and ADA analyses.

3.4 Pharmacodynamic analysis set

Pharmacodynamic (PD) analysis set includes all participants in the safety analysis set who also have baseline and/or at least one post-baseline evaluable PD/biomarker data point.

4. ANALYSIS VARIABLES

4.1 Demographic and Baseline Characteristics

The following demographic and Baseline characteristics variables will be summarized:

- Following continuous demographic variables and baseline characteristics will be summarized descriptively:
  - Age
  - Height
  - Baseline weight
  - Baseline body mass index (BMI)
  - Duration of AA
  - Duration of current AA episode

  - Baseline SALT score
  - Baseline Investigator's Assessment of a Target Scalp Lesion (IATS)
  - Baseline investigator's global assessment (eyebrows [IGA-EB], eyelashes [IGA-EL], fingernails [IGA-FN])
  - Baseline patient's global impression of severity (overall AA [PGIS-AA], AA on scalp [PGIS-S], eyebrows [PGIS-EB], eyelashes [PGIS-EL], fingernails [PGIS-FN])
  - Baseline alopecia areata patient priority outcome (AAPPO)
  - Baseline hospital anxiety and depression scale (HADS)
  - Baseline Eosinophil
- Following categorical demographic variables and baseline characteristics will be summarized with numbers and percentages.
  - Gender
  - Ethnicity
  - Race
  - Participants with AT or AU
  - Participants with baseline SALT: 50 - <75, 75 - <95, and 95 – 100,
  - Participants with atopic disease history/comorbidities
  - Participants with autoimmune history/comorbidities
  - Participants with elevated IgE (>ULN) at baseline
  - Participants with eyebrow, eyelash and fingernail involvement
  - Participants who are JAK-I experienced

Duration of AA (Years): (Date of enrolment – Diagnosis date of AA)/365.25.

Duration of current AA episode (Years): (Date of enrolment – Current episode start date)/365.25.

In cases where only a partial date is available for AA diagnosis or current episode start date, the imputation process will involve substituting "01" if only the day is absent, or "01 Jan" if both the day and month are missing, prior to the calculation of the duration.

4.2 Medical History and Alopecia Disease History

Medical history will be coded according to the latest available version (26.0 or higher) of Medical Dictionary for Regulatory Activities (MedDRA). Information on conditions related to AA includes diagnosis of AA, AA history, scalp AA subtype etc.

4.3 Prior and Concomitant Medications/Procedures

Medications/Procedures (excluding non-drug) will be recorded from the day of informed consent until the end of extended follow-up period. Medications will be coded with anatomical therapeutic chemical (ATC) levels, according to the latest available version (WHO Drug B3 Global, Sep 2022 or higher) of World Health Organization Drug Dictionary (WHODrug).

Prior medications/procedures: Medications taken or procedures performed prior to the first dose of Investigational Medicinal Product (IMP). All the medications that are stopped prior to the first administration of the study drug are considered under this category.

Concomitant medications/procedures: medications taken or procedures performed following the first dose of study drug through the end of extended follow-up period. i.e., procedures or medication with end date on or after the first administration of the study drug irrespective of the start date, or ongoing during the study period.

Prohibited medications and non-drug therapies:
Treatment with the following concomitant medication is prohibited:

- Use of topical treatments for AA within 2 weeks before the Baseline (Day 1) visit and until completion of the follow-up (including the extended follow-up) period, such as corticosteroids, calcineurin inhibitors, JAK inhibitors (e.g., ruxolitinib), antimicrobials, anthralin, DPCP, squaric acid, minoxidil or any other medication which, in the opinion of the investigator, may affect hair regrowth;

  Note: Topical treatments are permitted outside of the scalp, eyebrows and eyelashes.

- Use of non-biologic systemic (oral or injectable) agents including conventional immunosuppressants or immunomodulators (e.g., corticosteroids, methotrexate, MMF, cyclosporine A, azathioprine, hydroxychloroquine, sulfasalazine and other approved drugs with potential immunosuppressive effects, within 4 weeks or 5 half-lives, whichever is longer, prior to the Baseline (Day 1) visit and until completion of the follow-up (including the extended follow-up) period;

- Use of oral JAK inhibitors within 8 weeks prior to the Baseline (Day 1) visit and until completion of the follow-up (including the extended follow-up) period;

- Use of oral or injectable agents (minoxidil, apremilast, finasteride, hydroxymethylglutaryl coenzyme A (HMG-CoA) reductase inhibitors [statins], herbal medicines) for the treatment of AA within 4 weeks prior to the Baseline (Day 1) visit and until completion of the follow-up (including the extended follow-up) period;

  *Note that the listed medications are permitted if they are not indicated for the treatment of AA **AND** have been used at a stable dose until the completion of the study. These medications are prohibited if they are indicated for the treatment of AA **OR** if they have been newly initiated or had their dose modified during the study.*

- Use of any biologic therapy (e.g., mAbs against IL-17, IL-4, and IL-13 or other investigational products) or platelet-rich plasma within 3 months or 5 half-lives, whichever is longer, prior to the Baseline (Day 1) visit and until completion of the follow-up (including the extended follow-up) period;

- Use of phototherapy for the treatment of AA within 4 weeks before the Baseline (Day 1) visit and until completion of the follow-up (including the extended follow-up) period, such as ultraviolet (UV) A or UVB, or any other type of light therapy that, in the opinion of the investigator, may affect hair regrowth.

- Receipt of a live vaccine, including live attenuated, within 2 months before the Baseline (Day 1) visit and until 3 months after the last administration.

- Other medications or non-drug therapies, in the opinion of the investigator, that could affect AA from screening to study completion.

4.4 Prior and concomitant non-drug therapies and procedures

Non-drug therapies will be recorded from the day of informed consent until the end of extended follow-up period and each therapy will be coded according to the latest available version (26.0 or higher) of MedDRA.

4.5 Efficacy Variables

Since the primary objective of the study is to assess the safety arising from multiple doses of IMG-007, the analysis of efficacy will be conducted as secondary and exploratory.

4.5.1 Secondary Efficacy Variable

The secondary efficacy endpoint is the percentage change in SALT from baseline to Week 24.

Severity of Alopecia Tool

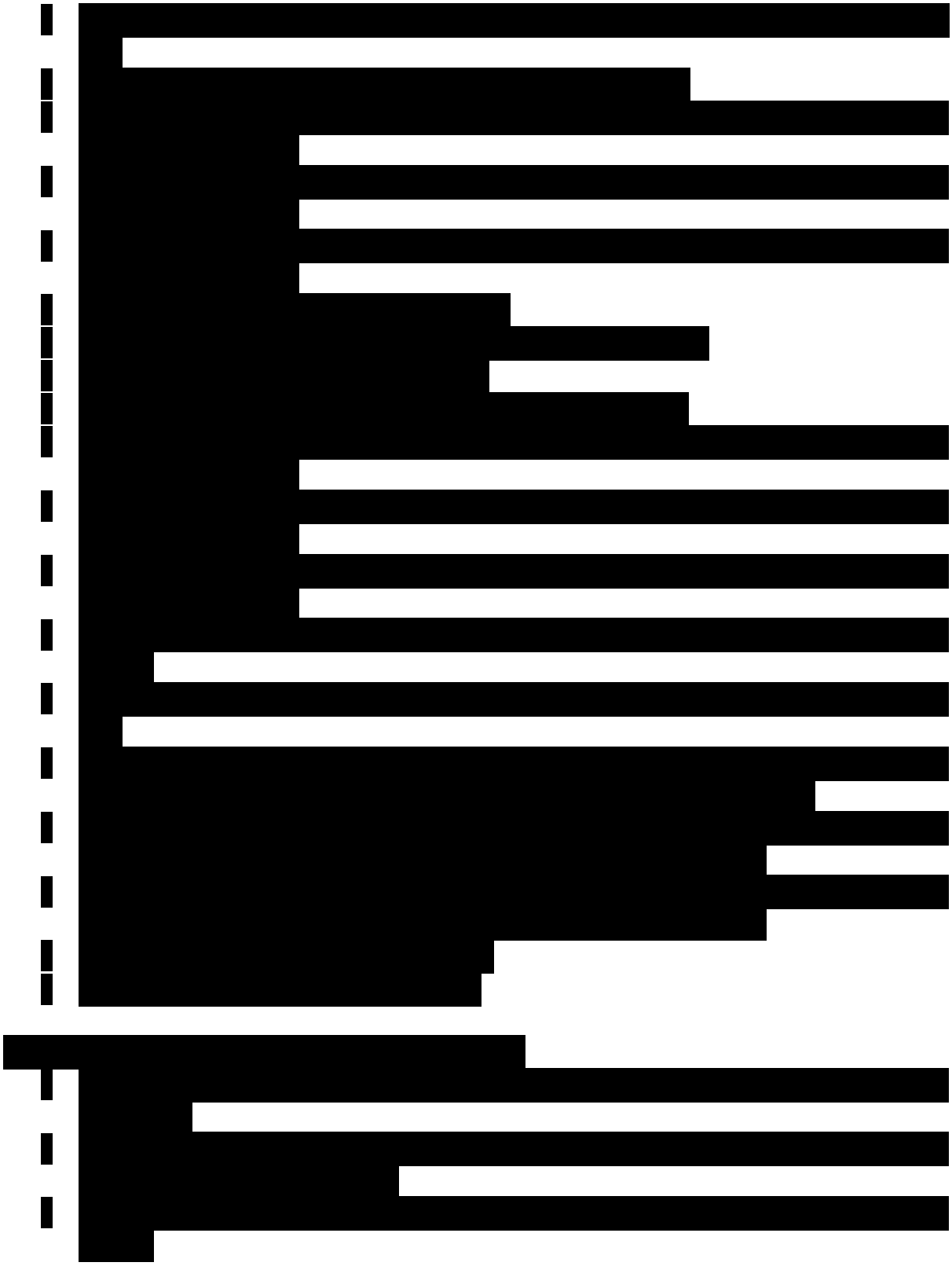
SALT is a quantitative assessment of AA severity by the investigator based on scalp terminal hair loss. The investigator utilizes a visual aid showing the division of the scalp hair in four quadrants, with the top constituting 40%, the back 24%, and the right and left side of the scalp of 18% each of the total surface (Olsen et al 2004). A composite score is derived based on the percentage of terminal hair loss in each of the four scalp views (areas). The SALT score will range from 0 to 100.

4.5.2 Exploratory Efficacy Variables

4.5.2.1 Key Exploratory Endpoints

The key exploratory endpoints are:

- Absolute and percentage changes from baseline in SALT by visit
- Proportion (%) of participants achieving a 30% improvement in SALT score (SALT30) by visit



Investigator's Assessment of a Target Scalp Lesion

A target scalp lesion that best represents the overall severity (50% or greater hair loss) of AA, in the upper parietal region of scalp, if feasible, will be selected at the Baseline (Day 1) visit. The same target scalp lesion will be assessed at all subsequent visits.

At the scheduled clinic visits, the investigator will rate the severity of target scalp lesion as it looks on the day of study visit on a 5-point scale ranging from 0 = "no" to 4 = "very severe". The investigator's assessment of a target scalp lesion (IATS) will be performed by the investigator.

Investigator's Global Assessment (Eyebrows, Eyelashes, and Fingernails)

At the scheduled clinical visits, the investigator will rate the severity of eyebrow hair loss (IGA-EB), eyelashes hair loss (IGA-EL), and fingernail changes (IGA-FN) as it looks on the day of study visit on a 5-point scale ranging from 0 = "no" to 4 = "very severe".

The investigator's global assessment will be performed by the investigator.

Patient's Global Impression of Severity of Alopecia Areata

At scheduled clinic visits, participants will be asked to rate patient's global impression of severity (PGIS) of their overall AA (PGIS-AA) and AA on the scalp (PGIS-S), eyebrows (PGIS-EB), eyelashes (PGIS-EL), and fingernails changes (PGIS-FN) using a 5-point scale ranging from 0 = "none" to 4 = "very severe".

Patient's Global Impression of Change of Alopecia Areata

At scheduled clinic visits, participants will be asked to rate patient's global impression of change (PGIC) in AA (PGIC-AA) and AA on scalp (PGIC-S), eyebrows (PGIC-EB), eyelashes (PGIC-EL), and fingernails (PGIC-FN) using a 5-point scale ranging from 1 = "much better" to 5 = "much worse". Participants will be asked to provide this rating in comparison to just before they started taking study treatment.

Alopecia Areata Patient Priority Outcomes

The alopecia areata patient priority outcome (AAPPO) scale is a participant self-administered 11-item questionnaire that measures hair loss (4 items using a 5-point scale), emotional symptoms (4 items using a 5-point scale), and activity limitations (3 items using a 5-point scale) over the past week (Wyrwich et al 2022).

The AAPPO is completed by the participant in the study clinic.

Hospital Anxiety and Depression Scale

The hospital anxiety and depression scale (HADS) is a 14-item self-assessment scale that determines the levels of anxiety (7 items) and depression (7 items) that a patient is experiencing over the past week. The HADS utilizes a 4-point Likert response scale (e.g., 0 to 3) for each item. Scores for each domain (anxiety and depression) can range from 0 to 21, with higher scores indicating greater anxiety or depression (Zigmond et al 1983).

The HADS is completed by the participant in the study clinic.

4.6 Safety Variables

4.6.1 Adverse Events and Serious Adverse Events Variables

Adverse events and serious adverse events will be collected from the time of informed consent signature until the end of the study. All adverse events will be coded according to the latest available version (26.0 or higher) of MedDRA.

An **Adverse Event** is the development of any untoward medical occurrence in a participant or clinical study participant who is administered with a medicinal product that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product, including the following conditions:

1) Any newly occurred undesirable medical condition (including newly diagnosed disease or signs and symptoms when a diagnosis is pending);
2) Exacerbation of a chronic or intermittent pre-existing condition including either an increase in frequency and/or intensity of the condition. However, events that are unequivocally due to natural disease progression of the underlying disease being studied should not be reported as an AE during the study unless judged by the investigator to be more severe than expected for the participant condition;
3) Clinically significant laboratory abnormality.

A **Serious Adverse Event** is defined as any untoward medical occurrence that, at any dose, meets one or more of the criteria listed:

- **Results in death**
- **Is immediately life threatening**
- **Requires in-patient hospitalization or prolongation of existing hospitalization**
- **Results in persistent or significant disability or incapacity**
- **Is a congenital abnormality or birth defect**
- **Is an important medical event** (i.e., that may jeopardize the participant or may require medical treatment to prevent one of the outcomes listed above.)

Details for each criterion above are presented in the study protocol section 8.1.2.

Non-treatment emergent AEs are AEs that are developed or worsened in severity compared to the baseline during the period between participant enrolment and the first study drug administration. All AEs collected during the screening period are considered as non-TEAEs.

Treatment-emergent AEs (TEAEs) are AEs that developed or worsened in severity compared to the baseline during the treatment and follow-up period (including the extended follow-up). As only the worsening pre-existing AEs and new AEs reported during the treatment and follow-up period (including the extended follow-up) will be collected in the study, all AEs collected

during the treatment and follow-up period (including the extended follow-up) are considered as TEAEs.

TEAE that are infusion related reaction will be summarized. Localized injection/infusion reactions that may include pruritus, pain, erythema, swelling, rashes, or bleeding around the injection/infusion site. Systemic injection/infusion-related reactions may be immediate type or delayed type immune complex-associated hypersensitivity reactions (e.g., serum sickness).

4.6.2 Laboratory Safety Variables

Hematology, chemistry, urinalysis, and pregnancy testing samples will be drawn at the timepoints as described in the Schedule of assessment (SoA) (Appendix 11.1) and analyzed at central laboratories.

Hematology	**Serum chemistry**[a]	**Urinalysis**[b]
Red blood cell count Hemoglobin Reticulocyte % White blood cell count Neutrophils % Neutrophils Lymphocytes % Lymphocytes Monocytes % Monocytes Eosinophils % Eosinophils Basophils % Basophils Platelets	Total protein Albumin Alkaline phosphatase Total bilirubin Aspartate aminotransferase Alanine aminotransferase Lactate dehydrogenase Sodium Potassium Chloride Urea/ blood urea nitrogen Creatinine Calcium Phosphate Glucose	pH Glucose Protein Blood Ketones Nitrite Leukocyte Urobilinogen Bilirubin Specific gravity
Other tests		
HBsAg HBsAb HBcAb HCV antibody HIV antibody QuantiFERON-TB Gold or an equivalent test Pregnancy test (women of childbearing potential only)[c] Serum tryptase[d]		

a) Fasting is recommended but not mandatory. The status of fasting or non-fasting should be recorded in the study source document.

b) If any abnormalities are found in urinalysis, then microscopy should be conducted to examine the red cells, white cells, bacteria, casts, and crystals.

c) Serum hCG will be performed at the Screening, Baseline (Day 1), Week 2 (Day 15), Week 4 (Day 29) visits, and at selected follow-up visits (including the extended follow-up). In addition, urine pregnancy test must be performed prior to dosing at Baseline (Day 1), Week 2 (Day 15) and Week 4 (Day 29) visits.

d) For diagnostic purposes, any participant who experiences any systemic infusion-related event should have a blood sample taken ideally 30-60 minutes after the onset for tryptase testing, and samples may be analyzed by a local laboratory.

4.6.3 Vital Signs and Physical Examination Variables

The following vital signs (VS) parameters will be collected:

- Systolic and diastolic blood pressure (mmHg)

- Pulse rate (bpm)
- Temperature (C)
- Respiratory rate (breaths/min)

Vital signs parameters will be collected as specified in the SoA (Appendix 11.1). On study treatment dosing days, i.e., Baseline (Day 1), Week 2 (Day 15), and Week 4 (Day 29), vital signs should be assessed before initiation of infusion; 15 (± 5) minutes after the initiation of the infusion; 15 (± 5) minutes after EOI, and 1 hour (± 15 minutes) post EOI.

A complete physical examination will include, at a minimum, assessments of the skin, head and neck, cardiovascular, respiratory, gastrointestinal, and neurological systems. Measurement of weight, height, and BMI will be conducted only at baseline, unless any supplementary evaluations necessitate further measurements. All the assessment will be performed as specified in the SoA (Appendix 11.1).

A brief physical examination will include, at a minimum, assessments of the skin, lungs, cardiovascular system, and abdomen (liver and spleen). Symptom-directed physical examinations will be completed at each follow-up (including the extended follow-up) visit at the discretion of the investigator.

Investigators will be instructed to pay special attention to clinical signs related to previous serious illnesses. Unscheduled physical examinations can be conducted at the discretion of the PI or designee.

4.6.4 12-Lead Electrocardiogram (ECG) Variables

The following ECG parameters will be collected:

- Heart rate (bpm)
- PR interval (msec)
- QRS duration (msec)
- QT interval (msec)
- QTcB interval (msec)
- QTcF interval (msec)
- Overall interpretation

Triplicate ECG will be taken if there are any clinically significant abnormalities detected by the physician in a single ECG. The ECG assessment will be performed as specified in the SoA (Appendix 11.1).

4.7 Pharmacokinetic (PK) Variables

The blood samples will be collected at day 1/baseline (pre-dose and EOI), days 8, 15 (pre-dose and EOI), 29 (pre-dose and EOI), 43, 57, 85, 113/EOT, 141, and 169/EOS.

4.8 Pharmacodynamic (PD) Variables

[redacted]

4.9 Immunogenicity Variable

The variables include ADA status (positive or negative) as follows:

- Total participants negative in the ADA assay at all time points analyzed
- Total participants positive in the ADA assay at any time point analyzed
- Total participants with pre-existing ADA
- Total participants with treatment emergent response
- Total participants with treatment boosted response

- *Pre-existing ADA*: Either an ADA positive response in the assay at baseline with all post first dose ADA results negative, OR a positive response at baseline with all post first dose ADA responses less than 4-fold over baseline titer levels.
- *Treatment-boosted response*: Pre-existing ADA that is increased to a higher concentration (4-fold or higher level) after administration of therapeutic protein product.
- *Treatment-emergent response*: ADA developed de novo (seroconversion) following administration of therapeutic protein product in a participant who lacked detectable pre-existing ADA

    a. *Persistent response*: Treatment-emergent response detected at 2 or more sampling time points during the treatment (including follow-up period if any), where the first and last ADA-positive samples (irrespective of any negative samples in between) are separated by a period of 16 weeks or longer.

b. *Indeterminate Response*: Treatment-emergent response with only the last collected sample positive in the ADA assay
c. *Transient response:* Treatment emergent ADA positive assay response that is not considered persistent or indeterminate.

Blood sample for the immunogenicity analysis will be collected at Day 1/Baseline (pre-dose), days 15(pre-dose), 29 (pre-dose), 43, 57, 85, 113/EOT, 141, and 169/EOS.

5. STATISTICAL METHODS

For continuous variables, at the reported visits or in overall summary, descriptive statistics will consist of: number of non-missing observations (n), mean, median, standard deviation (SD), minimum, and maximum. It is to be noted that number of participants with observations could include participants with data that were observed as well as those that were imputed for specific types of missing data or determined based on handling of intercurrent events, as explained in later sections.

For categorical variables, frequencies and percentages will be displayed for each category.

In the context of efficacy-related tables, percentages will be calculated based on the denominator of number of participants with data depending on the handling of intercurrent events as well as imputations of missing data as explained in the later sections. For non-efficacy tables, percentages will be calculated based on the corresponding analysis population unless otherwise specified in the mock shell.

Listed below are some subgroups for potential exploratory subgroup analysis:

- Race (Black/African American vs. Non-Black/Non-African American)
- Age group (<30 years old vs. ≥30 years old)
- SALT Score at baseline (50 to <75, 75 to <95, 95 to 100)
- Age at disease onset (≤12 years old vs. >12 years old)
- Presence of autoimmune comorbidities (Yes vs. No)
- Presence of atopic comorbidities (Yes vs. No)
- Duration of current episode (< 2 years vs. ≥ 2 years)
- Baseline elevated IgE (Yes vs. No)

5.1 Demographics and Baseline Characteristics

Demographics and baseline characteristics will be summarized by treatment groups based on safety analysis set. Listing of demographics and baseline characteristics will be presented.

5.2 Medical and Disease History

Non-alopecia medical history and comorbid (concomitant) non-alopecia medical illness will be summarized by primary system organ class (SOC) and preferred term (PT) for each treatment group. Alopecia disease history and comorbid (concomitant) alopecia medical illness will be summarized separately in the safety analysis set by current scalp AA subtype and treatment group. The table will be sorted by decreasing frequency of SOC followed by PT (or

scalp AA subtype in case of alopecia disease history) based on the overall incidence across treatment groups.

Medical history will be listed by SOC and PT, sorted by treatment groups based on the safety analysis set.

5.3 Prior and Concomitant Medications/Procedures and Prohibited Medications

Below summaries will be provided on prior and concomitant medications/procedures for the safety analysis set, sorted by decreasing frequency of ATC level 2 and preferred term, based on the overall incidence for the combined IMG-007 treatment group.

- Summary of prior alopecia medications by ATC level 2 term and preferred term.
- Summary of prior alopecia medications by reason for discontinuation, ATC level 2, and preferred term.
- Summary of prior non-alopecia medications ATC level 2 term and preferred term.
- Summary of concomitant medications by ATC level 2 term and preferred term.

Listings will be provided for prohibited medications, prior alopecia and non-alopecia medications/procedures, and concomitant medications by treatment for the safety analysis set. The listings will include reported term, ATC level 2, preferred term, Indication, dose, frequency, route, start date, study day onset (for medications started before treatment, the study day onset (defined as date of medication start - date of the first dose; for medications started on or after treatment, the study day onset = date of medication start - date of the first dose+1), the study end date (defined similarly as for study onset day).

5.4 Prior and Concomitant Non-Drug Therapies and Procedures

Below summaries will be provided on prior and concomitant non-drug therapies/ procedures for the safety analysis set.

- Summary of prior non-drug therapies/procedures related to AA by SOC and PT.
- Summary of prior non-drug therapies by SOC and PT for treating conditions other than AA.
- Summary of concomitant non-drug therapies by SOC and PT.

A listing will be provided for non-drug therapies and procedures. The listing will include reported term, dictionary terms, Indication, start date, study day onset (defined similarly as for medications in above section), end date and end study day (defined similarly as for medications in above section).

5.5 Participant Disposition

Summaries will be provided for the following data in each treatment group for the full study sample (i.e., all screened participants who signed informed consent):

- The number and percentage of participants screened, and who failed screening, along with the reasons for screen failure. (This will be reported only in the overall group.)
- The number and percentage of participants included in each treatment group as well as in each study analysis set.
- The number and percentage of participants who completed the 4-week dosing period, discontinued the 4-week dosing period with the reason for discontinuation, completed the 16-week treatment period, discontinued 16-week treatment period with reason for discontinuation, completed the study, and discontinued the study with reason for discontinuation, consented for the extended follow-up, completed the extended follow-up, and discontinued the extended follow-up with reason for discontinuation.

A summary will be provided for major protocol deviations by deviation category and treatment group for the safety analysis set. The protocol deviations flagged as 'CSR Reportable" will be classified as major protocol deviations.

The following listings will be provided.

- The participant disposition listing comprises various details, including the date of informed consent form (ICF) signing, ICF and protocol versions, enrolment or screen failure dates, and the completion/discontinuation date of the 4-week dosing period, date of 16-week treatment period/discontinuation, reason for discontinuation, study completion status, date of study completion, among other factors.
- A listing of screen failures with inclusion criteria not met and/or exclusion criteria met.
- Listing of protocol deviation.

5.6 Treatment Exposure and Compliance

A descriptive summary of treatment exposure will be provided on safety analysis set for the following data.

- summary of dose administered (in mg) by treatment and visit
- summary for dose-weight proportion with the categories; < 3 mg/kg, 3-6 mg/kg, >6-9 mg/kg, and >9 mg/kg.
- Number and percentage the participants with infusion frequency (1, 2 and 3 infusions).
- Summary on overall duration of the treatment.

Overall duration of each treatment will be provided irrespective of intermittent dose interruptions. The duration of treatment exposure in the study is calculated in days as:

(Date of last dose of IMP – date of first dose of IMP) + 84

Categorical summary of visit wise treatment compliance showing the number (n) and percentage of participants falling within the following ranges: <80%, 80%-<100%,100%-

120%, >120% will be presented for each treatment. The compliance with protocol-defined investigational product will be calculated as follows: Treatment Compliance= (actual total dose administered) / (total planned dose) x 100%.

A listing of treatment exposure will be provided on safety analysis set, which includes start and date/time of infusion, infusion administered arm, dose, infusion rate, dose interruption, and details of dose interruption.

5.7 Analysis of Efficacy Variables

All the efficacy evaluations will be performed on modified full analysis set unless otherwise specified.

5.7.1 Analysis of Secondary Efficacy Variable

A descriptive summary (n, mean, median, standard deviation, minimum, maximum, Q1, Q3, standard error) will be provided for percentage change from baseline in SALT score at Week 24 by treatment.

A mixed model repeated measure (MMRM) analysis will be performed for percentage change from baseline in SALT score over time up to Week 24 by considering treatment, visits (up to week 24), and treatment-visit interaction as fixed effects, along with baseline SALT score as a covariate; unstructured covariance matrix will be used for the model errors (Alternative covariance matrices such as Compound symmetry will be used if the unstructured covariance matrix fails to converge) and Kenward-Roger (KR) approximation is used to estimate denominator degrees of freedom.

MMRM will compare the effect of each IMG-007 doses at each post baseline visit versus the baseline based on difference relative to zero. Least square means and their corresponding 95% confidence intervals will be provided for each treatment along with the p-value at nominal two-sided 5% significance level.

In case of convergence issue occurred for the MMRM model, analysis of covariance (ANCOVA) will be used to compare the effect of IMG-007 with the same factors and covariate considered for MMRM. Least square means and their corresponding 95% confidence intervals will be provided at each visit.

Based on the estimand framework introduced in ICH E9(R1) additional details relating to the definition of the estimand is proposed.

[redacted]

[redacted]

Line graphs will be generated to illustrate the percentage change from baseline in the total SALT scores. The X-axis will represent visit, while the Y-axis will denote the change from baseline or percentage change from baseline.

5.7.2 Analysis of Key Exploratory Efficacy Variables

5.7.2.1 Continuous efficacy endpoints

All continuous exploratory efficacy endpoints will be analyzed using the same approach as that used for the main analysis of percentage change in SALT from baseline to Week 24.

For the timepoints beyond Week 24, separate MMRM models will be developed to include all the post-baseline visits until Week 36. However, the estimates and p-values will be reported only for the timepoints beyond Week 24 from these models. The results of earlier timepoints will be reported from the models up to Week 24.

ANCOVA will be utilized as explained in the main analysis section if the MMRM model fails to converge.

Sensitivity analysis

Sensitivity analysis that are specified for the secondary endpoint will be repeated for the key continuous exploratory endpoints as well. For the timepoints beyond Week 24, a separate MMRM model will be developed to include all the post-baseline visits until Week 36. However, the estimates and p-values will be reported only for the timepoints beyond Week 24 from these models. The results of earlier timepoints will be reported from the model up to Week 24.

5.7.2.2 Responder type (binary) efficacy endpoints

The responder type (binary) endpoints will be reported using frequency and percentage by treatment along with the 95% Clopper-Pearson exact confidence interval for the proportion.

Based on the estimand framework introduced in ICH E9(R1), additional details relating to the definition of the estimand is proposed.

Handling of intercurrent events (for responder type binary endpoints) of treatment discontinuation and prohibited medication:

- *Treatment discontinuation*: Treatment policy strategy will be followed. i.e., all the collected data available after treatment discontinuation will be included in the analysis.
- *Any prohibited medication*: Participant will be reported as non-responder at all the visits occurring after the prohibited medication start.

Handling of missing data

After the handling of intercurrent events explained above, missing data will be managed in two steps as given below.

1) Non-responder imputation will be performed for all scheduled visits following participant discontinuation from the study with the reason ‘lack of efficacy’.
2) LOCF approach will be applied for all missing visits, except for missing data that arises following study discontinuation with reason 'lack of efficacy'.

Sensitivity analysis

No prespecified sensitivity analyses will be performed. Additional post-hoc sensitivity analysis will be considered as appropriate later.

Line plots will be included to depict responder-type of endpoints of SALT for each treatment group. The X-axis will feature visits, and the Y-axis will represent the proportion of participants, expressed as a percentage.

5.7.3 Analysis of Other Exploratory Efficacy Variables

All the continuous exploratory variables will be analyzed using descriptive statistics (n, mean, median, standard deviation, minimum, and maximum).

All the binary exploratory variables will be summarized with frequency and percentages.

Intercurrent events will be handled as described in section 5.7.1 and 5.7.2.2 based on the characteristics of the analysis variable. No additional missing data imputations and sensitivity analysis are applicable for other exploratory endpoints.

5.8 Analysis of Safety Data

The summary of safety data will be performed based on safety analysis set.

The safety analysis will be based on the reported AEs, clinical laboratory evaluations, physical examination, vital signs, and 12-lead ECG.

5.8.1 Analysis of Adverse Events

Incidence tables for both non-TEAEs and TEAEs will be presented for each treatment group and collectively for the combined IMG-007 group. TEAEs will be classified into two groups as follows:

- TEAEs occurred through the 24 weeks of study period: TEAEs with the starting date between the date of first treatment administration and week 24 visit (or end of study, if achieved prior to week 24 visit) will be considered here.
- TEAEs occurring through the 36 weeks of study period: TEAEs with starting between the date of first treatment administration and week 36 visit (or end of study, if achieved prior to week 36 visit) will be considered here.

The table will include the number (n) and percentage (%) of participants who are experiencing an adverse event, along with the corresponding number of episodes of AEs. Participants with multiple adverse events in a particular category will be counted only once in that category.

Participants with multiple severities/grading will be counted only once under maximum severity/grading.

The number and proportion of participants reporting non-TEAEs/TEAEs will be summarized, sorted by decreasing frequency of SOC and PT in the combined IMG-007 group, and in case of ties, then sorted by decreasing frequency of SOC and PT in the IMG-007 [redacted] group, and finally, in case of further ties, then alphabetically.

Listings will be provided by SOC and PT, for non-TEAEs, TEAEs and TESAEs, TEAEs of infusion related reactions, and TEAEs leading to study treatment discontinuation.

The following summaries will be provided for the adverse events by treatment group.

- Overall summary of AEs during the 24-Week Period: The overall summary of AEs will be provided with number and proportions of participants with any:
    - non-TEAE
    - TEAE
    - Related TEAE
    - SAE
    - TEAE by CTCAE grades
    - TEAE that are infusion related reaction
    - TEAE leading to 4-week dosing period discontinuation
    - TEAE leading to 16-week dosing period discontinuation
    - TEAE leading to study discontinuation
    - TEAE with outcome of death
- Overall summary of AEs during the 36 weeks of study period: The overall summary of AEs will be provided with number and proportions of participants with any:
    - TEAE
    - Related TEAE
    - SAE
    - TEAE by CTCAE grades
    - TEAE leading to study discontinuation
    - TEAE with outcome of death
- Summary of non-TEAEs by SOC and PT
- Summary of TEAEs by SOC and PT during 24-Week period
- Summary of TEAEs by SOC and PT during 36-Week period
- Summary of TEAEs occurring for at least 2 participants in any of the treatment group by PT during 24-Week period
- Summary of TEAEs occurring for at least 2 participants in any of the treatment group by PT during 36-Week period
- Summary of Serious TEAEs by SOC and PT during 24-Week period
- Summary of Serious TEAEs by SOC and PT during 36-Week period
- Summary of TEAEs by PT and worst CTCAE grade during 24-Week period
- Summary of TEAEs by PT and worst CTCAE grade during 36-Week period
- Summary of TEAEs with CTCAE grade 3 or higher by PT during 24-Week period
- Summary of treatment related TEAEs by SOC and PT during 24-Week period
- Summary of treatment related TEAEs by SOC and PT during 36-Week period

- Summary of TEAEs leading treatment discontinuation by SOC and PT during 24-Week period
- Summary of TEAEs leading to death by SOC and PT during 24-Week period

5.8.2 Analysis of Clinical Laboratory Measurements

Laboratory measurements include clinical chemistry, hematology and urinalysis results. Summaries of laboratory variables will include:

- Descriptive statistics of continuous laboratory result and change from baseline by visit
- Frequency and percentage summary for categorial lab data (urinalysis)
- The number (n) and percentage (%) of participants with abnormal lab value during study using a shift table
- Number (n) and percentage (%) of participants with CTCAE grade for key hematology parameters (white blood cell [WBC], neutrophils, lymphocytes, platelets, and hemoglobin)
- Number (n) and percentage (%) of participants with CTCAE grade for key serum chemistry parameters (alanine aminotransferase [ALT], aspartate aminotransferase [AST], serum creatinine, and bilirubin)
  Note: When participants have multiple CTCAE grades within the same parameters, the worst CTCAE grade will be considered. Refer Appendix 11.4 for more details on CTCAE grading.

All the above tables will be through the Week 36 visit.

Listing of all laboratory parameters original results, standard results, normal range, abnormal flag and CTCAE grade (wherever applicable) by participant and visit will be provided. Additionally, listings will be provided for pregnancy test, and tuberculosis test.

A line graph illustrating absolute values for key parameters will be presented by visit for each treatment group.

5.8.3 Analysis of Vital Signs

Summaries of vital sign variables will include:

- Descriptive statistics of vital sign variables and change from baseline by treatment and visits/timepoints
- Notable findings in vital signs will be summarized by treatment and visit/timepoint, which are defined as,
  - Temperature: >39.0 degrees
  - An increase in Pulse Rate from baseline by ≥25% for on-treatment values >100 beats/min
  - A decrease in Pulse Rate from baseline by ≥25% for on-treatment values <50 beats/min.
  - Systolic BP≥ 140 mmHg and increase by 20 mm Hg.
  - Diastolic BP≥ 90 mmHg and increase by 10 mm Hg.
  - Systolic BP≤ 80 mmHg and decrease by 20 mm Hg.
  - Diastolic BP≤ 50 mmHg and decrease by 10 mm Hg.

All the above tables will be presented through the Week 36 visit.

A listing of vital signs data will be provided for each participant by treatment and visit.

5.8.4 Analysis of 12-Lead ECG

Summaries of 12-lead ECG parameters by treatment and visit will include:

- Descriptive statistics of actual and change from baseline.
- ECG status (i.e., normal, abnormal) summarized by a shift table
- Notable findings in ECG, which are defined as:
    - a new onset in the QT interval >500 ms
    - a new onset in the QTcF interval >500 ms
    - an increase from baseline in QTcF >60 ms
    - an increase in heart rate from baseline by ≥25% for on-treatment values >100 bpm
    - a decrease in heart rate from baseline by ≥25% for on-treatment values <50 bpm
    - an increase in PR interval from baseline by ≥25% for on-treatment values >200 ms
    - an increase in the QRS interval from baseline by ≥10% for on-treatment values >110 ms, any time on treatment.

All the above tables will be presented through the Week 36 visit.

A listing will be provided for each participant by treatment and visit.

5.8.5 Physical Examination

Results from physical examinations will be listed by participant and treatment at each visit.

5.9 Analysis of Pharmacokinetic Data

Descriptive summary tables (geometric mean, arithmetic mean, minimum, maximum, SD, and % coefficient of variation etc.) will be presented for the below categories by visit.

- Serum concentration for each treatment group
- PK concentration in ADA positive and ADA negative participants by treatment group
- Dose adjusted PK concentration in ADA positive and ADA negative participants

Following figures will be provided for the serum concentration data,

- Mean (±SD) serum concentration vs time profile: Linear scale
- Mean (±SD) serum concentration vs time profile: Semi-log scale
- Individual serum concentrations vs time profile: Linear scale
- Individual serum concentrations vs time profile: Semi-log scale

Serum concentration will be listed for each participant by treatment and visit.

5.10 Analysis of Pharmacodynamic Data

5.10.1 Handling of PD data based on the prohibited medication use

All the PD assessments (except OX40 occupancy on CD4+ T cell and OX40+/CD4+ T cell in CD4+ T cell) will be treated similar to the secondary efficacy assessment for handling the intercurrent event (prohibited medication). That is, all PD assessments after the start date of first prohibited medication use of each participant will be set to missing. The results for OX40 occupancy on CD4+ T cells and OX40+/CD4+ T cells within CD4+ T cells will be used as collected.

Statistical analysis of the following pharmacodynamic variables will be presented.

- Listing of RO (%) by visit for individual
- Table and figure of RO (%) over time for each dose group
- Listing of Percentage of OX40+/CD4+ T cell in CD4+ T cell (%) by visit for individual
- Table and figure of Percentage of OX40+/CD4+ T cell in CD4+ T cell over time for each dose group
- Listing of Olink target 48 cytokine panel proteins levels in serum (pg/mL), by visit for individual (45 proteins)
- Table and figure of Olink target 48 cytokine panel proteins levels in serum (pg/mL) log10 transformed change from baseline over time for each dose group (45 proteins)
- Listing of Olink target 48 immune surveillance panel proteins levels in serum (pg/mL), by visit for individual (44 proteins)
- Table and figure of Olink target 48 immune surveillance panel proteins levels in serum (pg/mL) log10 transformed change from baseline over time for each dose group (44 proteins)
- Figure of baseline Th1/Th2/Th17/Th22 fold change vs healthy subject for individual
- Figure of baseline, Week 16 and Week 24 Th1/Th2/Th17/Th22 fold change vs healthy subject for each dose group
- Table and figure of IgE (IU/mL) log10 transformed change from baseline over time for each dose group
- Listing of levels of IgE for individual
- Listing of OX40 positive cells (cells/mm2) in biopsy by visit for individual
- Table and figure of Week 24 LS (Lesion) vs Week 16 LS vs baseline LS vs baseline NL (non-lesion) OX40 positive cells in biopsy for each dose group
- Listing of OX40L positive cells (cells/mm2) in biopsy by visit for individual
- Table and figure of Week 24 LS vs Week 16 LS vs baseline LS vs baseline NL OX40L positive cells in biopsy for each dose group
- Listing of Tryptase positive cells (cells/mm2) in biopsy by visit for individual
- Table and figure of Week 24 LS vs Week 16 LS vs baseline LS vs baseline NL Tryptase positive cells in biopsy for each dose group
- Listing of CD3 positive cells (cells/mm2) in biopsy by visit for individual
- Table and figure of Week 24 LS vs Week 16 LS vs baseline LS vs baseline NL CD3 positive cells in biopsy for each dose group
- Listing of CD8 positive cells (cells/mm2) in biopsy by visit for individual

- Table and figure of Week 24 LS vs Week 16 LS vs baseline LS vs baseline NL CD8 positive cells in biopsy for each dose group
- Listing of FcEpsilonR1 positive cells (cells/mm2) in biopsy by visit for individual
- Table and figure of Week 24 LS vs Week 16 LS vs baseline LS vs baseline NL FcEpsilonR1 positive cells in biopsy for each dose group
- Listing of expression of KRT35 in biopsy by visit for individual
- Listing of H&E staining results description in biopsy by visit for individual

Additionally, further analysis of the pharmacodynamic variables, including RNAseq data and related considerations will be performed by Dr. Emma Guttman's lab at Icahn School of Medicine at Mount Sinai and biomarker team at sponsor, which will be documented separately.

5.11 Analysis of Immunogenicity Data

The ADA variables will be summarized using descriptive statistics by treatment in the immunogenicity analysis set. Frequency tables of the proportion of participants developing ADA positivity in the ADA assay, pre-existing ADA, treatment-emergent, treatment-boosted, persistent, indeterminate and transient ADA responses will be presented as absolute occurrence (n) and percent of participants (%), presented by treatment groups.

A listing of ADA data will be provided. The number and percentage of participants with ADA positive at each visit will be presented in the listing. The percentage will be based on the number of participants with ADA assessment at each visit.

The following summaries will be performed on the immunogenicity analysis set:

- Number (%) of patients negative ADA at all the time points analyzed by treatment group
- Number (%) of patients ADA positive at time points analyzed by treatment group
- Number (%) of patients with pre-existing ADA, treatment-emergent ADA, and treatment boosted ADA response by treatment group
- Number (%) of patients with persistent, transient and indeterminate treatment-emergent ADA response by treatment group
- Descriptive statistics of PK concentration in ADA positive and ADA negative participants by treatment group
- Descriptive statistics of dose adjusted PK concentration in ADA positive and ADA negative participants

6. DATA CONVENTIONS

The following analysis conventions will be used in the statistical analysis.

6.1 Definition of Baseline for Efficacy/Safety Variables

Unless otherwise specified, the baseline assessment for all measurements will be the latest available valid measurement taken prior to the administration of study drug (Week 0 (Day 1)).

When it is not possible to determine the time of assessment, baseline value would be determined based on the measurement recorded on the day administration of the first dose of IMP.

6.2 Missing Data Handling

Missing data will not be imputed in listings. This section includes the methods for missing data imputation for some summary analyses, if necessary.

Adverse event

If the intensity of a TEAE is missing, it will be classified as "severe" in the frequency tables by intensity of TEAE. If the assessment of relationship of a TEAE to the investigational product is missing, it will be classified as "related" in the frequency tables by relation to the investigational product.

The partial date values will be imputed as specified in the Appendix 11.2. Imputed dates will not be presented in the listings.

6.3 Analysis Visit Window

For summaries that include data collected over multiple visits, where appropriate, the data will be summarized by analysis visit window. If there are multiple measurements within a scheduled visit window (refer Appendix 11.3), the closest measurement to the scheduled timepoint of the visit will be used in the analysis. If there are two observations which have the same difference in days to the planned day, but which are not measured on the same day, the later value will be selected. If there is more than one observation on the same day, then;

- Latest value will be considered in all cases except for vital signs, ECG.
- Average value will be considered in cases of vital signs and continuous ECG values.
- The worst value will be considered for ECG interpretation.

For PK and ADA data, if multiple measurements are taken within a scheduled visit window, the earliest value will be used for the analysis.

All measurements will be presented in the listing.

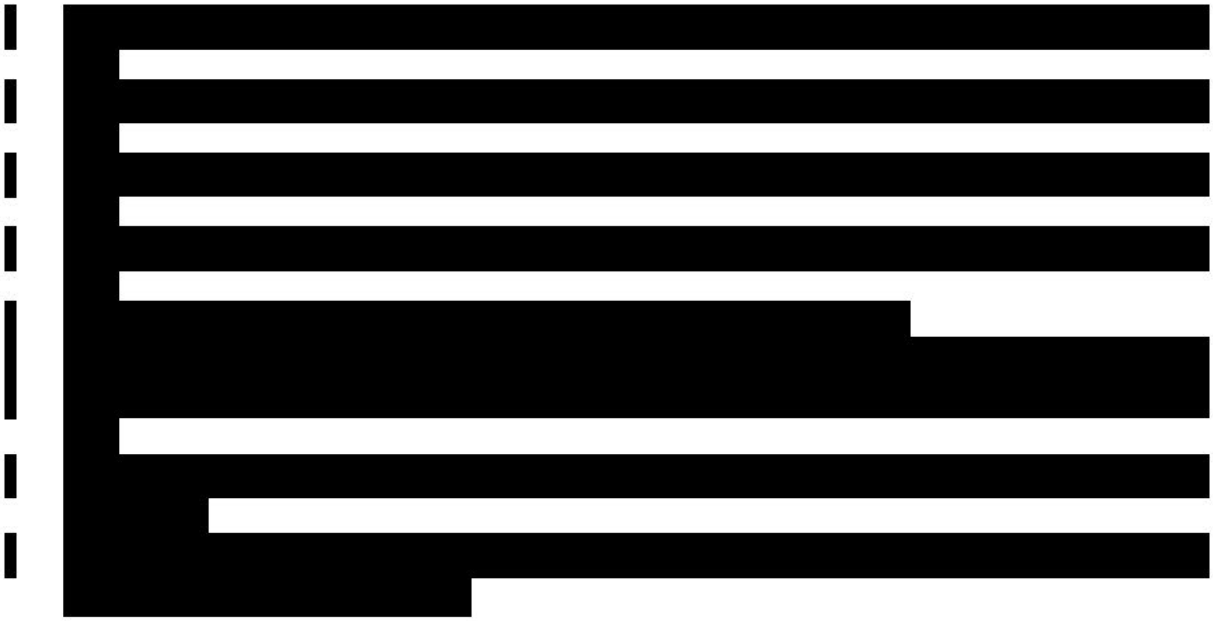
7. PLANNED ANALYSES

7.1 Interim Analysis

[redacted]

7.1.1 Interim Analyses Outputs

[redacted]



TEAE

- Overall summary of TEAE
- Summary of TEAEs by SOC and PT
- Summary of Serious TEAEs by SOC and PT
- Summary of TEAEs occurring for ≥2 participants in any of the treatment group by SOC and PT
- Summary of TEAEs by PT and maximum severity
- Summary of TEAEs with CTCAE grade 3 or higher by PT
- Summary of treatment related TEAEs by SOC and PT

Lab values

- Descriptive statistics of continuous laboratory result and change from baseline by visit in hematology and chemistry parameters
- Number (n) and percentage (%) of participants with CTCAE grade for key hematology parameters (WBC, neutrophils, lymphocytes, platelet, and hemoglobin)
- Number (n) and percentage (%) of participants with CTCAE grade for key serum chemistry parameters (ALT, AST, serum creatinine, and bilirubin)

Vital signs

- Proportion of participants with notable findings in vital signs

ECG

- Proportion of participants with notable findings in ECG

IHC results

- Listing of OX40 positive cells (cells/mm2) in biopsy by visit for individual and for each dose group
- Listing of OX40L positive cells (cells/mm2) in biopsy by visit for individual and for each dose group

- Listing of Tryptase positive cells (cells/mm2) in biopsy by visit for individual and for each dose group
- Listing of CD3 positive cells (cells/mm2) in biopsy by visit for individual and for each dose group
- Listing of CD8 positive cells (cells/mm2) in biopsy by visit for individual and for each dose group
- Listing of FcEpsilonR1 positive cells (cells/mm2) in biopsy by visit for individual and for each dose group
- Listing of KRT35 staining results in biopsy by visit for individual and for each dose group
- Listing of H&E staining results in biopsy by visit for individual and for each dose group

7.2 Final Analysis

[redacted]

8. SAFETY REVIEW COMMITTEE

A safety review committee (SRC) consisting of three independent physicians will be convened to review safety data, dose escalation criteria, and the study stopping criteria.

SRC analysis outputs will be prepared as outlined in the document '*Statistical Considerations for the SRC Analysis of IMG-007-202 Data'* dated 11Apr2024. The list of SRC outputs is given in the Appendix 11.5.

9. SOFTWARE

All analyses will be done using SAS Version 9.4 or above.

10. REFERENCES

IMG-007-202 clinical trial protocol: A Phase 1b/2a Study to Evaluate the Safety, Pharmacokinetics, and Efficacy of IMG-007 in Adult Alopecia Areata Participants with 50% or Greater Scalp Hair Loss. V4.0 and 4.1(02Aug2024)

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11. APPENDIX

11.1 Schedule of Assessments

Procedures	**Screening**	**Treatment Period**								**Follow-up Period**		**Extended Follow-up Period post EOS**	
		Baseline							**EOT**[21]	**EOS**[21]			
Visit	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13
		Week 0	Week 1	Week 2	Week 4	Week 6	Week 8	Week 12	Week 16	Week 20	Week 24	Week 30	Week 36
	Day -35 to -1	Day 1	Day 8	Day 15	Day 29	Day 43	Day 57	Day 85	Day 113	Day 141	Day 169	Day 211	Day 253
Time window			± 3d	± 3d	± 3d	± 3d	± 3d	± 3d	± 3d	± 3d	± 3d	± 7d	± 7d
Informed consent[1]	X												
Demographics and medical history[2]	X												
Vital signs[3]	X	X	X	X	X	X	X	X	X	X	X	X	X
Physical examination[4]	X	X	X	X	X	X	X	X	X	X	X	X	X
12-lead ECG	X	X							X		X		X
Inclusion/exclusion criteria	X	X											
Prior and concomitant therapies	X	X	X	X	X	X	X	X	X	X	X	X	X
AE	X	X	X	X	X	X	X	X	X	X	X	X	X
Hematology and serum chemistry[5]	X	X	X	X	X	X	X	X	X	X	X		X
Total IgE[5]		X											
Urinalysis[5]	X	X		X	X				X		X		X
TB testing and TB risk follow up[5,6]	X								X		X		X
Viral disease screening[5,7]	X												
Pregnancy tests (WCBP only)[5,8]	X^{S}	X^{S+U}		X^{S+U}	X^{S+U}		X^{S}	X^{S}	X^{S}	X^{S}	X^{S}		X^{S}
Administration of study treatment[9]		X		X	X								
SALT, IGA-EB, IGA-EL, IGA-FN[10]	X	X			X	X	X	X	X	X	X	X	X
IATS[10]		X			X	X	X	X	X	X	X	X	X
PGIS-AA, PGIS-S, PGIS-EB, PGIS-EL, PGIS-FN[11], AAPPO[12], HADS[13]		X			X	X	X	X	X	X	X	X	X
PGIC-AA, PGIC-S, PGIC-EB, PGIC-EL, PGIC-FN[14]					X	X	X	X	X	X	X	X	X
PK sampling[15]		X	X	X	X	X	X	X	X	X	X		
ADA sampling[16]		X		X	X	X	X	X	X	X	X		

Procedures	**Screening**	**Treatment Period**								**Follow-up Period**		**Extended Follow-up Period post EOS**	
		Baseline							**EOT**[21]	**EOS**[21]			
Visit	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13
		Week 0	Week 1	Week 2	Week 4	Week 6	Week 8	Week 12	Week 16	Week 20	Week 24	Week 30	Week 36
	Day -35 to -1	Day 1	Day 8	Day 15	Day 29	Day 43	Day 57	Day 85	Day 113	Day 141	Day 169	Day 211	Day 253
Time window			± 3d	± 3d	± 3d	± 3d	± 3d	± 3d	± 3d	± 3d	± 3d	± 7d	± 7d

[redacted]

1. Study-specific procedures will be performed after receipt of signed informed consent.
2. Medical history includes prior/concurrent relevant conditions and medications, prior/current AA treatment, and surgical history. At the Baseline (Day 1) visit, medical history is updated prior to administration of study treatment. Demographics include year of birth, gender, race and ethnicity, height, and body weight. BMI will be calculated as weight (kg) / [height (m) x height (m)].
3. Vital signs include blood pressure, pulse, respiratory rate and body temperature. On study treatment dosing days, i.e., Baseline (Day 1), Week 2 (Day 15), and Week 4 (Day 29), vital signs should be assessed before initiation of infusion; 15 (± 5) minutes after the initiation of the infusion; 15 (± 5) minutes after EOI, and 1 hour (± 15 minutes) post EOI. Participants need to rest for 5 minutes before having their vital signs measured.
4. Physical examination: A full physical examination will be performed at Screening. A brief physical examination will be completed at the Baseline visit, and symptom-directed physical examinations will be completed at each follow-up (including the extended follow-up) visit at the discretion of the investigator.
5. Laboratory assessments will be analyzed at a central laboratory. If lab test results do not meet the inclusion/exclusion criteria at Screening, a repeat test may be performed. The sample should be taken before dosing on dosing days.
6. All participants will undergo TB test (QuantiFERON-TB Gold [QFT-G] test or an equivalent test) at Screening. Participants who receive study treatment will be followed up by a TB risk assessment questionnaire at Week 16 (Day 113)/EOT, Week 24 (Day 169)/EOS and Week 36 (Day 253). If the participants have a negative TB test at the initial screening evaluation, the TB test could be waived at the rescreening if no changes in the participant's medical history that warrant retesting, and no more than 90 days have passed.
7. Viral disease screening includes HBsAg, HBsAb, HBcAb, HCV antibody and HIV antibody.
8. Pregnancy tests are only for women who are of childbearing potential. Serum hCG will be performed at the Screening, Baseline (Day 1), Week 2 (Day 15), Week 4 (Day 29) visits, and at the selected follow-up (including the extended follow-up) visits. In addition, a urine pregnancy test must be performed prior to dosing at the Baseline (Day 1), Week 2 (Day 15), and Week 4 (Day 29) visits, which will be conducted at the study site.
9. On dosing days, study treatment will be administered as an IV infusion over approximately 60 minutes with a slower rate during the first 15 minutes. Participants will be closely monitored at the study site for a minimum of 1 hour after completion of each infusion or until any AEs observed have resolved or stabilized, whichever is longer. For diagnostic purposes, any participant who experiences any systemic infusion-related event should have a blood sample taken, ideally 30–60 minutes after the onset, for tryptase testing, and samples should be analyzed by a local laboratory if feasible. Study sites should have access to equipment or facilities for the management of potential hypersensitivity reactions. On dosing days, study treatment infusion should be performed after other study assessments have been performed. If a dose is not administered on schedule due to a visit occurring beyond the visit window specified or due to dose interruption for reasons stated in Section 6.10.1.2 of protocol, the dose may be administered if it is no later than 5 days after the allocated visit day (a 10-day delay will be allowed for the last dose at Week 4) specified. Otherwise, the dose will be considered missed, and dosing will resume with the next scheduled dose. The study site will contact the participants by telephone approximately 24 hours after the infusion for general AE query.

10. SALT, IATS, IGA-EB, IGA-EL, IGA-FN should be performed only by adequately trained investigators or sub-investigators. Efforts should be made that the same assessor performs the assessments of a particular participant throughout the study. IGA-EB, IGA-EL, IGA-FN will only be performed in participants with AA on eyebrows, eyelashes and/or nails.
11. Participants will complete the questionnaire for PGIS-AA, PGIS-S, PGIS-EB, PGIS-EL and PGIS-FN. PGIS-EB, PGIS-EL and PGIS-FN will only be performed in participants with AA on eyebrows, eyelashes and/or nails.
12. Participants will complete the AAPPO questionnaire to measure hair loss, emotional symptoms, and activity limitations over the past week.
13. Participants will complete the HADS to assess states of anxiety and depression over the past week.
14. Participants will complete the questionnaires for PGIC-AA, PGIC-S, PGIC-EB, PGIC-EL and PGIC-FN. PGIC-EB, PGIC-EL and PGIC-FN will only be performed in participants with AA on eyebrows, eyelashes and/or nails.
15. On dosing days, blood sample should be taken within 60 minutes before dosing and within 10 minutes after end of infusion.
16. On dosing days, blood sample should be taken within 60 minutes before dosing.

[redacted]

21. Participants who discontinue treatment early (before completing the 4-week dosing period) should continue with all the remaining study visits. Participants who withdraw from the study any time before the Week 16 visit should complete the Week 16 (Day 113)/EOT visit at withdrawal. Participants who withdraw from study early during the follow-up period should complete the Week 24 (Day 169)/EOS visit at withdrawal. Participants who discontinue early after the Week 24/EOS visit but before the Week 36 visit should complete Week 36 (Day 253) visit at withdrawal.

Abbreviations: AA = alopecia areata; ADA = anti-drug antibody; AAPPO= alopecia areata patient priority outcomes; AE = adverse event; BMI = body mass index; ECG = electrocardiogram; EOI = end of infusion; EOS = end of study; EOT = end of treatment; HADS= hospital anxiety and depression scale; HBcAb = antibody to hepatitis B core antibody; HBsAb= hepatitis B surface antibody; HBsAg= hepatitis B surface antigen; hCG = human chorionic gonadotropin; HCV = hepatitis C virus; HIV = human immunodeficiency virus; IATS = investigator's assessment of a target scalp lesion; IGA-EB = investigator's global assessment of eyebrows; IGA-EL = investigator's global assessment of eyelashes; IGA-FN = investigator's global assessment of fingernails; IgE = immunoglobulin E; IV = intravenous; PD = pharmacodynamic; PGIC-AA = patient's global impression of change of alopecia areata; PGIC-EB = patient's global impression of change of alopecia areata on eyebrows; PGIC-EL = patient's global impression of change of alopecia areata on eyelashes; PGIC-FN = patient's global impression of change of alopecia areata on fingernails; PGIC-S= patient's global impression of change of alopecia areata on scalp; PGIS-AA = patient's global impression of severity of alopecia areata; PGIS- EB = patient's global impression of severity of alopecia areata on eyebrows; PGIS- EL = patient's global impression of severity of alopecia areata on eyelashes; PGIS-FN = patient's global impression of severity of alopecia areata on fingernails; PGIS-S = patient's global impression of severity of alopecia areata on scalp; PK = pharmacokinetic; S = serum; SALT= severity of alopecia tool; TB = tuberculosis; U = urine; V = visit; WCBP = women of childbearing potential

11.2 Partial Date Conventions

Algorithms for Adverse Events, Medical History, and Prior and Concomitant Medications

Partial date to be imputed as:

Start Date	**Stop Date**	**Action**
Complete	Complete	No action
Partial, but known components shows it can't be on or after study medication start	Complete	Impute the start date as "01", if only the day is missing. Impute the start date as "01 January", if month and day are missing.
	Date and/or month missing	Impute the stop date as the latest possible date (i.e., last day of the month, if only the day is missing or "31 December" if month and day are missing).
Partial, could be on or after the study medication start Or missing	Complete	1) If stop date < study medication start then, Impute the start date as earliest possible date (i.e., "01", if only the day is missing or "01 January", if month and day are missing). 2) If stop date >= study medication start then, impute the start date equal to the study medication start date.
	Partial	Impute the stop date as the latest possible date (i.e., last day of the month, if only the day is missing or "31 December" if month and day are missing). then, 1) If stop date < study medication start then, impute the start date earliest possible date. 2) If stop date >= study medication start, then impute the start date equal to the study medication start date.
	Missing	Missing date will not be imputed.

11.3 Analysis Visit Window

Analysis Visit	Target Day	Group 1	Group 2	Group 3	Group 4	Group 5*	Group 6	Group 7
Baseline	1	Up to day 1	Up to day 1	Up to day 1	Up to day 1	Up to day 1	Up to day 1	Up to day 1
Week 1	8	2-11	-	-	-	-	-	-
Week 2**	15	12-25	2-25	2-25	2-25	-	-	2-25
Week 4	29	26-36	26-36	26-71	26-43	2-36	-	>25
Week 6	43	37-50	37-50	-	-	37-50	-	-
Week 8	57	51-71	51-71	-	44-71	51-71	-	-
Week 12	85	72-99	72-99	-	72-99	72-99	-	-
Week 16	113	100-127	100-127	72-141	100-127	100-127	2-141	-
Week 20	141	128-155	128-155	-	128-155	128-155	-	-
Week 24	169	156-190	156-190	142-211	156-211	156-190	142-190	-
Week 30	211	191-232	-	-	-	191-232	191-232	-
Week 36	253	233-274	-	212-274	212-274	233-274	233-274	-

Group 1: Vital signs, Physical examination, Adverse events, Prior and concomitant therapies, Hematology, blood chemistry, PK sampling.
Group 2: ADA sampling
Group 3: Urinalysis
Group 4: Pregnancy test
Group 5: SALT, IATS, IGA-EB, IGA-EL, IGA-FN, PGIS-AA, PGIS-S, PGIS-EB, PGIS-EL, PGIS-FN, AAPPO, HADS
Group 6: ECG, TB testing and TB risk follow up
Group 7: Study treatment administration

*Use group 5 for PD blood sample by removing week 6 and changing the Week 4 window from “2-36” to “2-43” and Week 8 window from ’51-71’ to “44-71”.
** The upper bound of window period extended by 3 days to accommodate the unscheduled Week 2 assessments.

11.4 CTCAE Version 5.0 for Key Hematology and Serum Chemistry Parameters

CTCAE Term	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
White blood cell decreased	<LLN - 3000/mm3; <LLN - 3.0 x 10e9 /L	<3000 - 2000/mm3; <3.0 - 2.0 x 10e9 /L	<2000 - 1000/mm3; <2.0 - 1.0 x 10e9 /L	<1000/mm3; <1.0 x 10e9 /L	-
Neutrophil count decreased	<LLN - 1500/mm3; <LLN - 1.5 x 10e9 /L	<1500 - 1000/mm3; <1.5 - 1.0 x 10e9 /L	<1000 - 500/mm3; <1.0 - 0.5 x 10e9 /L	<500/mm3; <0.5 x 10e9 /L	-
Lymphocyte count decreased	<LLN - 800/mm3; <LLN - 0.8 x 10e9/L	<800 - 500/mm3; <0.8 - 0.5 x 10e9 /L	<500 - 200/mm3; <0.5 - 0.2 x 10e9 /L	<200/mm3; <0.2 x 10e9 /L	-
Anemia	Hemoglobin (Hgb) <LLN - 10.0 g/dL; <LLN - 6.2 mmol/L; <LLN - 100 g/L	Hgb <10.0 - 8.0 g/dL; <6.2 - 4.9 mmol/L; <100 - 80g/L	Hgb <8.0 g/dL; <4.9 mmol/L; <80 g/L; transfusion indicated	Life-threatening consequences; urgent intervention indicated	Death
Platelet count decreased	<LLN - 75,000/mm3; <LLN - 75.0 x 10e9 /L	<75,000 - 50,000/mm3; <75.0 - 50.0 x 10e9 /L	<50,000 - 25,000/mm3; <50.0 - 25.0 x 10e9 /L	<25,000/mm3; <25.0 x 10e9 /L	-
Alanine aminotransferase increased	>ULN - 3.0 x ULN if baseline was normal; 1.5 - 3.0 x baseline if baseline was abnormal	>3.0 - 5.0 x ULN if baseline was normal; >3.0 - 5.0 x baseline if baseline was abnormal	>5.0 - 20.0 x ULN if baseline was normal; >5.0 - 20.0 x baseline if baseline was abnormal	>20.0 x ULN if baseline was normal; >20.0 x baseline if baseline was abnormal	
Aspartate aminotransferase increased	>ULN - 3.0 x ULN if baseline was normal; 1.5 - 3.0 x baseline if baseline was abnormal	>3.0 - 5.0 x ULN if baseline was normal; >3.0 - 5.0 x baseline if baseline was abnormal	>5.0 - 20.0 x ULN if baseline was normal; >5.0 - 20.0 x baseline if baseline was abnormal	>20.0 x ULN if baseline was normal; >20.0 x baseline if baseline was abnormal	
Blood bilirubin increased	>ULN - 1.5 x ULN if baseline was normal; > 1.0 - 1.5 x baseline if baseline was abnormal	>1.5 - 3.0 x ULN if baseline was normal; >1.5 - 3.0 x baseline if baseline was abnormal	>3.0 - 10.0 x ULN if baseline was normal; >3.0 - 10.0 x baseline if baseline was abnormal	>10.0 x ULN if baseline was normal; >10.0 x baseline if baseline was abnormal	
Creatinine increased*	>ULN - 1.5 x ULN	>1.5 - 3.0 x baseline; >1.5 - 3.0 x ULN	>3.0 x baseline; >3.0 - 6.0 x ULN	>6.0 x ULN	

*The reference range for Grade 2 and Grade 3, that includes the baseline value, is not applicable if the baseline value is abnormal.

11.5 List of SRC outputs

Efficacy Output:

- Mean and mean % change from baseline in SALT by visit

Safety Outputs:

TEAE

- Overall summary of TEAE
- Summary of TEAEs by SOC and PT
- Summary of Serious TEAEs by SOC and PT
- Summary of TEAEs with CTCAE grade 3 or higher by PT
- Summary of treatment related TEAEs by SOC and PT

Lab values

- Number (n) and percentage (%) of participants with CTCAE grade for key hematology parameters (WBC, neutrophils, lymphocytes, eosinophils, platelet, and hemoglobin)
- Number (n) and percentage (%) of participants with CTCAE grade for key serum chemistry parameters (ALT, AST, serum creatinine, and bilirubin)

Vital signs

- Notable findings in vital signs

ECG

- Notable findings in ECG