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A Long-Term Extension Study of JNJ-77242113 in Participants with Moderate-to-Severe Plaque Psoriasis

Submission date
03/08/2022

Recruitment status
No longer recruiting

Registration date
11/10/2022

Overall study status
Completed

Last Edited
09/08/2024

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Plaque psoriasis is a common, chronic, inflammatory condition, affecting about 3.5 million patients in the United States, European Union, and Japan. Despite advanced treatment options, large numbers of patients are not receiving these therapies. There is a need for safer options, fewer injections, and more effective oral medications. Janssen has an investigational drug called JNJ-77242113, which targets immune responses in the body and skin that impact diseases, such as psoriasis. It is hoped that targeting immune response processes may lead to less inflammation and a reduction in psoriasis disease activity.

This study is a follow-on trial of 77242113PSO2001 (https://www.isrctn.com/ISRCTN76915275), which is designed to evaluate long-term efficacy and safety of the investigational drug JNJ-77242113 in adults with moderate to severe plaque psoriasis.

Who can participate?
Patients who have completed the week 16 weeks in the study 77242113PSO2001 and who, in the opinion of the investigator, may benefit from inclusion in this long-term extension study.

What does the study involve?
This is a long-term extension study of JNJ-77242113 in eligible participants who completed the Week 16 visit of the originating 77242113PSO2001 study. All participants will receive active JNJ-77242113 study medication. The total study duration will be up to 40 weeks which will include:
1. A 36-week treatment period
2. A 4-week safety follow-up period after the last study intervention administration

Safety will be assessed by clinical safety laboratory assessments, electrocardiograms (ECGs), vital signs, physical examinations, and monitoring adverse events (AEs) throughout the study.

What are the possible benefits and risks of participating?
Possible benefits for patients taking JNJ-77242113 include improvements in plaque psoriasis symptoms based on current scientific theory. Only patients who may benefit from such drug

treatment (i.e., with specific disease characteristics identified by study investigators) are eligible for study inclusion. Such patient participation may help other psoriasis patients in the future.

Study participants also may experience some benefits not due to receiving the study drug, but instead due to regular visits, assessments, and overall health monitoring. Long-term benefits, however, are not guaranteed to happen and there may not be any benefit to participants by being in this study.

Not all possible side effects and risks related to JNJ-77242113 are known, such that unexpected side effects may arise or be life-threatening.

A participant information sheet (which will be signed by every participant agreeing to participate in the study) includes a detailed section outlining all known risks/side effects to study participants.

To minimize any study-associated risks participants are frequently reviewed at every visit for side effects and adverse events and participants are educated to report any such problems to the study staff without delay.

Any serious adverse events that are reported to the sponsor are thoroughly reviewed by a specialist drug safety team and the sponsor has implemented an Independent Data Review Committee.

Where is the study run from?
Janssen-Cilag International NV (Belgium) 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?
June 2022 to November 2023

Who is funding the study?
Janssen Research and Development, LLC (USA)

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

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Scientific

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ClinicalTrials.gov (NCT)
NCT05364554

Clinical Trials Information System (CTIS)
2021-004320-16

Integrated Research Application System (IRAS)
1005014

Central Portfolio Management System (CPMS)
52237

Protocol serial number
77242113PSO2002

Study information

Scientific Title
A Phase 2b Multicenter, Long-Term Extension, Dose-ranging Study to Evaluate the Efficacy and Safety of JNJ-77242113 for the Treatment of Moderate-to-Severe Plaque Psoriasis.

Acronym
FRONTIER 2

Study objectives
Main objectives:
1. To evaluate long-term clinical response of JNJ-77242113 treatment in participants with moderate-to-severe plaque psoriasis

Secondary objectives:
1. To evaluate and assess additional long-term clinical response of JNJ-77242113 treatment in participants with moderate-to-severe plaque psoriasis
2. To evaluate and assess the effect of JNJ-77242113 treatment on patient-reported psoriasis severity in participants with moderate-to-severe plaque psoriasis

3. To evaluate and assess the safety and tolerability of JNJ-77242113 in participants with moderate-to-severe plaque psoriasis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/08/2022, South Central - Berkshire B Research Ethics Committee (Meeting held by video-conference via Zoom; +44 (0)207 104 8253, +44 (0)207 104 8068, +44 (0)207 104 8276; berkshireb.rec@hra.nhs.uk), ref: 22/SC/0224

Study design
Multicentre, long-term extension, double-blind, dose-ranging, parallel group, randomized interventional study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
The total duration of this study is up to 40 weeks which includes a 36-week treatment period, and a 4-week safety follow-up period. Participants will continue to receive the dose randomly assigned by the online interactive web randomisation system tool from the preceding study (77242113PSO2001).

Those participants assigned to the placebo treatment arm in the preceding study will be assigned to an active treatment arm in this study. Each active cohort group will also receive placebo to maintain blinding of dose regimens throughout the trial:
1. Group 1 will receive dose 1 of JNJ-77242113 once daily and placebo
2. Group 2 will receive dose 2 of JNJ-77242113 once daily and placebo
3. Group 3 will receive dose 3 of JNJ-77242113 once daily and placebo
4. Group 4 will receive dose 1 of JNJ-77242113 twice daily and placebo
5. Group 5 will receive dose 3 of JNJ-77242113 twice daily and placebo
6. Group 6 will receive dose 3 of JNJ-77242113 once daily and placebo

Intervention Type
Drug

Phase
Phase II

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

Primary outcome(s)

Percentage of participants achieving Psoriasis Area Severity Index (PASI) 75 score (≥75% improvement in PASI from baseline of the originating study [77242113PSO2001]) at Week 36. 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. Percentage of participants achieving PASI 90 score (≥90% improvement in PASI from baseline of the originating study [77242113PSO2001]) at week 36
2. Percentage of participants achieving PASI 100 score (≥100% improvement in PASI from baseline of the originating study [77242113PSO2001]) at week 36
3. Change from baseline of the originating study (77242113PSO2001) in PASI Total Score at Week 36
4. Percentage of participants achieving an Investigator's Global Assessment (IGA) Score of Cleared (0) or Minimal (1) determined at Week 36. 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).
5. Change from baseline of originating study (77242113PSO2001) in Psoriasis Symptoms and Signs Diary (PSSD) Symptoms Scores reported at Week 36. 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 subscores 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. Change from baseline of originating study (77242113PSO2001) in Psoriasis Symptoms and Signs Diary (PSSD) Signs Scores reported at Week 36
7. Percentage of participants achieving PSSD Symptoms Score of 0 at Week 36 among participants with a baseline (in the originating study 77242113PSO2001) symptoms score ≥1
8. Percentage of participants achieving PSSD Signs Score of 0 at Week 36 among participants with a baseline (in the originating study 77242113PSO2001) signs score ≥1
9. Number of participants with Adverse Events (AEs) monitored up to Week 40. 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.
10. Number of participants with Serious Adverse Events (SAEs) monitored up to Week 40. SAE is an adverse event resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly/birth defect; suspected transmission of any infectious agent via a medicinal product or medically important.

Completion date

13/11/2023

Eligibility

Key inclusion criteria
1. Must have completed the Week 16 visit in Protocol 77232114PSO2001
2. In the opinion of the investigator, may benefit from inclusion in this long-term extension (LTE) study
3. Must agree to avoid prolonged sun exposure and avoid the use of tanning booths or other ultraviolet light sources during the study
4. Must agree to discontinue all topical therapies that could affect psoriasis or the psoriasis area severity index (PASI) or Investigator's global assessment (IGA) evaluation, other than nonmedicated emollient and salicylic acid shampoos, prior to first administration of study intervention.
5. Agree not to receive a live virus or live bacterial vaccination during the study, or within 4 weeks after the last administration of the study intervention

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
227

Key exclusion criteria
1. Was permanently discontinued from study intervention in Protocol 77242113PSO2001 for any reason
2. Has received any biologic therapy or experimental therapy since completion of the originating study 77242113PSO2001
3. Has received any live virus or bacterial vaccination within 12 weeks before the first administration of study intervention
4. Has received the bacille Clamette-Guerin (BCG) vaccine within 12 months of the first administration of study intervention
5. Currently has hepatitis B surface antigen (HBsAg) or hepatitis C antibody (antiHCV) positive, or has another clinically active liver disease, or tests positive for HBsAg or anti-HCV

Date of first enrolment
10/06/2022

Date of final enrolment
06/02/2023

Locations

Countries of recruitment
United Kingdom

Canada

France

Germany

Japan

Korea, South

Poland

Spain

Taiwan

United States of America

Study participating centre
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H2H2B5

Study participating centre
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Sponsor information

Organisation
Janssen (Belgium)

ROR
https://ror.org/04yzcpd71

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 datasets generated during and/or analysed during the current study are/will be available upon request. 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?
HRA research summary			28/06/2023	No	No
Other unpublished results	Immunogenicity results have been redacted		09/08/2024	No	No