Inclusion/Exclusion Criteria

Inclusion Criteria

Participants are eligible to be included in the study only if all the following criteria apply:

Age

1. Participant must be aged ≥ 18 years at the time of signing the informed consent.

Type of participant and disease characteristics

2. Participant has chronic ATD (according to American Academy of Dermatology Consensus Criteria) that has been present for at least ≥1 year prior to initiating the study (ie, signing of the Informed Consent Form [ICF]) and with:

- **a.** A validated Investigator Global Assessment (vIGA) score ≥3 at screening and baseline
- **b.** An Eczema Area and Severity Index (EASI) score of ≥16 at screening and baseline
- **c.** Peak Pruritus Numerical Rating Scale (PP-NRS) score of ≥4 at screening and baseline

  NOTE: The screening PP-NRS is defined as the worst pruritus in the last 24 hours prior to the assessment. The baseline PP-NRS is defined as the weekly average of daily assessments of the PP-NRS reported continuously for 7 days before and on the baseline (ie, study day –6 to day 1).
- **d.** ≥10% body surface area (BSA) of AtD involvement at screening and baseline

e. Documented recent history (within 6 months prior to screening) of inadequate response to treatment with topical medications, or study participants for whom topical treatments are otherwise medically inadvisable (eg, due to important side effects or safety risks) and who are candidates for systemic therapy. Inadequate response is defined as failure to achieve and maintain remission or low disease remission or a low disease activity state (validated Investigator Global Assessment [vIGA] 0=clear to vIGA 2=mild) despite treatment with a daily regimen of topical corticosteroid (TCS) of medium to higher potency (±TCI as appropriate), applied for at least 4 weeks or for the maximum duration recommended by the product prescribing information (eg, 2 weeks for high-potency TCS), whichever of these is shorter.

Sex and contraceptive/barrier requirements

3. Participants can be male or female.

- A male participant must agree to use contraception as detailed in Appendix 4 of the protocol during the initial intervention period and for at least 60 days after the final dose of study intervention and refrain from donating sperm during this period.
- A female participant is eligible to participate if she is not pregnant (see Appendix 4 of the protocol), not breastfeeding, and at least one of the following conditions applies:
- Not a WOCBP as defined in Appendix 4 of the protocol.

OR

- A WOCBP who agrees to follow the contraceptive guidance in Appendix 4 of the protocol during the initial Intervention Period and Maintenance intervention period and for at least 8 weeks after the final dose of study intervention. Justification for the duration of contraception use following the final dose of study intervention is provided in Appendix 4 of the protocol.

Informed consent

4. Participant is capable of giving signed informed consent as described in Appendix 10 of the protocol, which includes compliance with the requirements and restrictions listed in the ICF and in this protocol. Participants should be willing and able to comply with all clinical visits and study-related procedures and able to understand and complete study-related questionnaires.

Exclusion Criteria

Participants are excluded from the study if any of the following criteria apply:

Medical conditions

1. Participant has any history or presence of any medical or psychiatric condition, physical examination finding, laboratory test result, or ECG signal that, in the opinion of the investigator, could constitute a risk when taking the study intervention; or interfere with the interpretation of data and could jeopardize or would compromise the study participant's ability to participate in this study.

2. History of uncompensated heart failure, fluid overload, or myocardial infarction, or evidence of new onset ischemic heart disease or in the opinion of the Investigator other serious cardiac disease, within 12 months prior to screening.

3. Active dermatologic conditions that may confound the diagnosis of AtD or would interfere with assessment of treatment, such as but not limited to scabies, seborrheic dermatitis, cutaneous lymphoma, ichthyosis, psoriasis, active allergic or irritant contact dermatitis.

4. Presence or family history (first degree) of inflammatory bowel disease (includes Crohn's disease and ulcerative colitis).

5. Uncontrolled neuropsychiatric disorder, active suicidal ideation, or positive suicide behavior (participant with controlled, mild or past depression could be enrolled).

6. Lifetime history of suicide attempt (including an actual attempt, interrupted attempt, or aborted attempt), or has suicidal ideation in the past 6 months as indicated by a positive response ("Yes") to either Question 4 or Question 5 of the Screening/Baseline version of the C-SSRS at baseline.
7. History of chronic or recurrent infections, or a serious or life-threatening infection within the 6 months prior to the baseline (including herpes zoster) as judged by the investigator.
8. Participants are not permitted to enroll into the study if they meet any of the following TB exclusion criteria (see section 10.2.1 of the protocol):
   - Known active TB disease.
   - History of active TB involving any organ system unless adequately treated according to WHO/CDC therapeutic guidance and proven to be fully recovered upon consult with an appropriate relevant specialist.
   - LTBI (unless appropriate treatment is initiated at least 1 week prior to study intervention dosing and will be continued to completion). TB preventive therapy should be in accordance with applicable clinical guidelines and appropriate specialist judgment based on the origin of infection.
   - High risk of acquiring TB infection as described in Section 10.2.1.1.3. of protocol
9. Clinically significant multiple or severe drug allergies, , or severe posttreatment hypersensitivity reactions (including, but not limited to, erythema multiforme major, linear immunoglobulin A dermatosis, toxic epidermal necrolysis, and exfoliative dermatitis).
10. Known hypersensitivity to any excipients of galvokimig.
11. Lymphoma, leukemia, or any malignancy within the past 5 years except for completely treated in situ carcinoma of the cervix, and basal cell or squamous epithelial carcinomas of the skin that have been resected with no evidence of metastatic disease for 3 years.
12. Breast cancer within the past 10 years.
13. Current or chronic history of liver disease. This includes (but is not limited to hepatitis virus infections, drug- or alcohol-related liver disease, nonalcoholic steatohepatitis, autoimmune hepatitis, hemochromatosis, Wilson's disease, α-1 antitrypsin deficiency, primary biliary cholangitis, primary sclerosing cholangitis, or any other liver disease considered clinically significant by the investigator).
14. Known hepatic or biliary abnormalities (except for Gilbert's syndrome or asymptomatic gallstones).

Prior/Concomitant therapy

15. Previous treatment with galvokimig.
16. Participant has relevant safety events to one or more IL-13 biologic response modifiers (ie, dupilumab, tralokinumab and lebrikizumab) that resulted in discontinuation and change of treatment.
17. Phototherapy, tanning bed, laser therapy, or extended sun exposure that could affect disease severity or interfere with disease assessments within 4 weeks of baseline.
18. Systemic therapy (corticosteroids, cyclosporine A or other calcineurin inhibitors, Janus kinase (JAK) inhibitors, mycophenolate mofetil, azathioprine, or methotrexate) within 4 weeks prior to baseline.
19. Topical therapies (except for topical emollient treatments on a stable dose), including but not limited to topical JAK and PDE-4 inhibitors within 4 weeks of baseline.
20. All topical TCS and TCIs within 2 weeks of baseline (see Protocol Section 6.9.2).
21. Live vaccine(s) within 4 weeks prior to screening or plans to receive such vaccines during the study.
22. Bacillus Calmette-Guerin vaccinations within 1 year prior to baseline or is anticipated to do so within 60 days after the final dose of study intervention.
23. Treatment with biologic agents (such as monoclonal antibodies including marketed drugs) within 3 months or 5 half-lives (whichever is longer) prior to Baseline. Treatment with allergen immunotherapy and IFN-γ as described in (see Protocol Table 6–2).

Prior/Concurrent clinical study experience

24. Participant has previously received study intervention in this study.

25. Participant has participated in another study of an investigational medicinal product (IMP) (and/or an investigational device) within the previous 30 days or 5 half-lives of study intervention (whichever is longer) from baseline or is currently participating in another study of an IMP (and/or an investigational device).

Diagnostic assessments

26. Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) >2× upper limit of normal (ULN).

27. Total bilirubin >1.5×ULN (participants with Gilbert's syndrome can be included with total bilirubin >1.5×ULN as long as direct bilirubin is ≤1.5×ULN).

28. QTcF >450msec for male participants or QTcF >470msec for female participants or QTcF >480msec in participants with bundle branch block.The QTcF is the QT interval corrected for heart rate according to Fridericia's formula. It is either machine read or manually overread.

29. Positive human immunodeficiency virus (HIV) antibody test.

30. Presence of HBsAg, hepatitis B core antibody, or positive hepatitis C antibody test result at screening or within 3 months prior to first dose of investigational intervention.

NOTE: Participants with positive hepatitis C antibody test results due to prior resolved disease can be enrolled only if a confirmatory negative hepatitis C ribonucleic acid (RNA) test is obtained.

NOTE: The hepatitis C antibody test is a standard test used at screening to determine eligibility, and hepatitis C RNA testing is optional and only performed when the antibody test is positive to consider participants with positive hepatitis C antibody test for enrollment into the study. Where hepatitis C RNA testing is unavailable, a positive hepatitis C antibody test will be used for exclusion.

31. Participants with concurrent acute or chronic human T-cell lymphotropic virus type-1 (HTLV-1) infection. A positive test for HTLV-1 is defined as a positive result for human T-cell lymphotropic virus type-1 antibodies HTVL-1Ab (HTLV-1Ab+) (Japan only).

Other exclusions

32. History of past (within the last 12 months prior to screening) or current chronic alcohol or drug abuse.

33. Any other condition which, in the Investigator's judgement, would make the participant unsuitable for inclusion in the study.

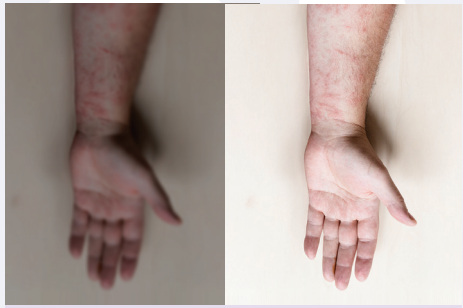
34. Investigator site personnel directly affiliated with this study and/or their immediate families. The immediate family is defined as a spouse, parent, child, or sibling, whether biological or legally adopted.

35. UCB employees or employees of third-party organizations involved in the study.

Digital Photography Guidance

If your site is taking photographs of study participants, follow these tips to increase the quality of the photos taken:

- Tell the participant not to apply creams or ointments to their atopic dermatitis before a study visit where photos will be taken.
- Remove anything extraneous to the area being photographed (clothing, bandages, jewelry, etc).
- Take photos using light settings according to QuantifiCare instructions. Avoid natural light or light sources from behind to ensure the photos are free of shadows.



Left image:
out of focus and too dark;
Right image:
in focus with good lighting.

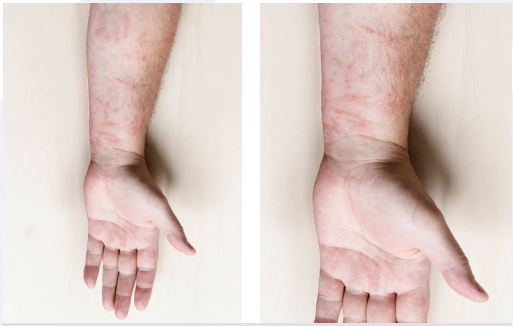
- Maintain camera distance. Do not zoom in or out if using QuantifiCare cameras, as they are preset to take high-quality images at the exact same distance each time. Only include one body part in each photo.
- Try to position the participant in the same manner for each photo.

- Keep the same camera orientation across each visit (depending on anatomical location).

Too many body parts in this photo.

- For better results, take images in front of a neutral, clean (uncluttered) background; for example, a bare wall would work.
- Hold the camera parallel to the area you are photographing and not at an angle.
- Avoid taking a close-up of each patch of atopic dermatitis. If taking a series of photos, use the single preset distance even if taking photos at different angles.
  - QuantifiCare will post-process the images to zoom in and crop any area of interest. This ensures that the result will be of the highest quality.

- Try taking a photo of where the affected skin meets the unaffected skin to indicate how severe the rash is.
- Do not apply any filters to the photos.
- Review each image after taking it to ensure it's of high quality.
- Take multiple images of the same region of interest for backup.



Pictures at different zoom settings

Inspired by patients. Driven by science.

PossibILity