ForPatients
by Roche

Atopic DermatitisAutoimmune Disorder

A study to look at the effects of a new medicine (astegolimab) in comparison to placebo - in patients with eczema (atopic dermatitis)

A Study to Assess the Efficacy and Safety of MSTT1041A in Participants With Moderate to Severe Atopic Dermatitis

Trial Status	Trial Runs In	Trial Identifier
Completed	3 Countries	NCT03747575 2018-003429-27 GS40965

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase II, Randomized, Double-Blind, Placebo-Controlled Multicenter Study to Assess the Efficacy and Safety of MSTT1041A in Patients With Moderate to Severe Atopic Dermatitis

Trial Summary:

This study will assess the efficacy and safety of MSTT1041A (astegolimab) in participants with moderate to severe atopic dermatitis (AD). The study consists of a screening period, a 16-week treatment period, and an 8-week follow-up period.

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT03747575 2018-003429-27 GS40965
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years & # 75 Years	No

This clinical trial was done to study a new medicine called, “astegolimab”, for the treatment of patients with “eczema (atopic dermatitis)”. This study was done to find out if astegolimab – a new medicine – was effective for treating patients with a certain type of eczema (atopic dermatitis). Sixty-five patients took part in this study at 21 study centers in 3 countries.

Inclusion Criteria:

- Ability to comply with the study protocol
- Chronic AD that has been present for at least 3 years before the screening visit
- Documented recent history (within 6 months before the screening visit) of inadequate response to treatment with topical medications (medications or treatments applied directly to part of the body) or for whom topical treatments are otherwise medically inadvisable

Exclusion Criteria:

- Prior treatment with MSTT1041A
- Treatment with any investigational therapy (with the exception of biologics) within 8 weeks or within 5 half-lives whichever is longer, before screening
- Treatment with any cell-depleting agents within 6 months before screening, or until lymphocyte count returns to normal, whichever is longer
- Treatment with other biologics within 3 months or 5 half-lives before screening, whichever is longer
- Comorbid conditions that may interfere with evaluation of investigational medicinal product
- History or evidence of substance abuse that would pose a risk to participant safety, interfere with the conduct of the study, have an impact on the study results, or affect the participant's ability to participate in the study
- History of anaphylaxis, hypersensitivity to a biologic agent, or known hypersensitivity to any component of the MSTT1041A or placebo injection
- Planned surgical intervention during the course of the study
- Pregnant or breastfeeding, or intending to become pregnant during the study
- Participant who is a member of the investigational team or his/her immediate family