# A study of JNJ-77242113 for the treatment of participants with plaque psoriasis involving special areas (scalp, genital, and/or palms of hands and the soles of the feet)

Submission date 17/08/2023	<b>Recruitment status</b> No longer recruiting	Prospectively registered
		<pre>Protocol</pre>
Registration date 23/10/2023	Overall study status Ongoing	Statistical analysis plan
		Results
Last Edited	Condition category	Individual participant data
24/10/2025	Skin and Connective Tissue Diseases	[X] Record updated in last year

#### Plain English summary of protocol

Background and study aims

Plaque psoriasis is a skin disease that causes red, scaly, and sometimes painful and itchy patches on the skin.

Drugs that prevent interleukin IL-23\* from binding to its receptor\*\* may be an effective way to disease control. JNJ-77242113 is designed to target IL-23 receptor and block IL-23 from binding to it.

(\*A specific type of protein involved in inflammation.)

(\*\*A protein that binds to specific molecule.)

The purpose of this study is to see how effective JNJ-77242113 is in participants with plaque psoriasis involving special areas (scalp, genital, and/or palms of the hands and the soles of the feet).

Participants will receive JNJ-77242113 or placebo in a 2:1 ratio which means in every 2 participants who receive JNJ-77242113, 1 will receive placebo. JNJ-77242113 will be administered in all treatment groups (JNJ-77242113, placebo). This is a double-blind study, which means participant, caregiver, and study doctor will not know whether the participants are receiving JNJ-77242113 or placebo.

#### Who can participate?

Participants aged 18 years or older (in the UK) and aged 12 years or older (countries other than UK) with plaque psoriasis involving special areas (scalp, genital, and/or palms of the hands and the soles of the feet).

What does the study involve?

The study will be conducted in 3 periods:

- 1. Screening period (5 weeks)
- 2. Double-blind (156 weeks) treatment period: Participants will be randomly (like flip of a coin) divided to 2 groups:

Group 1: JNJ-77242113 orally from Week 0 through Week 156.

Group 2: Matching placebo of JNJ-77242113 orally from Week 0 through Week 16 and thereafter, JNJ-77242113 orally through Week 156.

Participants will undergo study assessments and tests, such as questionnaires, blood tests, vital signs, and physical exams. Blood samples will be taken at multiple timepoints to understand how the body responds to the study drug.

Follow-up period (4 weeks): Participants will be monitored for their health after the last dose of study drug until the study ends.

All side effects will be recorded until the study ends. The total study duration is approximately 3 years and 2 months.

What are the possible benefits and risks of participating?

There is no established benefit to participants of this study. Based on scientific theory, taking JNJ-77242113 may reduce plaque psoriasis (red, scaly, itchy patches on the skin). However, this cannot be guaranteed because JNJ-77242113 is still under investigation as a treatment and it is not known whether JNJ-77242113 will work.

If participants are put into the placebo treatment group, they will not receive JNJ-77242113 up to Week 16. Participants will start receiving JNJ-77242113 from Week 16 through Week 156 during this study.

Participants may experience some benefit from participation in the study that is not due to receiving JNJ-77242113, but due to regular visits and assessments monitoring overall health. Participation may help other people with plaque psoriasis in the future.

Participants may have side effects from the drugs or procedures used in this study that may be mild to severe and even life-threatening, and they can vary from person to person. Potential risks include hypersensitivity reactions, anti-drug antibody production, and infection. Skin biopsy (optional procedure) may cause mild bleeding, pain, discomfort, scarring, discoloration, and infection. The participant information sheet and informed consent form, which will be signed by every participant agreeing to participate in the study, includes a detailed section outlining the known risks of participating in the study.

Not all possible side effects related to JNJ-77242113 are known at this moment. During the study, the sponsor may learn new information about JNJ-77242113. The study doctor will tell participants as soon as possible about any new information that might make them change their mind about being in the study, such as new risks.

To minimize the risk associated with taking part in the study, participants are frequently reviewed for any side effects and other medical events. Participants are educated to report any such events to the study doctor who will provide appropriate medical care. Any serious side effects that are reported to the sponsor are thoroughly reviewed by a specialist drug safety team.

There are no costs to participants to be in the study. The sponsor will pay for the study drug and tests that are part of the study. The participant will receive reasonable reimbursement for study-related costs (e.g., travel/parking costs).

Where is the study run from?

Janssen-Cilag International NV is the sponsor for this study. The study will be run at multiple healthcare locations both within the UK and around the world.

When is the study starting and how long is it expected to run for? August 2023 to June 2027

Who is funding the study?

Janssen Research & Development, LLC

#### Contact information

#### Type(s)

Public, Scientific

#### Contact name

Dr. Medical Information and Product Information Enquiry

#### Contact details

50-100 Holmers Farm Way High Wycombe United Kingdom HP12 4DP +44 (0)800 731 8450 / 10494 567 444 JanssenUKRegistryQueries@its.jnj.com

### Additional identifiers

#### Clinical Trials Information System (CTIS)

2023-505122-34

#### **Integrated Research Application System (IRAS)**

1008238

#### ClinicalTrials.gov (NCT)

NCT06095102

#### Protocol serial number

77242113PSO3003, IRAS 1008238, CPMS 57585

### Study information

#### Scientific Title

A Phase III multicenter, randomized double-blind, placebo-controlled study to evaluate the efficacy and safety of JNJ-77242113 for the treatment of participants with plaque psoriasis involving special areas

#### Acronym

**ICONIC-TOTAL** 

#### **Study objectives**

Main objectives

1. To evaluate the effectiveness of JNJ-77242113 in participants with plaque psoriasis involving special areas.

#### Secondary objectives

- 1. To evaluate the effectiveness (in general psoriasis and special area psoriasis) of JNJ-77242113 in participants with plaque psoriasis involving special areas.
- 2. To evaluate how effective JNJ-77242113 is on patient-related outcomes (PROs) in participants with plaque psoriasis involving special areas.
- 3. To assess the safety, tolerability, and effect of JNJ-77242113 in participants with plaque psoriasis involving special areas.
- 4. To further evaluate the effect of JNJ-77242113 on PROs in participants with plaque psoriasis involving special areas.

#### Ethics approval required

Ethics approval required

#### Ethics approval(s)

approved 20/10/2023, North West – Liverpool Central Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8118; liverpoolcentral. rec@hra.nhs.uk), ref: 23/NW/0268

#### Study design

Randomized placebo-controlled double-blind trial

#### Primary study design

Interventional

#### Study type(s)

Efficacy, Safety, Treatment

#### Health condition(s) or problem(s) studied

Plaque psoriasis

#### Interventions

The total duration of this study is up to 165 weeks, which includes an up to 5-week screening period, a 156-week treatment period, and a 4-week safety follow-up period. At the beginning of the treatment period, participants will be randomly (like a flip of a coin) divided into one of two treatment groups:

Group 1: receive JNJ-77242113 orally from Week 0 through Week 156

Group 2: receive placebo from Week 0 through Week 16 and thereafter will receive JNJ-77242113 from Week 16 through Week 156.

#### Intervention Type

Drug

#### Phase

Phase III

#### Drug/device/biological/vaccine name(s)

JNJ-77242113

#### Primary outcome(s)

Percentage of participants achieving an Investigator's Global Assessment (IGA) Score of 0 or 1 and Greater Than or Equal to (>=) 2 Grade Improvement from Baseline at Week 16. 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).

#### Key secondary outcome(s))

- 1. Percentage of participants achieving Scalp-specific Investigator Global Assessment (ss-IGA) Score of 0 or 1 at Week 16. The ss-IGA instrument is used to evaluate the disease severity of scalp psoriasis. The lesions are assessed in terms of the clinical signs of redness, thickness, and scaliness which are scored as: absence of disease (0), very mild disease (1), mild disease (2), moderate disease (3), and severe disease (4).
- 2. Percentage of participants achieving Psoriasis Scalp Severity Index (PSSI) 90 at Week 16. The PSSI is a scalp-specific modification of the PASI based on the extent of involvement and the severity of erythema, infiltration, and desquamation. Involvement and severity of psoriasis on the PSSI is scored by physicians on a scale from 0 to 72, where 0 = no psoriasis and higher scores indicate more severe disease.
- 3. Percentage of participants achieving a Static Physician's Global Assessment of Genitalia (sPGA-G) Score of 0 or 1 at Week 16. The sPGA-G is a 6-point scale to assess the severity of genital psoriasis at a given time point. The sPGA-G evaluates erythema, plaque elevation, and scale of genital psoriatic lesions. The severity of genital psoriasis is assessed as clear (0), minimal (1), mild (2), moderate (3), severe (4), and very severe (5).
- 4. Percentage of participants achieving a Physician's Global Assessment of Hands and Feet (hf-PGA) Score of 0 or 1 at Week 16. The hf-PGA assesses the severity of hand and foot psoriasis using a 5-point scale to score the plaques on the hands and feet as: clear (0), almost clear (1), mild (2), moderate (3), and severe (4).
- 5. Percentage of participants achieving Psoriasis Symptom and Sign Diary (PSSD) Symptoms Score of 0 at Week 16. The PSSD includes a patient-reported outcome (PRO) questionnaire designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. The PSSD is a self-administered PRO instrument that includes 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 to 10 numerical rating scales for severity. Two sub-scores will be derived each ranging from 0 to 100: the psoriasis symptom score and the psoriasis sign score. A higher score indicates more severe disease.
- 6. Percentage of participants achieving >=4 point improvement from baseline in PSSD itch score at Week 16. The PSSD includes a PRO questionnaire designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. The PSSD is a self-administered PRO instrument that includes 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 to 10 numerical rating scales for severity. Two sub-scores will be derived each ranging from 0 to 100: the psoriasis symptom score and the psoriasis sign score. A higher score indicates more severe disease.
- 7. Percentage of participants achieving Genital Psoriasis Sexual Frequency Questionnaire (GenPs-SFQ) Item 2 score of 0 or 1 at Week 16. The GenPs-SFQ is a 2-item participant-reported instrument used to assess the impact of genital psoriasis on the frequency of sexual activity in the last 7 days. Item 1 assesses the overall frequency of sexual activity in the last 7 days (none /zero, once, or 2 or more times), and item 2 assesses how frequently genital psoriasis symptoms have limited the frequency of sexual activity in the last 7 days (never [0], rarely [1], sometimes [2], often [3], or always [4]).
- 8. Percentage of participants achieving >=4-point improvement from baseline in Scalp Itch Numeric Rating Scale (NRS) Score at Week 16. The Scalp Itch NRS is a single-item instrument that evaluates the severity of scalp itch in adult and adolescent populations over the past 24 hours.

The instrument uses an NRS score ranging from 0 (no scalp itch) to 10 (worst scalp itch imaginable).

- 9. Percentage of participants achieving >=4-point Improvement from Baseline in Genital Psoriasis Symptoms Scale (GPSS) Genital Itch NRS Score at Week 16. The GPSS is a participant-administered assessment of 8 symptoms: itch, pain, discomfort, stinging, burning, redness, scaling, and cracking. Each respondent is asked to answer the questions based on the psoriasis symptoms in his or her genital area. The overall severity for each individual genital psoriasis symptom is indicated by selecting the number from an NRS of 0 to 10 that best describes the worst level of each symptom in the genital area in the past 24 hours, ranging from 0 (no severity) to 10 (worst imaginable severity).
- 10. Number of participants with adverse events (AEs) up to week 165. An adverse event (AE) is any untoward medical event that occurs in a participant administered an investigational product, and it does not necessarily indicate only events with clear causal relationship with the relevant investigational product.
- 11. Number of participants with serious adverse events (SAEs) up to week 165. An SAE is any AE which results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, is a suspected transmission of any infectious agent via a medicinal product, or is medically important.
- 12. Percentage of participants achieving Psoriasis Area and Severity Index (PASI) 90 Response at Week 16. The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. 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.
- 13. Percentage of participants achieving PASI 75 Response at Week 16. The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. 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.
- 14. Change from baseline in PASI Total Score at Week 16. The PASI is a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body is divided into 4 regions: head, trunk, upper, and lower extremities. Each of these areas is assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90% to 100% involvement), and for erythema, induration, and scaling, which are each rated on a scale of 0 (none) to 4 (severe). The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease.
- 15. Change from baseline in BSA at Week 16. BSA is a commonly used measure of extent of skin disease. It is defined as the percentage of surface area of the body involved with the condition being assessed (that is, plaque psoriasis).
- 16. Percent change from baseline in Modified Nail Psoriasis Areas and Severity Index (mNAPSI) Score at Week 16. The mNAPSI is an index used for assessing and grading the severity of nail psoriasis. Each of the participant's ten fingernails are evaluated on 7 features. The first three features are each scored from 0 to 3 in severity and are (1) onycholysis and oil-drop dyschromia, (2) pitting, and (3) nail plate crumbling. The next four features are each scored 0 –absent or 1 present, and are (1) leukonychia, (2) splinter hemorrhages, (3) nail bed hyperkeratosis, and (4) red spots in the lunula. The score ranges from 0-13 per nail, and 0-130 for all fingernails.
- 17. Percentage of participants achieving Fingernail Physician's Global Assessment (f-PGA) Score

- of 0 or 1 at Week 16. The f-PGA is used to evaluate the current status of a participant's fingernail psoriasis on a scale of 0 to 4 similar (clear [0], minimal [1], mild [2], moderate [3], or severe [4]). A higher score indicated severe disease.
- 18. Percentage of participants achieving an IGA Score of 0 at Week 16. 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).
- 19. Percentage of participants achieving PSSD Symptom Score of 0 at Week 8. The PSSD includes a PRO questionnaire designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. The PSSD is a self-administered PRO instrument that includes 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 to 10 numerical rating scales for severity. Two sub-scores will be derived each ranging from 0 to 100: the psoriasis symptom score and the psoriasis sign score. A higher score indicates more severe disease.
- 20. Change from baseline in PSSD Symptom Score at Week 16. The PSSD includes a PRO questionnaire designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. The PSSD is a self-administered PRO instrument that includes 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 to 10 numerical rating scales for severity. Two sub-scores will be derived each ranging from 0 to 100: the psoriasis symptom score and the psoriasis sign score. A higher score indicates more severe disease.
- 21. Percentage of participants achieving >=4-point improvement from baseline in PSSD Itch Score at Week 4. The PSSD includes a PRO questionnaire designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. The PSSD is a self-administered PRO instrument that includes 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 to 10 numerical rating scales for severity. Two sub-scores will be derived each ranging from 0 to 100: the psoriasis symptom score and the psoriasis sign score. A higher score indicates more severe disease.
- 22. Change from baseline in PSSD sign score at Week 16. The PSSD includes a PRO questionnaire designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. The PSSD is a self-administered PRO instrument that includes 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 to 10 numerical rating scales for severity. Two sub-scores will be derived each ranging from 0 to 100: the psoriasis symptom score and the psoriasis sign score. A higher score indicates more severe disease.
- 23. Percentage of participants achieving PSSD Sign Score of 0 at Week 16. The PSSD includes a PRO questionnaire designed to measure the severity of psoriasis symptoms and signs over the previous 7 days for the assessment of treatment benefit. The PSSD is a self-administered PRO instrument that includes 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 to 10 numerical rating scales for severity. Two sub-scores will be derived each ranging from 0 to 100: the psoriasis symptom score and the psoriasis sign score. A higher score indicates more severe disease.
- 24. Percentage of participants achieving a Dermatology Life Quality Index (DLQI) Score of 0 or 1 at Week 16. 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 HRQoL.

- 25. Percentage of participants achieving Children's Dermatology Life Quality Index (CDLQI) score of 0 or 1 at Week 16. The CDLQI is a dermatology-specific quality of life (QoL) instrument designed to assess the impact of the disease on a child's QoL. The CDLQI, a 10-item questionnaire has 4-item response options and a recall period of 1 week. The CDLQI is calculated by summing the score of each question resulting in a maximum of 30 and a minimum of 0; the higher the score, the greater the impairment in QoL.
- 26. Change from baseline in Domain Scores of the Patient-reported Outcomes Measurement Information System-29 (PROMIS-29) Score at Week 16. The PROMIS-29 is a 29-item generic HRQoL instrument assessing 7 PROMIS domains (depression, anxiety, physical function, pain interference, fatigue, sleep disturbance, and ability to participate in social roles and activities) with 4 questions for each domain. These questions are ranked on a 5-point Likert scale. There is also a numerical rating scale that ranges from 0 (No pain) to 10 (Worst pain imaginable) for pain intensity. The raw domain scores are converted to standardized T-scores with a mean of 50 and a standard deviation of 10. Higher scores on anxiety, depression, fatigue, sleep disturbance, and pain interference indicate more severe symptoms. Higher scores on physical function and social participation indicate better health outcomes.
- 27. Change from baseline in Domain Scores of the Patient-reported Outcomes Measurement Information System-25 (PROMIS-25) Score at Week 16. The PROMIS-25 will be utilized in the adolescent population and is a 25-item generic HRQoL survey. Six PROMIS domains (physical function mobility, anxiety, depressive symptoms, fatigue, peer relationships, pain interference) are each assessed with 4 questions. There is also one 11-point rating scale for pain intensity. The instrument is designed for use in ages 8-17 years of age and can be self-administered. 28. Change from baseline in Palmoplantar Quality of Life Instrument (ppQLI) Score at Week 16. The ppQLI assesses the impact on patient quality of life due to palmoplantar psoriasis over the past month in adult and adolescent populations. Fifteen items evaluate hand functionality, pain, and social impact due to psoriasis. Fourteen items evaluate foot functionality, pain, and physical limitations due to psoriasis. All items use verbal rating scales ranging from 1 to 5. The ppQLI vields a score for hands, ranging from 15 to 80, and a score for feet, ranging from 14 to 70. 29. Change from baseline in Genital Psoriasis Symptoms Scale (GPSS) Total Score at Week 16. The GPSS is a participant-administered assessment of 8 symptoms: itch, pain, discomfort, stinging, burning, redness, scaling, and cracking. Each respondent is asked to answer the questions based on the psoriasis symptoms in his or her genital area. The overall severity for each individual genital psoriasis symptom is indicated by selecting the number from an NRS of 0 to 10 that best describes the worst level of each symptom in the genital area in the past 24 hours, ranging from 0 (no severity) to 10 (worst imaginable severity).

#### Completion date

14/06/2027

### **Eligibility**

#### Key inclusion criteria

- 1. Aged 18 years or older
- 2. Diagnosis of plaque psoriasis, with or without psoriatic arthritis (PsA), for at least 26 weeks prior to the first administration of study intervention
- 3. Candidate for phototherapy or systemic treatment for plaque psoriasis
- 4. Need to meet criteria:
- 4.1. Total body surface area (BSA) greater than or equal to (>=)1 percent (%) at screening and

baseline,

- 4.2. and investigator global assessment (IGA) (overall) >=2 at screening and baseline
- 4.3. and at least one of the following: scalp-specific investigator global assessment (ss-IGA) score >=3 at screening and baseline, and/or
- 4.4. static physician's global assessment of genitalia (sPGA-G) >= 3 at screening and baseline, and /or physician's global assessment of

hands and feet (hf-PGA) score >=3 at screening and baseline

- 5. Failed to respond to at least 1 topical therapy (example, corticosteroids, calcineurin inhibitors, and/or vitamin D analogs) used for treatment of psoriasis
- 6. Confirmation of plaque psoriasis in a non-special area (example, areas excluding scalp, genital, palmoplantar) at screening and baseline

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

#### Key exclusion criteria

- 1. Nonplague form of psoriasis (example, erythrodermic, guttate, or pustular)
- 2. Dermatoses other than plaque psoriasis (such as contact dermatitis) or palmoplantar pustulosis of the palmoplantar area (if hf-PGA >=3 at baseline)
- 3. Current drug-induced psoriasis (example, a new onset of psoriasis or an exacerbation of psoriasis from beta blockers, calcium channel blockers, or lithium)
- 4. A current diagnosis or signs or symptoms of severe, progressive, or uncontrolled renal, liver, cardiac, vascular, pulmonary, gastrointestinal, endocrine, neurologic, haematologic, rheumatologic, psychiatric, or metabolic disturbances
- 5. Known allergies, hypersensitivity, or intolerance to JNJ-77242113 or its excipients

#### Date of first enrolment

12/10/2023

#### Date of final enrolment

01/04/2024

#### Locations

#### Countries of recruitment

United Kingdom

Argentina

Hungary
Korea, South
Poland
Spain
Taiwan
Türkiye
United States of America

Canada

Germany

Study participating centre
Centro Privado de Medicina Familiar
Jose Pedro Varela 3954
Buenos Aires
Argentina
C1417EYG

Study participating centre
CEDIC Centro de Investigaciones Clinicas
Avenida Santa Fe 1480
Caba
Argentina
C1060ABN

Study participating centre
Conexa Investigacion Clinica S.A.
Libertad 1213
Caba
Argentina
C1012AAY

Study participating centre CIPREC Arenales 1611 2 Piso Ciudad Autonoma de Buenos Aires Argentina C1061AAS

#### Study participating centre Hospital Central Militar Cirujano Mayor Dr Cosme Argerich

Av. Luis Maria Campos 726 Caba Argentina C1426BOS

#### Study participating centre Instituto Medico de La Fundacion Estudios Clinicos

Italia 428 Rosario Argentina 2000

#### Study participating centre Skinsense Medical Research

411 2nd Avenue North Saskatoon Canada S7K 2C1

# Study participating centre Innovaderm Research Inc.

3530 boulevard Saint-Laurent Montreal Canada H2X 2V1

#### Study participating centre York Dermatology Clinic and Research Centre

250 Harding Blvd. West Richmond Hill Canada L4C 9M7

#### Study participating centre Skin Centre for Dermatology

775 Monaghan Rd South Peterborough Canada K9J 5K2

# Study participating centre Lynderm Research Inc.

25 Main Street Markham North Markham Canada L3P 1X3

#### Study participating centre Alberta DermaSurgery Centre

7609 - 109 Street NW Edmonton Canada T6G 1C3

### Study participating centre Centre De Recherche Dermatologique Du Quebec Metropolitan

2880 Chemin Quatre-Bouregois Quebec Canada G1V 4X7

#### Study participating centre

Medizinische Fakultat Carl Gustav Carus Technische Universitat Dresden

Fetscherstr. 74 Dresden Germany 01307

### Study participating centre Universitaetsklinikum Frankfurt

Theodor-Stern-Kai 7 Frankfurt am Main Germany 60590

#### Study participating centre ISA - Interdisciplinary Study Association GmbH

Rankestrasse 33-34 Berlin Germany 10789

#### Study participating centre Klinische Forschung Schwerin GmbH

Friedrichstrasse 1 Schwerin Germany 19055

### Study participating centre Hautarztpraxis

Annenstraße 151 Witten Germany 58453

#### Study participating centre Niesmann & Othlinghaus GbR

Alleestraße 80 Bochum Germany 44793

#### Study participating centre Rosenpark Research GmbH

Rheinstrasse 14 Darmstadt Germany 64283

# Study participating centre Dermatologikum Hamburg Gmbh

Stephansplatz 5

Hamburg Germany 20354

#### Study participating centre CRS Clinical Research Services Berlin GmbH

Siemensdamm 65 Berlin Germany 13627

#### Study participating centre Obudai Egeszsegugyi Centrum Kft.

Lajos utca 74 Budapest Hungary 1036

#### Study participating centre Somogy Megyei Kaposi Mor Oktato Korhaz

Tallian Gyula utca 20-32 Kaposvar Hungary 7400

#### Study participating centre

**SZTE AOK Szent-Gyorgyi Albert Klinikai Kozpont, Borgyogyaszati és Allergologiai Klinika** Koranyi fasor 6.

Szeged Hungary 6720

#### Study participating centre Pecsi Tudomanyegyetem

Akac u. 1 Borgyogyaszati Klinika Hungary 7632

### Study participating centre Derma-B Kft

Gyepusor utca 3. Fsz. Debrecen Hungary 4031

#### Study participating centre Medmare Egeszsegugyi Es Szolgaltato Bt.

Jozsef Attila u.17, Veszprem Hungary 8200

#### Study participating centre Debreceni Egyetem Klinikai Kozpont

Nagyerdei korut 98 Debrecen Hungary 4032

### Study participating centre Allergo-Derm Bakos Kft.

Baross utca 20. Szolnok Hungary 5000

#### Study participating centre Seoul National University Hospital

101 Daehak-ro, Jongno-gu Seoul Korea, South 03080

### Study participating centre Seoul National University Bundang Hospital

82, Gumi-ro 173beon-gil, Bundang-gu, Seongnam-si Gyeonggi-do Korea, South 13620

### Study participating centre Pusan National University Hospital

179 Gudeok-Ro, Seo-Gu Busan Korea, South 49241

#### Study participating centre Konkuk University Medical Center

120-1 NeunGdong-ro, Gwangjin-Gu Seoul Korea, South 05030

#### Study participating centre Korea University Guro Hospital

148, Gurodong-Ro Seoul Korea, South 152-703

#### Study participating centre WroMedica I.Bielicka, A.Strzałkowska s.c.

ul. A. Mickiewicza 91 Wrocław Poland 51-685

### Study participating centre

DermoDent Centrum Medyczne Aldona Czajkowska Rafał Czajkowski s.c.

Tuberozy 3 Osielsko Poland 86031

#### Study participating centre Osteo-Medic s.c A. Racewicz, J Supronik

ul. Wiejska 81

Bialystok Poland 15-351

#### Study participating centre Dermed Centrum Medyczne Sp. z o.o

ul. Piotrkowska 48 Lodz Poland 90-265

#### Study participating centre Klinika Ambroziak Estederm Sp. z o.o

Sikorskiego 13/U1 Warszawa Poland 02-758

#### Study participating centre

Lidia Rajzer - Specjalistyczny Gabinet Dermatologiczno-Kosmetyczny

Borkowska 29A/9 Krakow Poland 30-438

#### Study participating centre Przychodnia Specjalistyczna High-Med

27 Jana Kasprowicza Warszawa Poland 01-817

#### Study participating centre

Specjalistyczny gabinet dermatologiczny Aplikacyjno-Badawczy Marek Brzewski, Pawel Brzewski Spolka Cywilna

Zbozowa Krakow Poland 30-002

#### Study participating centre

#### Centrum Kliniczno Badawcze J. Brzezicki, B. Gornikiewicz-Brzezicka Lekarze Spolka Partnerska

Studzienna 35-36/A Elblag

Poland 82-300

Study participating centre Centrum Medvczne Promed

ul. Nad Struga 7 Krakow Poland 31-411

# Study participating centre SOLUMED Centrum Medyczne

ul. Dąbrowskiego 77a (Budynek Nobel Tower) Poznan Poland 60-529

#### Study participating centre Centrum Medyczne Oporow

ul. Ludwika Solskiego 4a/1 Wrocław Poland 52-416

#### Study participating centre Specderm Poznańska sp. j.

ul. Prezydenta Ryszarda Kaczorowskiego 7 lok. 50 U Bialystok Poland 15-375

# Study participating centre DERMMEDICA Sp.z o.o.

ul. Zakrzowska 19 a

Wroclaw Poland 51-318

#### Study participating centre Clinical Research Center sp. z o.o MEDIC-R s.k.

ul. Poznanska 3 lok. 31 Poznan Poland 60-848

### Study participating centre HOSP. UNIV. 12 DE OCTUBRE

Avenida de Cordoba, km 5,4 Madrid Spain 28041

#### Study participating centre HOSP. UNIV. I POLITECNI LA FE

Avda. Fernando Abril Martorell, 106 Valencia Spain 46026

### Study participating centre HOSP. DE MANISES

Avenida de la Generalitat Valenciana 50 Manises Spain 46940

### Study participating centre HOSP. UNIV. SAN CECILIO

Avenida del Conocimiento 33 Granada Spain 18016

### Study participating centre HOSP. VIRGEN MACARENA

Avenida Doctor Fedriani, nº 3 Sevilla Spain 41009

#### Study participating centre HOSP. UNIV. GERMANS TRIAS I PUJOL

Carretera de Canyet s/n Badalona Spain 08916

### Study participating centre HOSP. SANT JOAN DE DEU

Passeig Sant Joan de Déu 2 Esplugues de Llobregat Spain 08950

### Study participating centre HOSP. DEL MAR

Passeig Maritim, 25-29 Barcelona Spain 08003

#### Study participating centre National Taiwan University Hospital

No.1, Changde St., Zhongzheng Dist. Taipei Taiwan 10048

#### Study participating centre Linkou Chang Gung Memorial Hospital

No.5 Fuxing street
Taoyuan
Taiwan
33382

#### Study participating centre Kaohsiung Chang Gung Memorial Hospital

No. 123, DAPI Road, Niaosng District Kaohsiung Taiwan 83301

### Study participating centre National Taiwan University Hospital Hsin-Chu Branch

Room 57, 1F, No.25, Lane 442, Sec.1, Jingguo Rd. Hsinchu Taiwan 300

#### Study participating centre Istanbul University Cerrahpasa Medical Faculty

Kocamustafapasa Cad. Cerrahpasa No: 53 Istanbul Türkiye 34098

#### Study participating centre Ondokuz Mayis University

Ondokuz Mayis Unv Samsun Türkiye 55270

#### Study participating centre Karadeniz Teknik University Medical Faculty

Farabi cad. Trabzon Türkiye 61080

# Study participating centre Necmettin Erbakan University Meram Medical Faculty

Meram

Konya Türkiye 42080

### Study participating centre Pamukkale University Medical Faculty

Camlaraltı, Kinikli Yerleskesi, Universite Cd. No:11 Denizli Türkiye 20070

#### Study participating centre Ankara Etlik Speciality Hospital

Varlık, Halil Sezai Erkut Cd. No:5 Ankara Türkiye 06170

#### Study participating centre

Newcastle upon Tyne Hospitals NHS Foundation Trust

New Victoria Wing, Level 2, Queen Victoria Road Newcastle upon Tyne United Kingdom NE1 4LP

### Study participating centre

University Hospital Southampton NHS Foundation Trust

Southampton General Hospital Southampton United Kingdom SO16 6YD

#### Study participating centre Northwick Park Hospital

Watford Road London United Kingdom HA1 3UJ

# Study participating centre Victoria Hospital

Phase 1, Level 2 Kirkcaldy United Kingdom KY2 5AH

#### Study participating centre Salford Royal Hospital

Stott Lane Salford United Kingdom M6 8HD

#### Study participating centre Northshore Medical Group

9933 Woods Dr Skokie United States of America 60076

#### Study participating centre Oregon Dermatology and Research Center

2565 NW Lovejoy Portland United States of America 97210

# Study participating centre Arlington Research Center, Inc.

711 East Lamar Boulevard, Ste 200 Arlington United States of America 76011

#### Study participating centre Center for Clinical Studies

451 North Texas Avenue Webster United States of America 77598

#### Study participating centre Progressive Clinical Research

1973 N.W. Loop 410 San Antonio United States of America 78213

#### Study participating centre Skin Specialists

2802 Oak View Drive Omaha United States of America 68144

### Study participating centre Dermatology and Advanced Aesthetics

3635 Nelson Road Lake Charles United States of America 70605

#### Study participating centre Optima Research

1039 Boardman-Canfield Road Boardman United States of America 44512

#### Study participating centre Center for Clinical Studies

1401 Binz Street Houston United States of America 77004

Study participating centre
Austin Institute for Clinical Research
1601 E Pflugerville Pkwy

Pflugerville United States of America 78660

#### Study participating centre Minnesota Clinical Study Center

119-14th Street N.W., New Brighton United States of America 55112

#### Study participating centre MediSearch Clinical Trials

1427 Village Drive Saint Joseph United States of America 64506

#### Study participating centre Frontier Derm Partners CRO, LLC 15906 Mill Creek Blvd Mill Creek

Mill Creek
United States of America
98012

### Study participating centre Windsor Dermatology

59 One Mile Rd Ext Ste G East Windsor United States of America 8520

### Study participating centre

Dermatology Clinical Research Center of San Antonio

7810 Louis Pasteur Dr Ste 200 San Antonio United States of America 78229

### Study participating centre FORCARE CLINICAL RESEARCH, INC.

15416 North Florida Avenue Tampa United States of America 33613

#### Study participating centre Dawes Fretzin Clinical Research Group, LLC

7910 North Shadeland Avenue Indianapolis United States of America 46250

### Study participating centre Dundee Dermatology

1201 Water Tower Rd West Dundee United States of America 60118

### Study participating centre Indiana Clinical Trial Center

824 Edwards Drive Plainfield United States of America 46168

### Study participating centre Johnson Dermatology

5921 Riley Park Drive Fort Smith United States of America 72916

# Study participating centre Hamilton Research, LLC.

11800 Atlantis Place Alpharetta United States of America 30022

### Study participating centre University of Pittsburgh Medical Center

3601 5Th Ave Pittsburgh United States of America 15213

# Study participating centre Arlington Dermatology

5301 Keystone Ct. Rolling Meadows United States of America 60008

#### Study participating centre Hamzavi Dermatology

2950 Keewahdin Road Fort Gratiot United States of America 48059

### Study participating centre Allcutis Research

138 Conant Street Beverly United States of America 01915

### Study participating centre California Dermatology & Clinical Research Institute

561 Saxony Place Encinitas United States of America 92024

#### Study participating centre Center for Dermatology and Plastic Surgery 14301 N 87th St

Scottsdale United States of America 85260

Study participating centre Cope Family Medicine - Ogden Clinic 185 S 400 E Bountiful United States of America 84010

Study participating centre DermAssociates, PC 15245 Shady Grove Road Rockville United States of America 20850

Study participating centre Paddington Testing Co, Inc. 1845 Walnut Street Philadelphia United States of America 19103

### Sponsor information

#### Organisation

Janssen-Cilag International NV

### Funder(s)

Funder type Industry

#### Funder Name

Janssen Research and Development

#### Alternative Name(s)

Janssen R&D, Janssen Research & Development, Janssen Research & Development, LLC, Janssen Research & Development LLC, Janssen Pharmaceutical Companies of Johnson & Johnson, Research & Development at Janssen, JRD, J&J PRD

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

For-profit companies (industry)

#### Location

United States of America

#### **Results and Publications**

#### Individual participant data (IPD) sharing plan

The data sharing policy of the Janssen Pharmaceutical Companies of Johnson & Johnson is available at https://www.janssen.com/clinicaltrials/ transparency. As noted on this site, requests for access to the study data can be submitted through the Yale Open Data Access (YODA) Project site at yoda.yale.edu

#### IPD sharing plan summary

Available on request

#### **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No Yes