Janssen Pharmaceutical K.K.*

Statistical Analysis Plan

A Phase 3, Multicenter, Open-label Study to Evaluate the Efficacy and Safety of JNJ-77242113 for the Treatment of Participants With Generalized Pustular Psoriasis or Erythrodermic Psoriasis

Protocol 77242113PSO3005; Phase 3

JNJ-77242113

*This study is being conducted by Janssen Pharmaceutical K.K. in Japan.

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Compliance: The study described in this document will be performed according to the principles of Good Clinical Practice.

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VERSION HISTORY

This statistical analysis plan for Study JNJ-77242113 is based on the protocol dated 29 August 2023.

Table 1: SAP Version History Summary

SAP Version	Approval Date	Change	Rationale
1	6 December 2023	Not Applicable	Initial release
2	4 April 2025	4.3.4.6. DLQI: Removed the analysis of the number and proportion of participants with an improvement of 5 or more points from baseline in DLQI score with baseline score ≥5	Removed to be consistent with the analysis of other 77242113PsO study.
		4.5.1. Extent of Exposure: Removed the analysis of cumulative dose and newly added the summary of average of daily dose	Updated to more reasonable parameter for interpreting of extent exposure
		4.5.3.5. PHQ-9: Added the detailed definition of severity for PHQ-9 score. The description of shift table from baseline to post-baseline was updated.	Added more detailed score definition and updated the description of shift table to be consistent with other 77242113PsO study.
		6.5. Appendix 5 Prior/Concomitant/Follow-up Medications (including dictionary): Removed the analysis of concomitant treatment of moisturizer for psoriasis.	Removed since the analysis of concomitant treatment of moisturizer is not needed. Concomitant moisturizers can be found in the listing of concomitant medication.
		6.6. Appendix 6 Intervention Compliance: Changed the compliance categories to "> 120%, >100 to ≤ 120%, 80 to ≤ 100%, and < 80%"	Updated to more reasonable compliance categories including of the threshold of 100%.
		6.2. Appendix 2 Baseline Characteristics and Demographics Age categories of <65 and >=65 were added as demographic baseline variables.	Added an age category to better understand the demographics
		4.5.2. Adverse Event, clarified the description of treatment emergent adverse event as "In general, any AE occurring at or after the initial administration of study intervention up to 4 weeks after the last dose or treatment discontinuation is considered to be treatment emergent."	Further clarifications.
		4.2.2.2. supplemental estimand, ICE #2 description is updated for further clarification, and appendix 8 is added related to this update.	Further clarification of supplemental estimand.
		4.1.2 Baseline description is updated for further clarifications	Further clarifications.

SAP Version	Approval Date	Change	Rationale
		4.1, "The specific analysis for adolescent participants (ex. CDLQI) will be performed only when at least one adolescent participant appears in the analysis set" is added.	Further clarifications for the case no adolescent participants are enrolled.

LIST OF ABBREVIATIONS

ADA	antidrug antibody
AE	adverse event
ATC	anatomic and therapeutic class
BMI	body mass index
BSA	body surface area
CI	confidence interval
CRF	case report form
CTCAE	Common Terminology Criteria for Adverse Events
CV	coefficient of variation
ECG	electrocardiogram
EP	erythrodermic psoriasis
FAS	full analysis set
GPP	generalized pustular psoriasis
ICE	Intercurrent Event
IQ	interquartile
JDA	Japanese Dermatological Association
LLOQ	lower limit of quantification
MedDRA	Medical Dictionary for Regulatory Activities
NAb	neutralizing antibodies
PD	pharmacodynamic(s)
PK	pharmacokinetic(s)
SAE	serious adverse event
SAP	statistical analysis plan
SAS	Safety analysis set
SD	standard deviation
US NCI	United States National Cancer Institute
WHO-DD	World Health Organization Drug Dictionary

1. INTRODUCTION

This Statistical Analysis Plan (SAP) contains definitions of analysis sets, derived variables and statistical methods for analyses of efficacy, safety, pharmacokinetic (PK) and pharmacodynamics (PD) data of study JNJ-77242113PSO3005.

1.1. Objectives, Endpoints and Estimands

Objectives and Endpoints

Objectives	Endpoints
Primary	
• To evaluate the efficacy of JNJ-77242113 in participants with generalized pustular psoriasis (GPP) or erythrodermic psoriasis (EP)	• Proportion of participants with GPP who experience treatment success (based on Clinical Global Impression [CGI] according to Japanese Dermatological Association [JDA] total score) at Week 16. • Proportion of participants with EP who experience treatment success (based on CGI) at Week 16.
Secondary	
• To further evaluate the efficacy of JNJ-77242113 in participants with GPP or EP	• Proportion of participants with GPP or EP who experience treatment success (for GPP: based on CGI scale according to JDA total score and for EP: based on CGI scale) over time. • Change from baseline in the total score of the JDA severity index for GPP over time. • Change from baseline in severity classification (mild, moderate, severe) of the JDA severity index for GPP over time. • Change from baseline in body surface area (BSA) of involvement of lesion for EP over time. • Proportion of participants who achieve an Investigator's Global Assessment (IGA) score of cleared (0) or minimal (1) over time. • Proportion of participants who achieve an IGA score of cleared (0) over time. • Percent improvement from baseline in Psoriasis Area and Severity Index (PASI) over time.
• To evaluate the effect of JNJ-77242113 treatment on health-related quality of life (HRQoL) in participants with GPP or EP	• Change from baseline in Dermatology Life Quality Index (DLQI) score over time. • Proportion of participants who achieve a DLQI score of 0 or 1 over time. • Change from baseline in EQ-5D-5L (domain scores and visual analog scale [VAS]) over time.
• To assess the safety and tolerability of JNJ-77242113 in participants with GPP or EP	• Frequency and type of AEs and SAEs.

Objectives	Endpoints
Exploratory	
• To further explore the efficacy of JNJ-77242113 in participants with GPP	• Change from baseline in components (skin symptoms, systemic symptoms/laboratory findings) of the JDA severity index for GPP over time.
• To further evaluate the effect of JNJ-77242113 on HRQoL in adolescent participants with GPP or EP	• Change from baseline in Children's DLQI (CDLQI) over time. • Change from baseline in Children's DLQI (CDLQI) score of 0 or 1 and over time.
• To evaluate the PK and immunogenicity of JNJ-77242113	• JNJ-77242113 PK parameters. • Incidence of antidrug antibodies to JNJ-77242113.
• To explore biomarkers in participants with GPP or EP	• Change from baseline in levels of blood biomarkers.

1.2. Study Design

This is a Phase 3, open-label, multicenter study to evaluate the efficacy and safety of JNJ-77242113 for the treatment of participants with generalized pustular psoriasis (GPP) or erythrodermic psoriasis (EP).

A target of 16 (GPP, n=8; EP, n=8) participants will be enrolled in this study. All participants will take JNJ-77242113 from Week 0.

The total duration of this study for each participant is approximately 165 weeks, which includes: a ~5-week screening period, a 52-week treatment period, a 104-week long term extension treatment period (LTE), and a 4-week safety follow-up period.

All the participants will receive JNJ-77242113 200 mg once daily for 52 weeks. Participants completing Week 52 visit may be eligible to enroll in the LTE. The LTE will begin at the end of Week 52 and will continue until Week 156. All the participants will have a 4-week safety follow up period at the end of the treatment period or after the last dose of study intervention.

Efficacy, safety, PK, immunogenicity, and biomarkers will be assessed according to the Schedule of Activities in protocol Section 1.3. In addition, there will be 2 optional substudies for participants who provide consent. Sample collections for these substudies include a pharmacogenomic blood sample and photograph collection.

The first database lock (DBL) will occur when all participants complete Week 24 of the study. Additional DBLs may occur after Week 24 to support regulatory submissions and scientific disclosures.

2. STATISTICAL HYPOTHESIS

The primary hypothesis of this study is that JNJ-77242113 is efficacious in treating GPP or EP as assessed by proportion of participants with GPP and EP who experience treatment success defined

as at least "Minimally Improved" rating in CGI scale for GPP (according to Japanese Dermatological Association (JDA) total score) and EP, respectively at Week 16. No formal statistical hypothesis testing is planned in this study.

2.1. Multiplicity Adjustment

No formal hypothesis testing in this study.

3. ANALYSIS SETS

Analysis Sets	Description
Enrolled	All participants who sign the ICF
Full Analysis Set (FAS)	All enrolled participants who received at least 1 dose of JNJ-77242113.
Safety Analysis Set (SAS)	All enrolled participants who received at least 1 dose of JNJ-77242113.
PK Analysis Set	All enrolled participants who received at least 1 dose of JNJ-77242113 and had at least 1 valid blood sample drawn for PK analysis after their first dose of JNJ-77242113.
Immunogenicity Analysis Set	All enrolled participants who received at least 1 dose of JNJ-77242113 and who had at least 1 sample obtained after the first dose of JNJ-77242113 for the detection of antibodies to JNJ-77242113.

4. STATISTICAL ANALYSES

4.1. General Considerations

Data primarily will be summarized using descriptive statistics. Continuous variables will be summarized using the number of observations, mean, SD, median, interquartile range, minimum and maximum, as appropriate. Categorical values will be summarized using the number of observations and percentages as appropriate. The specific analysis for adolescent participants (ex. CDLQI) will be performed only when at least one adolescent participant appears in the analysis set.

4.1.1. Analysis Visit Windows

The schedules for visits of the study will follow per protocol ‘Schedule of Activities’ table. Unless otherwise specified, Nominal visits will be used for all by-visit analyses in the study.

4.1.2. Baseline

The baseline measurement for efficacy endpoints is defined as the closest measurement taken prior to or on the first study agent administration date. The baseline measurement for other endpoints including safety, PK and immunogenicity is defined as the closest measurement taken prior to the time of the first study agent administration.

4.1.3. Study Day and Relative Day

Week 0 refers to the start of the first study drug administration.

Study day or relative day for a visit is defined as:

- Visit date - (Date of Week 0) +1, if visit date is ≥date of Week 0
- Visit date - Date of Week 0, if visit date <date of Week 0

4.2. Primary Endpoint Analysis

Data will be summarized based on FAS and those will be presented by diagnosed disease (GPP or EP) unless specified.

4.2.1. Definition of Endpoint

Clinical Global Impression (CGI) Score

The CGI scale is a brief clinician-rated instrument. The CGI scale has proved to be a robust measure of efficacy in many clinical drug trials, and is easy and quick to administer, provided that the clinician knows the patient well. The CGI has 5 categories (Very much improved [1], Much improved [2], Minimally improved [3], No change [4], Worsened [5]) in this study. For GPP, the rating of the CGI scale is based on JDA severity index and for EP, the rating will be as provided in the study manual.

There are 2 primary endpoints for GPP and EP respectively as given below.

For GPP:

- Proportion of participants with GPP who experience GPP treatment success at Week 16. GPP treatment success is defined as at least "Minimally Improved" rating in CGI scale according to JDA total score for GPP at Week 16.

For EP:

- Proportion of participants with EP who experience EP treatment success at Week 16. EP treatment success is defined as at least "Minimally Improved" rating in CGI scale for EP a Week 16.

4.2.2. Estimands

4.2.2.1. Primary Estimand

The primary estimand (ie, a precise definition of the primary targeted treatment effect) is defined for GPP and EP, respectively by the following 5 attributes:

Study Intervention:

- Experimental: JNJ-77242113

Population:

- Patients ≥12 years of age with GPP
- Patients ≥12 years of age with EP

Variable:

Binary response variables for the primary endpoints:

- Treatment success for GPP: a responder (participant with treatment success defined as at least "Minimally Improved" rating in CGI scale for GPP according to the JDA total score) at Week 16.
- Treatment success for EP: a responder (participant with treatment success defined as at least "Minimally Improved" rating in CGI scale for EP) at Week 16.

Intercurrent Events (ICE) and Their Corresponding Strategies:

Intercurrent Event	Strategy	Description
Discontinuation of study intervention for any reason on or prior to Week 16.	Treatment-policy	Observed data will be used regardless of whether or not this ICE had occurred.

Summary Measure (Population-level Summary):

- Proportion of participants with GPP who experience treatment success at Week 16.
- Proportion of participants with EP who experience treatment success at Week 16.

4.2.2.2. Supplementary Estimand

The supplemental estimand has the same attributes as in primary estimand, except for the Intercurrent events and their corresponding strategies:

Intercurrent Event	Strategy	Description
1. Discontinuation of study intervention for any reason on or prior to Week 16.	Composite	Participants with these intercurrent event are considered as nonresponders. The occurrence of these intercurrent events is captured in the variable definition.
2. Initiation of other medication or therapy that could improve GPP/EP on or prior to Week 16 excluding medication or therapy that allowed in the protocol.		
3. Discontinuation of study intervention for reasons other than ICE 1	Treatment Policy	Observed data will be used regardless of whether or not this intercurrent event had occurred.

4.2.3. Analysis Methods

4.2.3.1. Main Analytical Approach

The number, proportion of participants with treatment success, and 95% Clopper-Pearson exact confidence interval (CI) will be provided for GPP and EP groups.

The primary endpoints will be analyzed using the primary estimand. After accounting for the ICE for the primary estimand, participants with missing data for the primary endpoints at Week 16 will be considered as nonresponders.

4.2.3.2. Supplementary Analyses

The same analysis in Main analytical approach in Section 4.2.3.1 will be applied to supplementary estimands.

4.3. Secondary Endpoints Analysis

Data will be summarized based on FAS and those will be presented by diagnosed disease (GPP or EP) unless specified.

4.3.1. Secondary Endpoints

4.3.2. Definition of Endpoint

4.3.2.1. Japanese Dermatological Association (JDA) Score

The JDA severity index for GPP consists of area of erythema with pustules, area of erythema (total), area of edema, fever, WBC, CRP, and serum albumin (provided in the study manual). The total score of JDA severity index for GPP ranges between 0 and 17 (0=best, 17=worst). Area of erythema with pustules, area of erythema (total), and area of edema are rated as 0 to 3. Fever, WBC, CRP, and serum albumin are rated as 0 to 2.

4.3.2.2. Body Surface Area (BSA)

The BSA is a commonly used measure of involvement of skin disease. It is defined as the percentage of surface area of the body involved with the condition being assessed. The handprint method for assessing BSA will be used in this study, where the surface area of the participant's hand including the palm and all 5 digits is used as a guide to estimate 1% BSA.

4.3.2.3. Investigator’s Global Assessment (IGA)

The IGA documents the investigator’s assessment of the participant’s psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The participant’s psoriasis is assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4) (provided in the study manual).

4.3.2.4. Psoriasis Area and Severity Index (PASI)

The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy (provided in the study manual). In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas is assessed and scored separately for erythema, induration, and scaling, which are each rated on a scale of 0 to 4 and extent of involvement on a scale of 0 to 6. The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease.

4.3.2.5. Dermatology Life Quality Index (DLQI)

The DLQI is a dermatology-specific health-related quality of life (HRQoL) instrument designed to assess the impact of the disease on a participant's HRQoL. It is a 10-item questionnaire that assesses HRQoL over the past week and in addition to evaluating overall HRQoL, can be used to assess 6 different aspects that may affect quality of life: symptoms and feelings, daily activities, leisure, work or school performance, personal relationships, and treatment. The total score ranges from 0 to 30 with a higher score indicating greater impact on QoL

For a partially answered questionnaire (eg, not all 10 answers in the DLQI questionnaire were available):

- If one question's answer is not available, this question will be scored 0. The total score will then be calculated.
- If two or more questions' answers are unavailable, the questionnaire is not scored. Hence, the total score and each of the 6 component scores will be set to missing.

4.3.2.6. EuroQuol 5-Dimension 5 Level Questionnaire

The EQ-5D-5L is a self-administered standardized measure of health status in a wide range of health conditions and treatments. The recall period for all items is "Today". The EQ-5D descriptive system is comprised of 5 items across the following 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each of the 5 dimensions uses a 5-point Likert response scale (Level 1 indicating no problem, Level 2 indicating slight problems, Level 3 indicating moderate problems, Level 4 indicating severe problems, and Level 5 indicating extreme problems). The EQ-5D also includes a visual analog scale that has endpoints labelled "best imaginable health state" and "worst imaginable health state" anchored at 100 and 0, respectively. Participants are asked to indicate how they rate their own health by indicating the point on the EQ VAS which best represents their own health on that day.

4.3.3. Estimand(s)

Not applicable.

4.3.4. Analysis Methods

For secondary endpoint, the observed data will be used without any imputation. Each endpoint will be summarized using descriptive statistics and its longitudinal change may be graphically displayed as appropriate.

4.3.4.1. CGI score

The number and proportion of participants with treatment success (for GPP: based on CGI scale according to JDA total score and for EP based on CGI scale) will be presented by postbaseline scheduled visit for GPP and EP respectively. The number and proportion of participants for each category will be also summarized with the same way.

4.3.4.2. JDA Score

JDA severity index total score will be analyzed only for the participants with GPP. The descriptive statistics of observed value and change from baseline will be presented by scheduled visit. The number and proportion of participants in each severity classification (mild(0-6), moderate(7-10), severe(11-17)) identified based on CRF will be also summarized by scheduled visit.

4.3.4.3. BSA Involvement by Psoriatic Lesions

For EP patients, BSA Involvement (%) and its change from baseline will be summarized using descriptive statistics for each scheduled visit.

4.3.4.4. IGA score

The number and proportion of the participants who achieve an IGA score of cleared (0) or minimal (1) will be presented by scheduled visit. In addition, the number and proportion of the participants who achieve an IGA score of cleared (0) will also be presented.

The proportion of participants with IGA total average score (cleared (0), minimal (1), Mild (2), Moderate (3), Severe (4)) by scheduled visit will be also summarized.

4.3.4.5. PASI score

The descriptive statistics of PASI total score, change from baseline and percent improvement from baseline will be presented by scheduled visit.

4.3.4.6. DLQI

The following by scheduled visit analyses will be performed for DLQI score.

- The descriptive statistics of the observed value and change from baseline
- The number and proportion of participants who achieved DLQI score of 0 or 1 with DLQI > 1 at baseline

4.3.4.7. EQ-5D

The observed value and change from baseline will be summarized using descriptive statistics for EQ-5D VAS score by scheduled visit. In addition, the domain score (5-point Likert response scale 0 - 4) will be summarized using descriptive statistics by scheduled time points separately.

4.4. Exploratory Analysis

Data will be summarized based on FAS and those will be presented by diagnosed disease (GPP or EP) unless specified.

4.4.1. Definition of Endpoints

4.4.1.1. Children's Dermatology Life Quality Index (CDLQI)

The CDLQI is an adapted version of the DLQI for the pediatric population and will be utilized in the adolescent population in this study. The adaption and validation of the CDLQI was undertaken

by the original developer of the DLQI to ensure it addressed the specific needs of the pediatric population. The CDLQI is a 10-item instrument that has 4 item response options and a recall period of 1 week. Higher scores indicate greater impact on HRQoL. The instrument is designed for use in children, is self-explanatory and can be simply handed to the participant who is asked to fill it in with the help of the child's parent or caregiver (provided in the study manual).

4.4.1.2. JDA severity index score

JDA severity index score contains 2 components: skin symptoms, systemic symptoms/laboratory findings. The additional definitions are described in 4.3.4.2.

4.4.2. Analysis Methods

4.4.2.1. CDLQI

CDLQI will be summarized as same way of DLQI.

4.4.2.2. JDA severity index score

The observed values and change from baseline for the 2 components of JDA severity index score will be presented by scheduled visit only for the participants with GPP.

4.5. Safety Analyses

The safety data will be summarized based on SAS and it will be presented by diagnosed disease (GPP or EP), and 'GPP+EP' column that combines GPP and EP will also be presented.

For all continuous safety variables, descriptive statistics will include the N, mean, standard deviation, median, minimum, and maximum. Categorical variables will be summarized by using frequency counts and percentages.

4.5.1. Extent of Exposure

For the following parameters, descriptive statistics will be presented of continuous variables and categorial variables frequency counts and percentages will be presented.

- Treatment duration (weeks)
  - (date of last dose of study intervention – date of first dose of study intervention + 1 day) /7.
- Average daily dose
  - (tablets dispensed – tables retuned) x tablet strength /(date of last dose of study intervention – date of first dose of study intervention + 1 day).

Study intervention compliance will also be summarized descriptively. See Appendix 7 for further details.

4.5.2. Adverse Events

The verbatim terms used in the CRF by investigators to identify adverse events will be coded using MedDRA. In general, any AE occurring at or after the initial administration of study intervention up to 4 weeks after the last dose or treatment discontinuation is considered to be treatment emergent. If the event occurs on the day of the initial administration of study intervention, and either event time or time of administration are missing, then the event will be assumed to be treatment emergent. If the event date is recorded as partial or completely missing, then the event will be considered to be treatment emergent unless it is known to be prior to the first administration of study intervention based on partial onset date or resolution date. All reported treatment-emergent adverse events will be included in the analysis. For each adverse event, the number and percentage of participants who experience at least 1 occurrence of the given event will be summarized.

Summary tables will be provided for treatment-emergent adverse events:

- AEs
- AEs with frequency of at least 2 participants in 'GPP+EP' column
- SAEs
- AEs leading to discontinuation of study intervention
- AEs by severity
- AEs by relationship to study intervention
- SAEs by relationship to study intervention
- AEs by study period

In addition to the summary tables, listings will be provided for treatment-emergent adverse events:

- AEs
- SAEs
- AEs leading to death
- AEs leading to discontinuation of study intervention
- AEs for psoriasis
- Suicidal ideation or suicidal behavior
- Had hypersensitivity including anaphylactic reactions

4.5.2.1. Adverse Events of Special Interest

Active TB, malignancy and possible Hy'sLaw cases are defined as AESI. The listing for each AESI will be provided.

4.5.3. Additional Safety Assessments

4.5.3.1. Clinical Laboratory Tests

Descriptive statistics will be presented for selected chemistry, hematology laboratory tests at scheduled time points.

Change/percent change from baseline will be summarized for chemistry, hematology tests and displayed. A box plot of laboratory measurements and change from baseline will be provided.

Applicable laboratory results will be graded according to NCI-CTCAE version 5.0.

Shift summaries from baseline laboratory value to the worst NCI-CTCAE, version 5.0 grade in chemistry and hematology tests with NCI-CTCAE, version 5.0 will be presented.

All laboratory parameters and the participants with toxicity grade ≥2 will be listed.

4.5.3.2. Vital Signs

Continuous vital sign parameters including temperature, respiratory rate, weight, pulse and blood pressure (systolic and diastolic) will be summarized at each assessment time point. Change from baseline will be also summarized. Descriptive statistics (mean, standard deviation, median, minimum and maximum) will be presented.

Incidence of markedly abnormal vital signs during intervention, as defined in Table 2, will be summarized for participants who had at least 1 postbaseline assessment for that vital sign. A listing of participants with treatment-emergent markedly abnormal vital signs will be presented, along with a listing of all vital sign measurements.

Incidence of treatment-emergent abnormal vital signs during intervention, as defined in Table 2, will be summarized for participants who had a baseline assessment and at least 1 postbaseline assessment for that vital sign.

Table 2: Markedly Abnormal Vital Signs

Vital Sign	Criteria
Pulse	>120 bpm and with >30 bpm increase from baseline
	<50 bpm and with >20 bpm decrease from baseline
Systolic blood pressure	>180 mm Hg and with >40 mm Hg increase from baseline
	<90 mm Hg and with >30 mm Hg decrease from baseline
Diastolic blood pressure	>105 mm Hg and with >30 mm Hg increase from baseline
	<50 mm Hg and with >20 mm Hg decrease from baseline
Temperature	>38°C and with ≥1°C increase from baseline
Respiratory rate	>20 breaths per minute

4.5.3.3. Columbia-Suicide Severity Rating Scale (C-SSRS)

The C-SSRS will be used as a screening tool to prospectively evaluate suicidal ideation and behavior among study participants. The C-SSRS measures 5 possible levels of suicidal ideation

and 4 possible suicidal behaviors, as well as nonsuicidal self-injurious behavior. The assessment is a fully-structured, participant self-report C-SSRS questionnaire, including standardized questions, follow-up prompts, error handling routines, and scoring conventions. Two versions of the C-SSRS will be used in this study, the *Baseline/Screening* version and the *Since Last Visit*version. The *Baseline/Screening* version will be conducted during the screening visit and the *Since Last Visit* version will be conducted at all other visits.

At the screening visit, the C-SSRS should be completed as the first assessment after signing informed consent and before any other tests, procedures, or other consultations. For subsequent visits, the C-SSRS should be completed after all PROs and before any other tests, procedures, or other consultations. Participants will be interviewed by the investigator or trained study site personnel in a private, quiet place.

The following are C-SSRS categories and have binary responses (yes/no). A "yes" response to any C-SSRS category will be assigned a score as below:

Suicidal Ideation (1-5)

1 = Wish to be Dead

2 = Nonspecific Active Suicidal Thoughts

3 = Active Suicidal Ideation with Any Methods (Not Plan) without Intent to Act

4 = Active Suicidal Ideation with Some Intent to Act, without Specific Plan

5 = Active Suicidal Ideation with Specific Plan and Intent

Suicidal Behavior (6-10)

6 = Preparatory Acts or Behavior

7 = Aborted Attempt

8 = Interrupted Attempt

9 = Actual Attempt (nonfatal)

10 = Completed Suicide

If no events qualify for a score of 1 to 10, a score of 0 will be assigned (0 = "Negative result [no suicidal ideation or behavior]"). Higher scores indicate greater severity.

Suicidal ideation and behavior will be summarized based on the most severe/maximum post baseline C-SSRS outcome or AE of suicidal ideation, suicidal behavior excluding completed suicide, or completed suicide. In addition, frequency distribution of the most severe/maximum post baseline C-SSRS outcome will be tabulated by C-SSRS categories. The baseline is defined as the most severe/maximum C-SSRS score at either screening or Week 0.

The maximum score assigned for each participant will also be summarized into one of three broad categories: No suicidal ideation or behavior, suicidal ideation, suicidal behavior. A shift table for change in C-SSRS categories of no suicidal ideation or behavior, suicidal ideation, and suicidal behavior from baseline will be presented, where the post baseline is based on C-SSRS or AE data.

4.5.3.4. Electrocardiogram

Descriptive statistics of ECG parameters and change from baseline will be presented at each scheduled visit.

The incidence of abnormalities with the interpretation of the ECGs as determined by a qualified physician (investigator or qualified designee) will be summarized.

A listing of clinically relevant ECG abnormalities will also be provided.

4.5.3.5. PHQ-9

The PHQ-9 is self-administered, 9-item questionnaire measuring symptoms and severity of depression. The recall period for all items is the past 2 weeks. The items include diminished interest or pleasure, depressed mood, insomnia/hypersomnia, fatigue or loss of energy, weight loss or weight gain/appetite loss or appetite gain, feelings of worthlessness, diminished concentration/indecisiveness, psychomotor agitation/retardation, and thoughts of death/suicide. Each item is rated on a 4-point Likert scale ranging from 0 “not at all” to 3 “nearly every day”. Higher scores indicate more severe depressive symptoms. The PHQ-9 scores for depression range from 0 to 27 with higher scores indicating worse state (more severe depressive symptoms). A score of 5 to 9 is considered to be minimal symptoms of depression. A score of 10 to 14 is considered minor depression, dysthymia, or mild major depression. A score of 15 to 19 is considered to indicate moderately severe major depression, and a score ≥20 is considered to be severe major depression.

- The PHQ-9 scores and change from baseline will be summarized over time.
- The shift table will be provided summarizing the shift in values from baseline to post-baseline.
- A listing will be produced for all PHQ-9 score for participants with PHQ-9 score ≥15.

4.5.3.6. Other Safety Parameters

Not applicable.

4.6. Other Analyses

4.6.1. Pharmacokinetics

4.6.1.1. JNJ-77242113 Concentrations

PK analyses will be performed on the PK analysis set (Section 3), defined as participants who have received at least 1 dose of JNJ-77242113 and have at least 1 valid blood sample drawn for PK analysis after their first dose of JNJ-77242113.

Descriptive statistics (N, mean, SD, median, range, coefficient of variation [%CV], and interquartile [IQ] range) will be used to summarize JNJ-77242113 concentrations at postdose sampling time intervals classified as peak, intermediate and trough, by scheduled visit, by diagnosed disease (GPP or EP) and 'GPP+EP'. PK data may be displayed graphically, such as mean +/-SD PK concentrations over time, and by diagnosed disease (GPP or EP) and 'GPP+EP'.

The following analyses will be performed.

- Summary of plasma JNJ-77242113 concentration over time by diagnosed disease (GPP or EP) and 'GPP+EP'
- Plots of median plasma JNJ-77242113 concentrations over time by diagnosed disease (GPP or EP) and 'GPP+EP'
- Proportion of participants with plasma JNJ-77242113 concentration below the lowest quantifiable concentration in a sample at each visit

The following subgroup analyses will be selected and may be performed if appropriate.

- Summary of plasma JNJ-77242113 concentrations over time by baseline body weight (≤median, >median)
- Summary of plasma JNJ-77242113 concentrations over time by age group (adult, adolescent) and other covariates may also be applied
- Plots of median plasma JNJ-77242113 concentrations over time by age group (adult, adolescent)

JNJ-77242113 concentrations below the lowest quantifiable concentration will be imputed as zero in the summary statistics. All plasma concentrations below the lowest quantifiable concentration or missing data will be labeled as such in the concentration database.

All participants and samples excluded from the analysis will be clearly documented.

If sufficient data are available, then population PK analysis using plasma concentration-time data of JNJ-77242113 will be performed using nonlinear mixed-effects modeling. Data may be combined with those of other selected studies to support a relevant structural model. Available baseline participant characteristics (eg, demographics, laboratory variables, race) will be evaluated as potential covariates affecting PK parameters. Details will be given in a population PK analysis plan and the results of the analysis will be presented in a separate report.

4.6.1.2. Data Handling Rules

Unless otherwise specified, the following data handling rules will apply to PK sample analyses:

- Plasma concentration summaries will be based on the actual treatment received.
- All plasma concentration summaries for a particular timepoint will include data obtained from treated participants at the timepoint of interest without imputing any missing data.

- A concentration not quantifiable (below the lower limit of quantification) will be treated as 0 in the summary statistics and shown as the lower limit of quantification (< LLOQ) in the data listings.
- The data from a participant who discontinued study agent will be excluded from the by-visit data analyses from that point onwards. In addition, the data from a participant who received an incomplete/ incorrect or skipped dose(s) based on previous dose prior to the PK sample collection or data from a participant who skip dose prior to PK sample collection will be excluded for that visit.

4.6.2. Immunogenicity

4.6.2.1. Immunogenicity Analysis

Immunogenicity data will be summarized cumulatively. Immunogenicity data will be summarized based on Immunogenicity analysis set (Section 3) for diagnosed disease (GPP or EP) and 'GPP+EP' unless otherwise specified.

4.6.2.2. Antibodies to JNJ-77242113

The incidence and titers of antibodies to JNJ-77242113 will be summarized.

Sample ADA status and sample titer as well as the cumulative participant ADA status and peak titer through the visit will be provided.

Participants with treatment-emergent antibodies to JNJ-77242113 include participants with treatment-induced antibodies to JNJ-77242113 and treatment-boosted antibodies to JNJ-77242113.

Participants with treatment-induced antibodies to JNJ-77242113 have a sample that is negative for antibodies to JNJ-77242113 prior to JNJ-77242113 administration and at least one sample that is positive for antibodies to JNJ-77242113 after JNJ-77242113.

Participants with treatment-boosted antibodies to JNJ-77242113 have a sample that is positive for antibodies to JNJ-77242113 prior to JNJ-77242113 administration and at least one sample that is positive for antibodies to JNJ-77242113 after JNJ-77242113 with a 4-fold increase in titer over baseline.

If titer remains the same or increases less than 4-fold after intervention or if ADA titer reduces or ADA disappears, the participant is classified as "treatment-emergent ADA negative". Participants with baseline negative and all post intervention samples negative are also classified as "treatment-emergent ADA negative".

The antibodies to JNJ-77242113 summary and analysis will be based on the observed data; therefore no imputation of missing data will be performed. Note: participant status is through each visit, thus, participant status and peak titers may change as the study progresses over time. Therefore, the 'participant ADA status' at a visit represents the cumulative ADA status through that visit. For example, datasets through Week 24 will have participant level status (eg, negative) but at Week 52, they may have developed ADA and the participant status becomes "treatment-

emergent ADA positive" from the interim to the final DBL. Peak titers can also change (increase) if a higher titer occurs after an initial DBL.

The summary of participants with baseline positive samples is taken from the sample status at baseline. There is no participant level status at baseline.

Incidence of antibody (evaluable, treatment-emergent ADA positive, treatment-emergent ADA negative) status will be summarized.

In addition, listings of participants with baseline positive ADA samples, participants who are classified as positive for treatment-emergent antibodies to JNJ-77242113 and participants who discontinue the study by antibodies to JNJ-77242113 status as well as graphical representation of median concentration by antibody status may be presented. The sample antibody status, the titer, and the neutralizing antibody status to JNJ-77242113 will be listed by visit. This listing will also provide information regarding JNJ-77242113 plasma concentration, CGI, for all applicable.

4.6.2.3. Neutralizing Antibodies to JNJ-77242113

The incidence of neutralizing antibodies (NAbs) to JNJ-77242113 will be summarized for participants who are positive for antibodies to JNJ-77242113 and have samples evaluable for NAbs to JNJ-77242113.

4.6.2.4. Antibody vs Efficacy/PK

To explore the relationship between antibodies to JNJ-77242113 status and plasma JNJ-77242113 concentrations and efficacy, the following analysis may be performed:

- Summary of clinical response (eg, CGI) data by diagnosed disease (GPP or EP) by participant antibody to JNJ-77242113 status
- Summary of plasma JNJ-77242113 concentrations over time by participant antibody to JNJ-77242113 status
- Plots of median (IQ) plasma JNJ-77242113 concentrations over time by participant antibody to JNJ-77242113 status

4.6.3. Pharmacokinetic/Pharmacodynamic Relationships

To explore the relationship between JNJ-77242113 plasma concentrations (if sufficient data are available, quartiles) and efficacy endpoints, the following analyses may be explored by diagnosed disease (GPP or EP):

- The relationship between JNJ-77242113 plasma concentrations and CGI may be explored for trough (eg, ≥12h postdose) samples, respectively. The relationship between JNJ-77242113 plasma concentrations and other endpoints may also be explored.

If data permit, the relationships between JNJ-77242113 concentrations and efficacy may be analyzed graphically. If any visual trend is observed, a suitable exposure-response (E-R) model may be developed to describe the E-R relationship. Details will be given in an E-R analysis plan and results will be presented in a separate technical report.

4.6.4. Biomarkers

The analyses will aim to identify biomarker relevant to treatment. These analyses are considered exploratory and may be summarized in a separate technical report.

4.6.5. Health Economics

Not applicable.

4.6.6. Subgroup Analysis

Not applicable excluding PK analyses.

4.7. Interim Analysis

No interim analyses are planned.

4.8. Changes to Protocol-planned Analyses

Section in the protocol	Description in SAP	Reason
Section 9.3.5. Clinical Laboratory Tests "the incidence and severity of abnormal laboratory parameters (hematology and chemistry) will be summarized." "Reference ranges and markedly abnormal results (specified in the SAP) will be used in the summary of laboratory data." "A listing of participants with any markedly abnormal laboratory results will also be provided."	None	Because the number of patients is small. The information of laboratory tests can be obtained easily from summary table and list of laboratory tests.
Section 9.3.5. Physical examination findings will be summarized at each scheduled time point. Descriptive statistics will be calculated at baseline and for observed values and changes from baseline at each scheduled time point. Frequency tabulations of the abnormalities will be made.	Note	The summary of descriptive statistics is not needed because the number of patients is small.

5. SAMPLE SIZE DETERMINATION

The number of patients with GPP or those with EP is limited with 1.5% to 2.3% of the entire patients with psoriasis in Japan. Therefore, based on the feasibility, approximately 16 participants (8 each for GPP and EP) will be targeted to enroll in the study.

6. SUPPORTING DOCUMENTATION

6.1. Appendix 1 Participant Dispositions

The number of participants in the following disposition categories will be summarized by diagnosed disease (GPP or EP), and 'GPP+EP' column that combines GPP and EP will also be presented based on FAS:

- Participants who received study intervention
- Participants who completed the study
- Participants who discontinued study intervention
- Reasons for discontinuation of study intervention
- Participants who terminated study prematurely
- Reasons for termination of study

Listings of participants will be provided for the following categories:

- Participants who discontinued study intervention
- Participants who terminated study prematurely

The number of participants in each analysis set will be also presented.

In addition, the participants with death will be listed.

6.2. Appendix 2 Baseline Characteristics and Demographics

Unless specified otherwise, the summaries related to subject information including baseline characteristics and demographics will be presented for FAS by diagnosed disease (GPP or EP). A 'GPP+EP' column that combines GPP and EP will be also presented.

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

Table 3 presents a list of the demographic variables that will be summarized.

Table 3: Demographic Variables

Continuous Variables:	**Summary Type**
Age (years)	Descriptive statistics (N, mean, standard deviation [SD], median and range [minimum and maximum], and IQ range).
Weight (kg)	
Height (cm)	
BMI (kg/m^2)	
Categorical Variables	
Age (adult, adolescent, <65, >=65)	Frequency distribution with the number and percentage of participants in each category.
Weight (=<90, >90)	
Sex	
Race	
BMI (<25 kg/m^2, 25-<30 kg/m^2, >=30 kg/m^2)	

Baseline disease characteristics (eg, duration of psoriasis disease, baseline PASI score, baseline IGA score, baseline CGI score, baseline JDA severity index for GPP, baseline BSA of involvement of lesion for EP, and baseline PRO related measurements) will be summarized.

All demographic variables and disease characteristics will be listed. The listing for the substance use of alcohol intake and smoking status will be also provided.

6.3. Appendix 3 Protocol Deviations

In general, the major protocol deviations may have the potential to impact participants' rights, safety or well-being, or the integrity and/or result of the clinical study. Participants with major protocol deviations will be identified prior to database lock and the participants with major protocol deviations will be summarized by diagnosed disease (GPP or EP). A 'GPP+EP' column that combines GPP and EP will be also presented based on FAS.

A listing of participants with major protocol deviations will also be provided. In addition, listings of COVID-19 related protocol deviations will be provided.

6.4. Appendix 4 Medical History

Medical history and Medical history of interest will be summarized by diagnosed disease (GPP or EP). A 'GPP+EP' column that combines GPP and EP will be also presented based on FAS.

Medical history and Medical history of interest will be presented.

6.5. Appendix 5 Prior/Concomitant/Follow-up Medications (including dictionary)

Prior and concomitant medication will be summarized by diagnosed disease (GPP or EP) based on FAS. A 'GPP+EP' column that combines GPP and EP will be also presented.

Prior medications are defined as any therapy used before the day of first dose (partial or complete) of study intervention. Previous psoriasis medication/therapy will be summarized.

Concomitant medications will be coded using the World Health Organization Drug Dictionary (WHO-DD). Concomitant medications are defined as any therapy used on or after the same day as the first dose of study intervention including those that started before and continue on after the first dose of study intervention.

Summaries of concomitant medications will be presented by ATC term. The proportion of participants who receive each concomitant medication will be summarized as well as the proportion of participants who receive at least 1 concomitant medication.

Participants' psoriasis medication history with topical agents, phototherapy, nonbiologic systemic therapies, and biologic medications will be summarized. If data are available, total cumulative duration of treatment with these medications will be summarized. In addition, reasons for which participants discontinued previous systemic therapies (contraindication, inadequate response, intolerance [ie, AEs], or other) will be summarized.

Participants who received concomitant corticosteroids will be listed. Participants with concomitant prophylactic treatments for latent TB infection will also be listed. The listing of participants with medication or therapy that could improve GPP/EP will be provided.All previous medication and concomitant medication will be listed.

6.6. Appendix 6 Intervention Compliance

Treatment compliance will be assessed based on FAS. Compliance will be summarized descriptively (N, mean, standard deviation, median, and range). Overall compliance will be categorized as > 120%, >100 to ≤ 120%, 80 to ≤ 100%, and < 80%.

Compliance will be calculated as follows:

Compliance (%)=(actual number of tablets taken/total number of tablets supposed to be taken) x100.

6.7. Appendix 7 Laboratory Toxicity Grading

The grading scale use for lab assessments is based on 'NCI-CTCAE v5.0'.

If a laboratory value falls within the grading as specified below but also within the laboratory normal limits, the value is considered to be normal and will be reset to grade 0.

Prebaseline measurements will use the same grading ranges as applied to baseline measurements. In case a test has two sets of ranges – one for baseline normal and one for baseline abnormal, the one for baseline normal will be applied for all measurements taken prebaseline and on baseline.

Text in gray italic in the table is present in the grading scale, but is not applied by Janssen when grading lab data.

CTCAE Term	Grade 1	Grade 2	Grade 3	Grade 4	Janssen Implementation Notes
Blood and lymphatic system disorders					
Anemia	Hemoglobin (Hgb) <LLN - 10.0 g/dL; <LLN - 6.2 mmol/L; <LLN - 100 g/L	Hemoglobin (Hgb) <10.0 - 8.0 g/dL; <6.2 - 4.9 mmol/L; <100 - 80g/L	Hemoglobin (Hgb) <8.0 g/dL; <4.9 mmol/L; <80 g/L; *transfusion indicated*	*Life-threatening consequences; urgent intervention indicated*	Clinical signs and symptoms are not taken into consideration for grading.
Leukocytosis	-	-	>100,000/mm3; >100 x 10e9 /L	*Clinical manifestations of leucostasis; urgent intervention indicated*	Clinical signs and symptoms are not taken into consideration for grading; Added ranges in SI unit (x 10e9 /L)
Investigations					
Activated partial thromboplastin time prolonged	>ULN - 1.5 x ULN	>1.5 - 2.5 x ULN	>2.5 x ULN; *bleeding*	-	Clinical signs and symptoms are not taken into consideration for grading.
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	Ranges defined for "abnormal baseline" are applied only if baseline > ULN. If baseline < ULN , then ranges for "normal baseline" are applied.
Alkaline phosphatase increased	>ULN - 2.5 x ULN if baseline was normal; 2.0 - 2.5 x baseline if baseline was abnormal	>2.5 - 5.0 x ULN if baseline was normal; >2.5 - 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	Ranges defined for "abnormal baseline" are applied only if baseline > ULN. If baseline < LLN, then ranges for "normal baseline" are applied.
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	Ranges defined for "abnormal baseline" are applied only if baseline > ULN. If baseline < LLN, then ranges for "normal baseline" are applied.

CTCAE Term	Grade 1	Grade 2	Grade 3	Grade 4	Janssen Implementation Notes
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	Ranges defined for "abnormal baseline" are applied only if baseline > ULN. If baseline < LLN, then ranges for "normal baseline" are applied.
CD4 lymphocytes decreased	<LLN - 500/mm3; <LLN - 0.5 x 10e9 /L	<500 - 200/mm3; <0.5 - 0.2 x 10e9 /L	<200 - 50/mm3; <0.2 x 0.05 - 10e9 /L	<50/mm3; <0.05 x 10e9 /L	
Cholesterol high	>ULN - 300 mg/dL; >ULN - 7.75 mmol/L	>300 - 400 mg/dL; >7.75 - 10.34 mmol/L	>400 - 500 mg/dL; >10.34 - 12.92 mmol/L	>500 mg/dL; >12.92 mmol/L	
CPK increased	>ULN - 2.5 x ULN	>2.5 x ULN - 5 x ULN	>5 x ULN - 10 x ULN	>10 x ULN	CPK (Creatine Phosphokinase) and CK (Creatine Kinase) are synonyms
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	
Fibrinogen decreased	<1.0 - 0.75 x LLN; if abnormal, <25% decrease from baseline	<0.75 - 0.5 x LLN; if abnormal, 25 - <50% decrease from baseline	<0.5 - 0.25 x LLN; if abnormal, 50 - <75% decrease from baseline	<0.25 x LLN; if abnormal, 75% decrease from baseline; absolute value <50 mg/dL	Ranges defined for "abnormal" are applied only on values < LLN. Grade 0 will be assigned to values > ULN.
GGT increased	>ULN - 2.5 x ULN if baseline was normal; 2.0 - 2.5 x baseline if baseline was abnormal	>2.5 - 5.0 x ULN if baseline was normal; >2.5 - 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	Ranges defined for "abnormal baseline" are applied only if baseline > ULN. If baseline < LLN, then ranges for "normal baseline" are applied.
Haptoglobin decreased	<LLN	-	-	-	
Hemoglobin increased	Increase in >0 - 2 g/dL; Increase in >0 - 20 g/L	Increase in >2 - 4 g/dL; Increase in >20 - 40 g/L	Increase in >4 g/dL; Increase in >40 g/L	-	The increase indicates the level of increase above normal (above ULN). Applied as, eg, grade 1 (g/dL): >ULN – ULN+2 g/dL; Added ranges in SI unit (g/L).

CTCAE Term	Grade 1	Grade 2	Grade 3	Grade 4	Janssen Implementation Notes
INR increased	>1.2 - 1.5; *>1 - 1.5 x baseline if on anticoagulation; monitoring only indicated*	>1.5 - 2.5; *>1.5 - 2.5 x baseline if on anticoagulation; dose adjustment indicated*	>2.5; *>2.5 x baseline if on anticoagulation; bleeding*	-	Concomitant therapy or clinical signs and symptoms are not taken into consideration for grading.
Lipase increased	>ULN - 1.5 x ULN	>1.5 - 2.0 x ULN; *>2.0 - 5.0 x ULN and asymptomatic*	>2.0 - 5.0 x ULN with signs or symptoms; *>5.0 x ULN and asymptomatic*	>5.0 x ULN and with signs or symptoms	"Asymptomatic" ranges are not taken into consideration for grading, ie, worst case grading is applied.
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	
Lymphocyte count increased	-	>4000/mm3 - 20,000/mm3; >4 - 20 x 10e9 /L	>20,000/mm3; >20 x 10e9 /L	-	Added ranges in SI unit (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	Both Neutrophils and segmented neutrophils are graded using these criteria.
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	
Serum amylase increased	>ULN - 1.5 x ULN	>1.5 - 2.0 x ULN; *>2.0 - 5.0 x ULN and asymptomatic*	>2.0 - 5.0 x ULN *with signs or symptoms;* *>5.0 x ULN and asymptomatic*	>5.0 x ULN *and with signs or symptoms*	"Asymptomatic" ranges are not taken into consideration for grading, ie, worst case grading is applied.
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	
Metabolism and nutrition disorders					
Acidosis	pH <normal, but ≥7.3	-	pH <7.3	*Life-threatening consequences*	pH <normal is implemented as pH <LLN. Clinical signs and symptoms are not taken into consideration for grading.

CTCAE Term	Grade 1	Grade 2	Grade 3	Grade 4	Janssen Implementation Notes
Alkalosis	pH >normal, but ≤7.5	-	pH >7.5	*Life-threatening consequences*	pH >normal is implemented as pH >ULN. Clinical signs and symptoms are not taken into consideration for grading.
Hypercalcemia	Corrected serum calcium of >ULN - 11.5 mg/dL; >ULN - 2.9 mmol/L; Ionized calcium >ULN - 1.5 mmol/L	Corrected serum calcium of >11.5 - 12.5 mg/dL; >2.9 - 3.1 mmol/L; Ionized calcium >1.5 - 1.6 mmol/L; *symptomatic*	Corrected serum calcium of >12.5 - 13.5 mg/dL; >3.1 - 3.4 mmol/L; Ionized calcium >1.6 - 1.8 mmol/L; *hospitalization indicated*	Corrected serum calcium of >13.5 mg/dL; >3.4 mmol/L; Ionized calcium >1.8 mmol/L; *life-threatening consequences*	Clinical signs and symptoms are not taken into consideration for grading. Note: For Hypercalcemia or Hypocalcemia in the CTCAE Lab Toxicity grading scale, the reference ranges from serum calcium (ULN /LLN) from the local or central lab are being utilized.
Hyperkalemia	Potassium >ULN - 5.5 mmol/L	Potassium >5.5 - 6.0 mmol/L; *intervention initiated*	Potassium >6.0 - 7.0 mmol/L; *hospitalization indicated*	Potassium >7.0 mmol/L; *life-threatening consequences*	Clinical signs and symptoms are not taken into consideration for grading.
Hypermagnesemia	Magnesium >ULN - 3.0 mg/dL; >ULN - 1.23 mmol/L	-	Magnesium >3.0 - 8.0 mg/dL; >1.23 - 3.30 mmol/L	Magnesium >8.0 mg/dL; >3.30 mmol/L; *life-threatening consequences*	Clinical signs and symptoms are not taken into consideration for grading.
Hypernatremia	Sodium >ULN – 150 mmol/L	Sodium >150 – 155 mmol/L; *intervention initiated*	Sodium >155 – 160 mmol/L; *hospitalization indicated*	Sodium >160 mmol/L; *life-threatening consequences*	Clinical signs and symptoms are not taken into consideration for grading.

CTCAE Term	Grade 1	Grade 2	Grade 3	Grade 4	Janssen Implementation Notes
Hypertriglyceridemia	Triglycerides 150 mg/dL - 300 mg/dL; 1.71 mmol/L - 3.42 mmol/L	Triglycerides >300 mg/dL – 500 mg/dL; >3.42 mmol/L - 5.7 mmol/L	Triglycerides >500 mg/dL – 1000 mg/dL; >5.7 mmol/L - 11.4 mmol/L	Triglycerides >1000 mg/dL; >11.4 mmol/L; *life-threatening consequences*	Clinical signs and symptoms are not taken into consideration for grading.
Hypoalbuminemia	Albumin <LLN - 3 g/dL; <LLN - 30 g/L	Albumin <3 - 2 g/dL; <30 - 20 g/L	Albumin <2 g/dL; <20 g/L	*Life-threatening consequences; urgent intervention indicated*	Clinical signs and symptoms are not taken into consideration for grading.
Hypocalcemia	Corrected serum calcium of <LLN - 8.0 mg/dL; <LLN - 2.0 mmol/L; Ionized calcium <LLN - 1.0 mmol/L	Corrected serum calcium of <8.0 - 7.0 mg/dL; <2.0 - 1.75 mmol/L; Ionized calcium <1.0 - 0.9 mmol/L; *symptomatic*	Corrected serum calcium of <7.0 - 6.0 mg/dL; <1.75 - 1.5 mmol/L; Ionized calcium <0.9 - 0.8 mmol/L; *hospitalization indicated*	Corrected serum calcium of <6.0 mg/dL; <1.5 mmol/L; Ionized calcium <0.8 mmol/L; *life-threatening consequences*	Clinical signs and symptoms are not taken into consideration for grading. Note: For Hypercalcemia or Hypocalcemia in the CTCAE Lab Toxicity grading scale, the reference ranges from serum calcium (ULN /LLN) from the local or central lab are being utilized.
Hypoglycemia	Glucose <LLN - 55 mg/dL; <LLN - 3.0 mmol/L	Glucose <55 - 40 mg/dL; <3.0 - 2.2 mmol/L	Glucose <40 - 30 mg/dL; <2.2 - 1.7 mmol/L	Glucose <30 mg/dL; <1.7 mmol/L; *life-threatening consequences; seizures*	Clinical signs and symptoms are not taken into consideration for grading. Urine glucose is not graded.
Hypokalemia	*Potassium <LLN - 3.0 mmol/L*	*Symptomatic with* Potassium <LLN - 3.0 mmol/L; intervention indicated	Potassium <3.0 - 2.5 mmol/L; *hospitalization indicated*	Potassium <2.5 mmol/L; *life-threatening consequences*	"Symptomatic" ranges are applied for grade 2, grade 1 not assigned, ie, worst case applied. Clinical signs and symptoms are not taken into consideration for grading of grade 3 and 4.

CTCAE Term	Grade 1	Grade 2	Grade 3	Grade 4	Janssen Implementation Notes
Hypomagnesemia	Magnesium <LLN - 1.2 mg/dL; <LLN - 0.5 mmol/L	Magnesium <1.2 - 0.9 mg/dL; <0.5 - 0.4 mmol/L	Magnesium <0.9 - 0.7 mg/dL; <0.4 - 0.3 mmol/L	Magnesium <0.7 mg/dL; <0.3 mmol/L; *life-threatening consequences*	Clinical signs and symptoms are not taken into consideration for grading.
Hyponatremia	Sodium <LLN – 130 mmol/L	*Sodium 125-129 mmol/L and asymptomatic*	*Sodium 125-129 mmol/L symptomatic; 120-124 mmol/L regardless of symptoms* Sodium <130-120 mmol/L	Sodium <120 mmol/L; *life-threatening consequences*	Clinical signs and symptoms are not taken into consideration for grading. Worst case ("<130-120 mmol/L" for grade 3 added by Janssen) is applied across grade 2/3 ranges: 120-129 mol/L assigned to grade 3, grade 2 not used.
Renal and urinary disorders					
Proteinuria	1+ proteinuria; urinary protein ≥ULN - <1.0 g/24 hrs; urinary protein ≥ULN - <1000 mg/day	**Adult:** 2+ and 3+ proteinuria; urinary protein 1.0 - <3.5 g/24 hrs; urinary protein 1000 - <3500 mg/day **Pediatric:** Urine P/C (Protein/Creatinine) ratio 0.5 - 1.9; Urine P/C (Protein/Creatinine) 56.5 – 214.7 g/mol	**Adult:** 4+ proteinuria; urinary protein ≥3.5 g/24 hrs; urinary protein ≥3500 mg/day; **Pediatric:** Urine P/C (Protein/Creatinine) ratio >1.9; Urine P/C (Protein/Creatinine) >214.7 g/mol	-	In case both 24-h urine collection and dipstick are collected, then worst case is taken, as opposed to having 24-h urine collection take precedence over dipstick. Added ranges in SI unit for urinary protein (mg/day) and for urine P/C (g/mol). Pediatric grading is applied to age range [0-18]. Adult grading is applied for ages [>18].

* Grade 0 is assigned to a lab assessment when the lab test is described in the table, but the lab value is not assigned a grade 1 or high

6.8. Appendix 8 medications or therapies that could improve EP/GPP

1. Medications of topical corticosteroids (strong) and topical non-corticosteroid antipsoriatic therapies. For topical corticosteroids (strong) will be identified by medical review.
2. The medications of conventional systemic immunosuppressive therapy, biologic therapy, and non-biologic immunomodulators excluding methotrexate, retinoid, and cyclosporine.
3. The medications of corticosteroids and whose administration routes are oral, intramuscular, intravenous, parenteral, subcutaneous, or nasogastric.
4. Medications including corticosteroids whose administration routes are intralesional or transdermal.
5. The therapies categorized as concomitant phototherapy. in CRF

7. REFERENCES

Not applicable.