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A Study of JNJ-77242113 for the treatment of participants with moderate to severe plaque psoriasis

Submission date	Recruitment status	[X] Prospectively registered
16/09/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/12/2023	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
26/10/2026	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 dry, itchy, thick, and raised skin patches on the skin. Drugs that prevent interleukin (IL)-23* from binding to its receptor** may be an effective way to disease control. The study drug, JNJ-77242113, is a medicine designed to target the IL-23 receptor and block IL-23 from binding to it.
*A specific type of protein involved in inflammation.
**a protein that binds to a specific molecule
The purpose of this study is to see how effective JNJ-77242113 is compared to placebo (looks like JNJ-77242113 but it does not contain any active medication) and deucravacitinib in participants with moderate to severe plaque psoriasis.
Participants will receive JNJ-77242113, placebo, or deucravacitinib in 2:1:2 ratio which means in every 2 participants who receive JNJ-77242113, 1 will receive placebo, and 2 will receive deucravacitinib. Placebo will be administered in all treatment groups (JNJ-77242113, placebo or deucravacitinib) to maintain the blind until Week 24. This is a double-blind study, which means that the participant, caregiver, and the study doctor will not know whether the participants are receiving JNJ-77242113, placebo or deucravacitinib.

Who can participate?
Participants of 18 years or older with moderate to severe plaque psoriasis.

What does the study involve?
The study will be conducted in three periods:
1. Screening period (5 weeks)
2. Double-blind (156 weeks) treatment period: Participants will be randomly (like the flip of a coin) divided into 3 groups, JNJ-77242113, placebo, and deucravacitinib.
Group 1: JNJ-77242113 from Week 0 through Week 156.
Group 2: JNJ-77242113 matching placebo from Week 0 through Week 16, and thereafter JNJ-77242113 from Week 16 through Week 156.
Group 3: Deucravacitinib from Week 0 to Week 24 and thereafter JNJ-77242113 from Week 24 to Week 156.

Participants will undergo study assessments and tests, such as questionnaires, blood tests, vital signs, and physical exams. The possible side effects of the study drug will be recorded till end of the study. Blood samples will be taken at multiple timepoints to understand how the body responds to study drug.
3. 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. Risks for deucravacitinib include hypersensitivity, infections including TB; malignancies; potential risks related to JAK inhibition (including major adverse cardiovascular events, deep vein thrombosis, and pulmonary embolism); rhabdomyolysis; laboratory abnormalities including elevations in creatine phosphokinase, triglycerides, liver enzymes, and decreased glomerular filtration rate; and advice to avoid use of live vaccines during deucravacitinib treatment.
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 to 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 N.V. (Netherlands)

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

Who is funding the study?
Janssen-Cilag International N.V. (Netherlands)

Who is the main contact?
JanssenUKRegistryQueries@its.jnj.com

Contact information

Type(s)
Public, Scientific

Contact name
None - Medical Information and Product Information Enquiry

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT06143878

Clinical Trials Information System (CTIS)
2023-505121-14

Integrated Research Application System (IRAS)
1008235

Central Portfolio Management System (CPMS)
57592

Protocol serial number
77242113PSO3002

Study information

Scientific Title
A phase 3 multicentre, randomised, double-blind, placebo-controlled and deucravacitinib active comparator-controlled study to evaluate the efficacy and safety of JNJ-77242113 for the treatment of participants with moderate to severe plaque psoriasis - ICONIC-ADVANCE 1

Acronym
ICONIC-ADVANCE 1

Study objectives
Primary objective:
To evaluate the efficacy of JNJ-77242113 compared with placebo in participants with moderate to severe plaque psoriasis.

Secondary objectives:
1. To further evaluate efficacy (general and special area psoriasis) of JNJ-77242113 compared with placebo in participants with moderate to severe plaque psoriasis.
2. To evaluate effect of JNJ-77242113 compared with placebo on patient reported outcomes in participants with moderate to severe plaque psoriasis.
3. To evaluate effect and efficacy of JNJ-77242113 compared with deucravacitinib on clinician-reported outcomes and patient reported outcomes in participants with moderate to severe plaque psoriasis.
4. To evaluate the safety and tolerability of JNJ-77242113 compared with placebo and deucravacitinib in participants with moderately to severely plaque psoriasis.
5. To further evaluate the efficacy of JNJ-77242113 compared with placebo and deucravacitinib in participants with moderate to severe plaque psoriasis.
6. To further evaluate the efficacy (special area psoriasis) of JNJ-77242113 compared with placebo in participants with moderate to severe plaque psoriasis.
7. To further evaluate the effect of JNJ-77242113 compared with placebo on patient related outcomes in participants with moderately to severely plaque psoriasis.
8. To further evaluate the efficacy of JNJ-77242113 compared with deucravacitinib on patient related outcomes in participants with moderate to severe plaque psoriasis.
9. To evaluate the efficacy of JNJ-77242113 in participants with moderate to severe plaque psoriasis who switched from deucravacitinib to JNJ-77242113 treatment at Week 24.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/10/2023, East Midlands - Leicester Central REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8284; leicestercentral.rec@hra.nhs.uk), ref: 23/EM/0227

Primary study design
Interventional

Study design
Interventional double-blind randomized controlled trial

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Plaque psoriasis

Interventions
There are three treatment arms: JNJ-77242113 (experimental) arm, placebo comparator arm and active comparator (deucravacitinib) arm. Participants will be randomised via the online IWRS in a 2:1:2 ratio to one of these treatment arms. For the JNJ-77242113 (experimental) arm, participants will receive JNJ-77242113 from Week 0 through Week 156 and deucravacitinib matching placebo from Week 0 through Week 24. For the placebo comparator arm, participants will receive matching placebo for JNJ-77242113 from Week 0 through Week 16, matching placebo for deucravacitinib from Week 0 through Week 24 and JNJ-77242113 from Week 16 through Week 156. For the active comparator (deucravacitinib) arm, participants will receive deucravacitinib from Week 0 through Week 24 and matching placebo for JNJ-77242113 from Week 0 through Week 24 and JNJ-77242113 through Week 156.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
JNJ-77242113, deucravacitinib

Primary outcome(s)
1. Percentage of participants who achieve an IGA score of 0 or 1 and >=2-Grade improvement from baseline to Week 16. The IGA documents the investigator's assessment of the participants 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).
2. Percentage of participants achieving PASI 90 response (>=90% improvement in PASI from baseline) at Week 16 will be reported. 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.

Key secondary outcome(s)
1. JNJ-77242113 and Placebo Group: Percentage of participants achieving an IGA score of 0 at Week 16
2. JNJ-77242113 and Placebo Group: Percentage of participants achieving PASI 75 response from baseline at Weeks 4 and 16
3. JNJ-77242113 and Placebo Group: Percentage of participants achieving PASI 90 response at Week 8
4. JNJ-77242113 and Placebo Group: Percentage of participants achieving PASI 100 response at Week 16
5. JNJ-77242113 and Placebo Group: Percentage of participants achieving scalp-specific

Investigator Global Assessment (ss-IGA) score of 0 or 1 and >=2 grade improvement from baseline at Week 16
6. JNJ-77242113 and Placebo Group: Percentage of participants achieving Psoriasis Symptoms and Signs Diary (PSSD) Symptom Score of 0 at Weeks 8 and 16
7. JNJ-77242113 and Placebo Group: Percentage of participants achieving >=4-point improvement from baseline in PSSD Itch score at Weeks 4 and 16
8. JNJ-77242113 and Deucravacitinib Group: Percentage of participants achieving an IGA score of 0 or 1 and >=2 grade improvement from at Weeks 16 and 24
9. JNJ-77242113 and Deucravacitinib Group: Percentage of Participants Achieving an IGA Score of 0 at Weeks 16 and 24
10. JNJ-77242113 and Deucravacitinib Group: Percentage of Participants Achieving PASI 75 Response at Weeks 16 and 24
11. JNJ-77242113 and Deucravacitinib Group: Percentage of Participants Achieving PASI 90 Response at Weeks 16 and 24
12. JNJ-77242113 and Deucravacitinib Group: Percentage of Participants Achieving PASI 100 Response at Weeks 16 and 24
13. JNJ-77242113 and Deucravacitinib Group: Percentage of Participants with PSSD Symptom Score of 0 at Week 16
14. Number of participants with adverse events (AEs) and serious adverse events (SAEs) which occur from screening to Week 165.
15. Change from baseline in Body Surface Area (BSA) at Week 16
16. Change from baseline in PASI total score at Week 16
17. Percent improvement in PASI score from Baseline at Week 16
18. JNJ-77242113 and Placebo Group: Percentage of participants achieving a Static Physician's Global Assessment of Genitalia (sPGA-G) score of 0 or 1 and at least a 2-grade improvement from baseline to Week 16
19. JNJ-77242113 and Placebo Group: Percentage of participants achieving a Physician's Global Assessment of Hands and Feet (hf-PGA) score of 0 or 1 and at least a 2-grade improvement from baseline to Week 16
20. JNJ-77242113 and Placebo Group: Percent Change from baseline in Modified Nail Psoriasis Severity Index (mNAPSI) score at Week 16
21. JNJ-77242113 and Placebo Group: Percent of participants achieving Fingernail Physician's Global Assessment (f-PGA) score of 0 or 1 at Week 16
22. JNJ-77242113 and Placebo Group: Change from baseline in PSSD Symptom score at Week 16
23. JNJ-77242113 and Placebo Group: Change from baseline in PSSD Sign score at Week 16
24. JNJ-77242113 and Placebo Group: Percentage of participants with PSSD Sign score of 0 at Week 16
25. JNJ-77242113 and Placebo Group: Percentage of participants achieving Genital Psoriasis Sexual Frequency Questionnaire (GenPs-SFQ) Item 2 score of 0 or 1 at Week 16
26. JNJ-77242113 and Placebo Group: Percentage of participants achieving Dermatology Life Quality Index (DLQI) score of 0 or 1 at Week 16
27. JNJ-77242113 and Placebo Group: Change from baseline in total DLQI score at Week 16
28. JNJ-77242113 and Placebo Group: Change from baseline in domain scores of the Patient-reported Outcomes Measurement Information System-29 (PROMIS-29) score at Week 16
29. JNJ-77242113 and Deucravacitinib Group: Percentage of participants achieving DLQI score of 0 or 1 at Weeks 16 and 24
30. JNJ-77242113 and Deucravacitinib Group: Percentage of participants achieving PSSD Symptom Score of 0 at Weeks 16 and 24
31. Percentage of participants who achieve PASI 75 response after Week 24 among PASI 75 non-responders to deucravacitinib at Week 24
32. Percentage of participants who achieve PASI 90 response after Week 24 among PASI 90 non-responders to deucravacitinib at Week 24

33. Percentage of participants achieving IGA score of 0 or 1 after Week 24, among participants with IGA score >=2 at Week 24 in the deucravacitinib group.

Completion date
01/06/2027

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 before the first administration of study intervention
3. Total body surface area (BSA) greater than or equal to (>=)10 percent (%) at screening and baseline;
4. Total psoriasis area and severity index (PASI) >=12 at screening and baseline;
5. Total investigator global assessment (IGA) >=3 at screening and baseline;
6. Candidate for phototherapy or systemic treatment for plaque psoriasis.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Nonplaque form of psoriasis (for example, erythrodermic, guttate, or pustular);
2. Current drug-induced psoriasis (for example, a new onset of psoriasis or an exacerbation of psoriasis from beta blockers, calcium channel blockers, or lithium);
3. 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;
4. Known allergies, hypersensitivity, or intolerance to JNJ-77242113 or its excipients;
5. Major surgical procedure, (for example, requiring general anesthesia) within 8 weeks before screening, or will not have fully recovered from surgical procedure, or has a surgical procedure planned during the time the participant is expected to participate in the study.

Date of first enrolment
09/02/2024

Date of final enrolment
19/04/2024

Locations

Countries of recruitment
United Kingdom

Argentina

Australia

Brazil

Canada

France

Germany

Hungary

Italy

Japan

Korea, South

Poland

Spain

Taiwan

United States of America

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Study participating centre
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Sponsor information

Organisation
Janssen-Cilag International N.V.

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