

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

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<b>Registration date</b> 19/03/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/10/2025	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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  
High Wycombe  
United Kingdom  
HP12 4DP

+44 800 731 8450 / 10494 567 444  
medinfo@its.jnj.com

## Type(s)

Principal investigator

## Contact name

Dr Andrew Pink

## Contact details

Great Maze Pond  
London  
United Kingdom  
SE1

## Additional identifiers

### Clinical Trials Information System (CTIS)

2024-517814-13

### Integrated Research Application System (IRAS)

1011362

### Protocol serial number

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; surreyboundaries.rec@hra.nhs.uk), ref: 25/LO/0053

### **Study design**

Interventional double blind randomized parallel group cross over controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Safety, Efficacy

### **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

### **Phase**

Phase II

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

dupilumab 300 mg, JNJ-95475939

### **Primary outcome(s)**

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.

### **Key secondary outcome(s))**

Current secondary outcome measures as of 15/09/2025:

#### **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 ( $\geq$ ) 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 $\geq$ 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  $\geq$  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  $\geq$  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-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.

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  $\geq 2$  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  $\geq 2$  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  $\geq 4$ -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  $\geq 4$ -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  $\geq 2$  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  $\geq 2$  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  $\geq 4$ -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 36]

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.

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Previous 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

( $\geq$ ) 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  $\geq$  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  $\geq$  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  $\geq$  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-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.

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  $\geq 2$  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  $\geq 2$  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  $\geq 4$ -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  $\geq 4$ -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  $\geq 2$  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  $\geq 2$  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  $\geq 4$ -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.

**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 ( $\geq$ ) 16 at the screening and baseline visits
3. Validated investigator global assessment for AD (VIGA-AD) score  $\geq$  3 at the screening and baseline visits
4.  $\geq$  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  $\geq$ 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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

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-4R $\alpha$ , 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**

22/09/2025

## **Locations**

**Countries of recruitment**

United Kingdom

Argentina

Brazil

Canada

Germany

Japan

Poland

Spain

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  
United Kingdom  
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  
Curitiba  
Brazil  
80.030-110

**Study participating centre**

**Dermatology Research Institute Inc**  
8500 Blackfoot Trail SE  
Meadows Mile Professional Building Suite 310  
Calgary  
Canada  
T2J 7E1

**Study participating centre**

**Studienzentrum Dr Schwarz Germany**  
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

## **Funder(s)**

**Funder type**  
Industry

**Funder Name**  
Janssen Research and Development LLC

## **Results and Publications**

**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](http://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](http://yoda.yale.edu)

**IPD sharing plan summary**

Available on request