

A Study to Assess Adverse Events and Change in Disease Activity Comparing Oral Upadacitinib to Subcutaneous Dupilumab in Children From 2 to Less Than 12 Years of Age With Moderate to Severe Atopic Dermatitis

NCT06461897

Status	RECRUITING
Phase	Phase 3
Sponsor	AbbVie
Enrollment	675 participants

Key Eligibility Criteria

Inclusion (12)

- A minimum weight of 10 kg and weight and height \geq 5th percentile for their age according to local standard growth charts at the Baseline Visit.
 - Atopic Dermatitis (AD), according to Hanifin and Rajka criteria, with onset of symptoms at least 6 months prior to Baseline.
 - Eczema Area and Severity Index (EASI) score \geq 16; vIGA-AD score \geq 3 (Note: In countries where dupilumab is only approved for severe AD, subjects to be included in the Randomized Cohort should have severe AD [vIGA-AD = 4]); \geq 10% Body Surface Area of AD involvement at the Baseline Visit; and Baseline weekly average of daily Worst Itch Scale (WIS) or Worst Scratch/Itch numerical rating scale (WSI-NRS) \geq 4.
 - Participant must satisfy at least one of the following criteria (Note: More than 1 criterion may apply to an individual participant. All applicable criteria for each individual participant should be reported):
 - To be included in the Randomized Cohort (Note: Participants must have severe AD [vIGA-AD = 4] in countries where dupilumab is approved only for severe AD.):
- ... and 7 more (see full listing online)

Exclusion (8)

- Current or past history of other active skin diseases (e.g., psoriasis or Netherton syndrome or lupus erythematosus) or skin infections (bacterial, fungal, or viral) requiring systemic treatment within 4 weeks of the Baseline Visit or which would interfere with the appropriate assessment of AD lesions.
 - Have used topical treatments for AD (except for topical emollient treatments) including but not limited to TCS, TCI, or topical phosphodiesterase type 4 (PDE-4) inhibitors, within 7 days of the Baseline Visit or any the following prohibited concomitant AD treatments within the specified timeframes below prior to the Baseline Visit:
 - Systemic therapy for AD, including but not limited to corticosteroids, methotrexate, cyclosporine, azathioprine, PDE-4 inhibitors, interferon- γ , and mycophenolate mofetil within 4 weeks;
 - Dupilumab within 8 weeks;
 - Targeted biologic treatments (other than dupilumab) within 5 half-lives (if known) or within 12 weeks, whichever is longer;
- ... and 3 more (see full listing online)

Locations (148 total)

Applied Research Center Of Arkansas /ID# 268547, Little Rock, Arkansas, United States
Stanford University School of Medicine - Palo Alto /ID# 269622, Palo Alto, California, United States
Integrative Skin Science and Research /ID# 265108, Sacramento, California, United States
... and 145 more locations

<https://clinicaltrials.gov/study/NCT06461897>

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