

Open Label, Long-term Study Evaluating Safety and Efficacy of Subcutaneous Amltelimab in Participants Aged 12 Years and Older With Moderate to Severe Atopic Dermatitis

NCT05769777

Status	RECRUITING
Phase	Phase 2
Sponsor	Sanofi
Enrollment	901 participants

Key Eligibility Criteria

Inclusion (10)

- Participant must be at least 12 years of age inclusive, at the time of signing the informed consent.
 - Participants must have AD as defined by the American Academy of Dermatology Consensus Criteria for 1 year or longer at baseline.
 - Participant must have documented history (within 6 months prior to screening visit), of inadequate response (including inadequate efficacy or medical inadvisability) to topical treatments and/or inadequate response to systemic therapies (within 12 months prior to screening visit).
 - Eczema Area Severity Index (EASI) of 16 or higher at baseline visit/Visit 2.
 - Validated Investigator Global Assessment scale for atopic dermatitis (vIGA-AD) of 3 or 4 at baseline visit/Visit 2.
- ... and 5 more (see full listing online)

Exclusion (16)

- Skin co-morbidity that would adversely affect the ability to undertake AD assessments as per investigator's judgement
 - Known history of or suspected significant current immunosuppression, including history of invasive opportunistic or helminthic infections despite infection resolution or otherwise recurrent infections of abnormal frequency or prolonged duration.
 - Any malignancies or history of malignancies prior to baseline (except for non-melanoma skin cancer that has been excised and completely cured for more than 5 years prior to baseline).
 - History of solid organ or stem cell transplant.
 - Any pre-planned major elective surgery known about at baseline that in the opinion of the investigator would necessitate that IMP be permanently discontinued or require more than three doses to be missed.
- ... and 11 more (see full listing online)

Locations (175 total)

Allervie Clinical Research - Birmingham- Site Number : 8400050, Birmingham, Alabama, United States
Research Solutions of Arizona- Site Number : 8400020, Litchfield Park, Arizona, United States
Dermatology Trial Associates- Site Number : 8400027, Bryant, Arkansas, United States
... and 172 more locations

<https://clinicaltrials.gov/study/NCT05769777>

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