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A study of JNJ-95475939 in the treatment of participants with moderate to severe atopic dermatitis

Submission date
20/12/2024

Recruitment status
Recruiting

Registration date
19/03/2025

Overall study status
Ongoing

Last Edited
01/04/2025

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Atopic dermatitis (AD) is a common inflammatory skin condition which causes itchy, dry, red skin. Biologically, AD is characterized by Type-2 immune response dysregulation and skin barrier disruption worsened by the itch-scratch cycle.
JNJ-95475939 blocks the two important biological pathways (called Interleukin-4 [IL-4]/IL-13 and IL-31*) involved in the Type-2 inflammation and itch-scratch cycle of AD.
*IL-4, IL-13 and IL-31 are proteins that regulate immune responses.
In this study, researchers want to learn how well JNJ-95475939 works as compared to placebo and a comparator in participants with moderate to severe AD.

Who can participate?
Participants aged 18 years or older with moderate to severe AD.

What does the study involve?
The study consists of 3 periods:
1. Screening period (up to 5 weeks): Eligible participants will be screened for participation in study.
2. Treatment period (up to 24 weeks): Participants will be randomly (by chance) assigned in one of the 5 treatment groups:
Group A: Dupilumab Dose regimen 1 administered subcutaneously (SC; under the skin) for 24 weeks.
Group B: JNJ-95475939 Dose regimen 1 SC for 24 weeks.
Group C: JNJ-95475939 Dose regimen 2 SC for 24 weeks.
Group D: JNJ-95475939 Dose regimen 3 SC for 24 weeks.
Group E: Placebo SC for 12 weeks, then switch to JNJ-95475939 Dose regimen 1 SC for another 12 weeks
3. Follow-up period (up to 12 weeks): Participants will be followed up to monitor their health.
Safety assessments will include physical examinations, body weight, vital signs, 12-lead ECG, pregnancy testing, clinical laboratory tests, and monitoring of adverse events and serious adverse events. The overall duration of the study is up to 41 weeks.

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-95475939 may improve AD. However, this cannot be guaranteed because JNJ-95475939 is still under investigation as a treatment, and it is not known whether JNJ-95475939 will work.
In addition, if participants are put into the placebo treatment group, they will receive placebo during the first 12 weeks before they are switched to JNJ-95475939 for another 12 weeks.
If participants are put in the dupilumab (active comparator) group, they will not receive JNJ-95475939 but treatment already on the market.
Participants may experience some benefit from participation in the study that is not due to receiving study drug, but due to regular visits and assessments monitoring overall health.
Participation may help other people with AD 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. The known potential risks include hypersensitivity (allergic reactions), injection-site reactions, parasitic infection, conjunctivitis/keratitis (inflammation of the surface of the eye[s]) after getting the study drug. 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 and risks related to JNJ-95475939 are known at this moment. During the study, the sponsor may learn new information about JNJ-95475939. 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 their study doctor who will provide appropriate medical care. Any serious side effects that are reported to the sponsor are thoroughly reviewed by 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?

When is the study starting and how long is it expected to run for?

Who is funding the study?

Who is the main contact?

Contact information

Type(s)
Public, Scientific

Contact name
Dr . Medical Information and Product Information Enquiry

Contact details
50-100 Holmers Farm Way
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HP12 4DP

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Type(s)
Principal Investigator

Contact name
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Additional identifiers

EudraCT/CTIS number
2024-517814-13

IRAS number
1011362

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
95475939ADM2001, CPMS 65442

Study information

Scientific Title
A phase 2b, multicenter, randomized, double-blind, placebo- and active-controlled, dose-ranging study to evaluate the efficacy and safety of JNJ-95475939 for the treatment of participants with moderate to severe atopic dermatitis

Acronym
DUPLEX-AD

Study objectives
Main objectives
• To evaluate how well the treatment with JNJ-95475939 works (efficacy) as compared to placebo in participants with moderate to severe Atopic Dermatitis (AD).

Secondary objectives
• To further evaluate how well JNJ-95475939 works (efficacy) as compared to placebo based on improvement in severity of the disease in participants with moderate to severe AD.
• To evaluate how well JNJ-95475939 works as compared to dupilumab in participants with

moderate to severe AD.
• To assess the safety and tolerability of JNJ-95475939 in participants with moderate to severe AD.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/02/2025, London - Surrey Borders Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8004; surreyborders.rec@hra.nhs.uk), ref: 25/LO/0053

Study design
Interventional double blind randomized parallel group cross over controlled trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Safety, Efficacy

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Atopic Dermatitis (AD)

Interventions
The study consists of 3 periods:
Screening period (up to 5 weeks): Eligible participants will be screened for participation in study.
Treatment period (up to 24 weeks): Participants will be randomly (by chance) assigned in 1 of the 5 treatment groups:

Group A: Dupilumab Dose regimen 1 administered subcutaneously (SC; under the skin) for 24 weeks.
Group B: JNJ-95475939 Dose regimen 1 SC for 24 weeks.
Group C: JNJ-95475939 Dose regimen 2 SC for 24 weeks.
Group D: JNJ-95475939 Dose regimen 3 SC for 24 weeks.
Group E: Placebo SC for 12 weeks, then switch to JNJ-95475939 Dose regimen 1 SC for another 12 weeks
Follow-up period (up to 12 weeks): Participants will be followed up to monitor their health.

Safety assessments will include physical examinations, body weight, vital signs, 12-lead ECG, pregnancy testing, clinical laboratory tests, and monitoring of adverse events and serious adverse events. The overall duration of the study is up to 41 weeks.

Intervention Type
Biological/Vaccine

Pharmaceutical study type(s)
Pharmacokinetic, Pharmacogenomic, Immunogenicity, Biomarkers

Phase
Phase II

Drug/device/biological/vaccine name(s)
dupilumab 300 mg, JNJ-95475939

Primary outcome measure
1. Percentage of Participants with Eczema Area and Severity Index (EASI) 75 Response at Week 12 [Time Frame: Baseline, Week 12]
EASI-75 response is defined as at least 75 percent (%) improvement in EASI total score. EASI-75 response is defined as at least 75% improvement from baseline in EASI total score. The EASI score is used to measure the severity and extent of atopic dermatitis (AD) and measures erythema, infiltration/papulation, excoriation and lichenification on 4 anatomic regions of the body: head/neck, trunk, upper and lower extremities. The total EASI score ranges from 0 (minimum) to 72 (maximum) points, with the higher scores reflecting a higher severity of AD.

Secondary outcome measures
1. Percentage of Participants With EASI-90 Response at Week 12 [Time Frame: Baseline, Week 12]
EASI-90 response is defined as at least 90% improvement in EASI total score. EASI-90 response is defined as at least 90% improvement from baseline in EASI total score. The EASI score is used to measure the severity and extent of AD and measures erythema, infiltration/papulation, excoriation and lichenification on 4 anatomic regions of the body:head/neck, trunk, upper and lower extremities. The total EASI score ranges from 0 (minimum) to 72 (maximum) points, with the higher scores reflecting a higher severity of AD.
2. Percentage of Participants With EASI-100 Response at Week 12 [Time Frame: Baseline, Week 12]
EASI-100 response is defined as at least 100% improvement in EASI total score. EASI-100 response is defined as at least 100% improvement from baseline in EASI total score. The EASI score is used to measure the severity and extent of AD and measures erythema, infiltration /papulation, excoriation and lichenification on 4 anatomic regions of the body:head/neck, trunk, upper and lower extremities. The total EASI score ranges from 0 (minimum) to 72 (maximum) points, with the higher scores reflecting a higher severity of AD.
3. Percentage of Participants Achieving Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) Score of 0 or 1 and a Reduction From Baseline of Greater Than Equal to (>=) 2 Points at Week 12 [Time Frame: Baseline, Week 12]
vIGA-AD is an assessment instrument used in clinical studies to rate the severity of AD, based on a 5-point scale ranging from 0, where 0=Clear: No inflammatory signs of AD; 1=almost clear: Barely perceptible erythema, induration/papulation and/or lichenification; 2=mild: Slight but definite erythema, induration/papulation and/or minimal lichenification. No oozing or crusting; 3=moderate: Clearly perceptible erythema, induration/papulation and/or lichenification, oozing or crusting may be present and 4=severe: Marked erythema, induration/papulation and/or lichenification; Oozing or crusting may be present. Higher scores are indicative of a more severe AD.

4. Percentage of Participants Achieving vIGA-AD Score of 0 and a Reduction From Baseline of >=2 Points at Week 12 [Time Frame: Baseline, Week 12]
vIGA-AD is an assessment instrument used in clinical studies to rate the severity of AD, based on a 5-point scale ranging from 0, where 0=Clear: No inflammatory signs of AD; 1=almost clear: Barely perceptible erythema, induration/papulation and/or lichenification; 2=mild: Slight but definite erythema, induration/papulation and/or minimal lichenification. No oozing or crusting; 3=moderate: Clearly perceptible erythema, induration/papulation and/or lichenification, oozing or crusting may be present and 4=severe: Marked erythema, induration/papulation and/or lichenification; Oozing or crusting may be present. Higher scores are indicative of a more severe AD.
5. Percent Change From Baseline in the EASI Total Score at Week 12 [Time Frame: Baseline, Week 12]
The EASI is a validated measure used in clinical practice and clinical trials to assess the severity and extent of AD. The EASI score is used to measure the severity and extent of AD and measures erythema, infiltration/papulation, excoriation and lichenification on 4 anatomic regions of the body: head/neck, trunk, upper and lower extremities. The total EASI score ranges from 0 (minimum) to 72 (maximum) points, with the higher scores reflecting a higher severity of AD.
6. Percentage of Participants Achieving a >= 4-Point Reduction in Skin Pain Numerical Rating Scale (NRS) Score From Baseline to Week 12 [Time Frame: Baseline, Week 12]
The Skin Pain NRS is a single item asking participants to assess their worst skin pain over the past 24 hours. The response categories range from 0 (no pain) to 10 (worst pain). Higher scores indicating greater severity.
7. Percent Change from Baseline in Peak Pruritus Numerical Rating Scale (PP-NRS) Score at Week 12 [Time Frame: Baseline, Week 12]
The PP-NRS is a single item asking participants to assess their worst itch over the past 24 hours. The response categories range from 0 (no pain) to 10 (worst pain). Higher scores indicating greater severity.
8. Percent Change from Baseline in Skin Pain NRS Score at Week 12 [Time Frame: Baseline, Week 12]
The Skin Pain NRS is a single item asking participants to assess their worst skin pain over the past 24 hours. The response categories range from 0 (no pain) to 10 (worst pain). Higher scores indicating greater severity.
9. Percent Change from Baseline in the Score of Item 2 of the AD Sleep Scale at Week 12 [Time Frame: Baseline, Week 12]
The AD sleep scale is a validated 3-item PRO instrument to capture self-reported impact of itch on sleep disturbance each day, including difficulty falling asleep, number of night-time awakenings, and difficulty falling back asleep after waking during the previous night. Each AD Sleep Scale item is scored individually. For Item 2, participants select the number of times they woke up each night, ranging from 0 to 29 times.
10. Percentage of Participants Achieving a >= 4-Point Reduction in PP-NRS Score From Baseline Through Week 12 [Time Frame: From Baseline through Week 12]
The PP-NRS is a single item asking participants to assess their worst itch over the past 24 hours. The response categories range from 0 (no pain) to 10 (worst pain). Higher scores indicating greater severity.
11. Percentage of Participants with EASI-75 Response at Week 16 [Time Frame: Baseline, Week 16]
EASI-75 response is defined as at least 75% improvement in EASI total score. EASI-75response is defined as at least 75% improvement from baseline in EASI total score. The EASI score is used to measure the severity and extent of AD and measures erythema, infiltration/papulation, excoriation and lichenification on 4 anatomic regions of the body:head/neck, trunk, upper and lower extremities. The total EASI score ranges from 0 (minimum) to 72 (maximum) points, with the higher scores reflecting a higher severity of AD.

12. Percentage of Participants with EASI-90 Response at Week 16 [Time Frame: Baseline, Week 16]
EASI-90 response is defined as at least 90% improvement in EASI total score. EASI-90 response is defined as at least 90% improvement from baseline in EASI total score. The EASI score is used to measure the severity and extent of AD and measures erythema, infiltration/papulation, excoriation and lichenification on 4 anatomic regions of the body:head/neck, trunk, upper and lower extremities. The total EASI score ranges from 0 (minimum) to 72 (maximum) points, with the higher scores reflecting a higher severity of AD.
13. Percentage of Participants with EASI-100 Response at Week 16 [Time Frame: Week 16]
EASI-100 response is defined as at least 100% improvement in EASI total score. EASI-100 response is defined as at least 100% improvement from baseline in EASI total score. The EASI score was used to measure the severity and extent of AD and measures erythema, infiltration /papulation, excoriation and lichenification on 4 anatomic regions of the body:head/neck, trunk, upper and lower extremities. The total EASI score ranges from 0 (minimum) to 72 (maximum) points, with the higher scores reflecting a higher severity of AD.
14. Percentage of Participants Achieving vIGA-AD Score of 0 or 1 and a Reduction From Baseline of >= 2 Points at Week 16 [Time Frame: Baseline, Week 16]
vIGA-AD is an assessment instrument used in clinical studies to rate the severity of AD, based on a 5-point scale ranging from 0, where 0=Clear: No inflammatory signs of AD; 1=almost clear: Barely perceptible erythema, induration/papulation and/or lichenification; 2=mild: Slight but definite erythema, induration/papulation and/or minimal lichenification. No oozing or crusting; 3=moderate: Clearly perceptible erythema, induration/papulation and/or lichenification, oozing or crusting may be present and 4=severe: Marked erythema, induration/papulation and/or lichenification; Oozing or crusting may be present. Higher scores are indicative of a more severe AD.
15. Percentage of Participants Achieving vIGA-AD Score of 0 and a Reduction From Baseline of >=2 Points at Week 16 [Time Frame: Baseline, Week 16]
vIGA-AD is an assessment instrument used in clinical studies to rate the severity of AD, based on a 5-point scale ranging from 0, where 0=Clear: No inflammatory signs of AD; 1=almost clear: Barely perceptible erythema, induration/papulation and/or lichenification; 2=mild: Slight but definite erythema, induration/papulation and/or minimal lichenification. No oozing or crusting; 3=moderate: Clearly perceptible erythema, induration/papulation and/or lichenification, oozing or crusting may be present and 4=severe: Marked erythema, induration/papulation and/or lichenification; Oozing or crusting may be present. Higher scores are indicative of a more severe AD.
16. Percent Change from Baseline in the EASI Total Score at Week 16 [Time Frame: Baseline, Week 16]
The EASI is a validated measure used in clinical practice and clinical trials to assess the severity and extent of AD. The EASI score is used to measure the severity and extent of AD and measures erythema, infiltration/papulation, excoriation and lichenification on 4 anatomic regions of the body: head/neck, trunk, upper and lower extremities. The total EASI score ranges from 0 (minimum) to 72 (maximum) points, with the higher scores reflecting a higher severity of AD.
17. Percentage of Participants Achieving a >= 4-Point Reduction in Skin Pain Numerical Rating Scale (NRS) Score From Baseline to Week 16 [Time Frame: Baseline, Week 16]
The Skin Pain NRS is a single item asking participants to assess their worst skin pain over the past 24 hours. The response categories range from 0 (no pain) to 10 (worst pain). Higher scores indicating greater severity.
18. Percent Change from Baseline in PP-NRS Score at Week 16 [Time Frame: Baseline, Week 16]
The PP-NRS is a single item asking participants to assess their worst itch over the past 24 hours. The response categories range from 0 (no pain) to 10 (worst pain). Higher scores indicating greater severity.
19. Percent Change from Baseline in Skin Pain NRS Score at Week 16 [Time Frame: Baseline,

Week 16]
The Skin Pain NRS is a single item asking participants to assess their worst skin pain over the past 24 hours. The response categories range from 0 (no pain) to 10 (worst pain). Higher scores indicating greater severity.
20. Percent Change from Baseline in the Score of Item 2 of the AD Sleep Scale at Week 16 [Time Frame: Baseline, Week 16]
The AD sleep scale is a validated 3-item PRO instrument to capture self-reported impact of itch on sleep disturbance each day, including difficulty falling asleep, number of night-time awakenings, and difficulty falling back asleep after waking during the previous night. Each AD Sleep Scale item is scored individually. For Item 2, participants select the number of times they woke up each night, ranging from 0 to 29 times.
21. Percentage of Participants Achieving a >= 4-Point Reduction in PP-NRS Score From Baseline Through Week 24 [Time Frame: From Baseline Through Week 24]
The PP-NRS is a single item asking participants to assess their worst itch over the past 24 hours. The response categories range from 0 (no pain) to 10 (worst pain). Higher scores indicating greater severity.
22. Percentage of Participants with EASI-75 Response at Week 24 [Time Frame: Baseline, Week 24]
EASI-75 response is defined as at least 75% improvement in EASI total score. EASI-75 response is defined as at least 75% improvement from baseline in EASI total score. The EASI score is used to measure the severity and extent of AD and measures erythema, infiltration/papulation, excoriation and lichenification on 4 anatomic regions of the body:head/neck, trunk, upper and lower extremities. The total EASI score ranges from 0 (minimum) to 72 (maximum) points, with the higher scores reflecting a higher severity of AD.
23. Percentage of Participants with EASI-90 Response at Week 24 [Time Frame: Week 24]
EASI-90 response is defined as at least 90% improvement in EASI total score. EASI-90 response is defined as at least 90% improvement from baseline in EASI total score. The EASI score is used to measure the severity and extent of AD and measures erythema, infiltration/papulation, excoriation and lichenification on 4 anatomic regions of the body:head/neck, trunk, upper and lower extremities. The total EASI score ranges from 0 (minimum) to 72 (maximum) points, with the higher scores reflecting a higher severity of AD.
24. Percentage of Participants with EASI-100 Response at Week 24 [Time Frame: Week 24]
EASI-100 response is defined as at least 100% improvement in EASI total score. EASI-100 response is defined as at least 100% improvement from baseline in EASI total score. The EASI score is used to measure the severity and extent of AD and measures erythema, infiltration /papulation, excoriation and lichenification on 4 anatomic regions of the body:head/neck, trunk, upper and lower extremities. The total EASI score ranges from 0 (minimum) to 72 (maximum) points, with the higher scores reflecting a higher severity of AD.
25. Percentage of Participants Achieving vIGA-AD Score of 0 or 1 and a Reduction From Baseline of >= 2 Points at Week 24 [Time Frame: Baseline, Week 24]
vIGA-AD is an assessment instrument used in clinical studies to rate the severity of AD, based on a 5-point scale ranging from 0, where 0=Clear: No inflammatory signs of AD; 1=almost clear: Barely perceptible erythema, induration/papulation and/or lichenification; 2=mild: Slight but definite erythema, induration/papulation and/or minimal lichenification. No oozing or crusting; 3=moderate: Clearly perceptible erythema, induration/papulation and/or lichenification, oozing or crusting may be present and 4=severe: Marked erythema, induration/papulation and/or lichenification; Oozing or crusting may be present. Higher scores are indicative of a more severe AD.
26. Percentage of Participants Achieving vIGA-AD Score of 0 and a Reduction From Baseline of >=2 Points at Week 24 [Time Frame: Baseline, Week 24]
vIGA-AD is an assessment instrument used in clinical studies to rate the severity of AD, based on a 5-point scale ranging from 0, where 0=Clear: No inflammatory signs of AD; 1=almost clear:

Barely perceptible erythema, induration/papulation and/or lichenification; 2=mild: Slight but definite erythema, induration/papulation and/or minimal lichenification. No oozing or crusting; 3=moderate: Clearly perceptible erythema, induration/papulation and/or lichenification, oozing or crusting may be present and 4=severe: Marked erythema, induration/papulation and/or lichenification; Oozing or crusting may be present. Higher scores are indicative of a more severe AD.
27. Percent Change from Baseline in the EASI Total Score at Week 24 [Time Frame: Baseline, Week 24]
The EASI is a validated measure used in clinical practice and clinical trials to assess the severity and extent of AD. The EASI score is used to measure the severity and extent of AD and measures erythema, infiltration/papulation, excoriation and lichenification on 4 anatomic regions of the body: head/neck, trunk, upper and lower extremities. The total EASI score ranges from 0 (minimum) to 72 (maximum) points, with the higher scores reflecting a higher severity of AD.
28. Percentage of Participants Achieving a >= 4-Point Reduction in Skin Pain NRS Score From Baseline to Week 24 [Time Frame: Baseline, Week 24]
The Skin Pain NRS is a single item asking participants to assess their worst skin pain over the past 24 hours. The response categories range from 0 (no pain) to 10 (worst pain). Higher scores indicating greater severity.
29. Percent Change From Baseline in PP-NRS Score at Week 24 [Time Frame: Baseline, Week 24]
The PP-NRS is a single item asking participants to assess their worst itch over the past 24 hours. The response categories range from 0 (no pain) to 10 (worst pain). Higher scores indicating greater severity.
30. Percent Change from Baseline in Skin Pain NRS Score at Week 24 [Time Frame: Baseline, Week 24]
The Skin Pain NRS is a single item asking participants to assess their worst skin pain over the past 24 hours. The response categories range from 0 (no pain) to 10 (worst pain). Higher scores indicating greater severity.
31. Percent Change from Baseline in the Score of Item 2 of the AD Sleep Scale at Week 24 [Time Frame: Baseline, Week 24]
The AD sleep scale is a validated 3-item PRO instrument to capture self-reported impact of itch on sleep disturbance each day, including difficulty falling asleep, number of night-time awakenings, and difficulty falling back asleep after waking during the previous night. Each AD Sleep Scale item is scored individually. For Item 2, participants select the number of times they woke up each night, ranging from 0 to 29 times.
32. Number of Participants with Adverse Events (AEs) and Serious Adverse Events (SAEs) [Time Frame: From Baseline up to Week 32]
Participants with AEs and SAEs will be reported. An AE can be any unfavorable and unintended sign (including an abnormal finding), symptom, or disease temporally associated with the use of a medicinal (investigational or non investigational) product, whether or not related to that medicinal (investigational or non investigational) product. TEAEs are AEs with onset during the intervention phase or that are a consequence of a preexisting condition that has worsened since baseline. A SAE is an AE 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 or incapacity; congenital anomaly.

Overall study start date
17/12/2024

Completion date
15/07/2026

Eligibility

Key inclusion criteria
Ages Eligible for Study: 18 Years and older
Sexes Eligible for Study: All
Gender Based: No
Accepts Healthy Volunteers: No

Inclusion criteria:
1. Chronic Atopic Dermatitis (AD), according to American Academy of Dermatology Consensus Criteria with onset of symptoms at least 1 year prior to the screening visit
2. Eczema Area and Severity Index (EASI) score greater than and equal to (>=) 16 at the screening and baseline visits
3. Validated investigator global assessment for AD (vIGA-AD) score >= 3 at the screening and baseline visits
4. >= 10% body surface area (BSA) of AD involvement at the screening and baseline visits
5. Baseline Peak Pruritus Numeric(al) Rating Scale (PP-NRS) average score of >=4
6. Documented history (within 6 months before screening) of either inadequate response or inadvisability to topical treatments, or inadequate response to systemic therapies (within 12 months before screening)
7. Participant has applied a moisturizer at least once daily for at least 7 days before the baseline visit

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240

Key exclusion criteria
1. Experienced primary efficacy failure (no response within 16 weeks) or an adverse event (AE) requiring discontinuation related to agents (eg, severe ocular surface disease, dupilumab-associated facial redness) inhibiting IL-4Rα, IL-4, and/or IL-13 signaling (eg, dupilumab, lebrikizumab, or tralokinumab)
2. Participant is pregnant or breastfeeding, or planning to become pregnant or breastfeed during the study
3. Active skin disease other than AD including eczema herpeticum, molluscum contagiosum, impetigo, psoriasis or has any other ongoing significant skin condition including skin infections, that, according to the investigator, could interfere with efficacy assessments
4. Current diagnosis or signs or symptoms of severe, progressive, or uncontrolled renal, cardiac, vascular, pulmonary, gastrointestinal, endocrine, neurologic, hematologic, rheumatologic, psychiatric, or metabolic disturbances

5. Recent case of eczema herpeticum, herpes zoster within 8 weeks before screening, or history of recurrent eczema herpeticum
6. History of chronic or recurrent infectious disease, including but not limited to chronic renal infection, chronic chest infection (eg, untreated latent tuberculosis), recurrent urinary tract infection, fungal infection, mycobacterial infection, or open, draining, or infected skin wounds, or ulcers.
7. Diagnosed active parasitic infection or at high risk of parasitic infection, unless treated with antihelminth therapy prior to randomization
8. Had major surgery (eg, requiring general anesthesia and hospitalization), within 8 weeks before screening, or will not have fully recovered from surgery, or has such surgery planned during the time the participant is expected to participate in the study

Date of first enrolment
26/02/2025

Date of final enrolment
13/10/2025

Locations

Countries of recruitment
Argentina

Brazil

Canada

Germany

Japan

Poland

Spain

United Kingdom

United States of America

Study participating centre
Guys and St Thomas NHS Foundation Trust
Guys Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
Northwick Park Hospital
Watford Road
Harrow
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HA1 3UJ

Study participating centre
Salford Royal NHS Foundation Trust
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
The Queen Elizabeth Hospital, King's Lynn, NHS Foundation Trust
Queen Elizabeth Hospital
Gayton Road
King's Lynn
United Kingdom
PE30 4ET

Study participating centre
Royal London Hospital
Whitechapel Road
London
United Kingdom
E1 1FR

Study participating centre
INAER - Investigación en Alergias y Enfermedades Respiratorias
Arenales 3146
Buenos Aires
Argentina
C1425

Study participating centre
CETI - Centro de Estudos em Terapias Inovadoras Ltda
Avenida Agostinho Leao Junior 306

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Brazil
80.030-110

Study participating centre
Dermatology Research Institute Inc
8500 Blackfoot Trail SE
Meadows Mile Professional Building Suite 310
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T2J 7E1

Study participating centre
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Bismarckstrasse 49
Langenau
Germany
89129

Study participating centre
Nomura Dermatology Clinic
4 27 14 tanmachi Kanagawa ku
Chario Tower 2F
Yokohama
Japan
221 0825

Study participating centre
Specjalistyczny gabinet dermatologiczny Aplikacyjno Badawczy Marek Brzewski Pawel Brzewski Spolka Cywilna
Zbozowa
2 25
Krakow
Poland
30 002

Study participating centre
GRUPO DERMATOLOGICO Y ESTETICO PEDRO JAEN
C Serrano 143

Madrid
Spain
28006

Study participating centre
Arlington Center for Dermatology
711 E. Lamar Blvd.
Suite 200
Arlington, TX
United States of America
76011

Sponsor information

Organisation
Janssen-Cilag International NV

Sponsor details
Archimedesweg 29
Leiden
Netherlands
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ClinicalTrialsEU@its.jnj.com

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Janssen Research and Development LLC

Results and Publications

Publication and dissemination plan

1. Peer reviewed scientific journals
2. Internal report
3. Conference presentation
The study's results will be available to the wider scientific community through publication in scientific journals and presentation at scientific meetings. At the end of the study, a plain language summary will be provided to participants. In addition, the results will be published in the EudraCT database in accordance with HRA requirements (a lay summary of the results will be included in the final HRA Report).

Intention to publish date
15/07/2027

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

IPD sharing plan summary
Available on request