ForPatients
by Roche

Atopic DermatitisAutoimmunerkrankung

Eine Studie zur Beurteilung der Wirksamkeit und Sicherheit von MSTT1041A bei Teilnehmenden mit mittelschwerer bis schwerer atopischer 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
Abgeschlossen	3 Countries	NCT03747575 2018-003429-27 GS40965

Die Informationen stammen direkt von Websites öffentlicher Register wie ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com usw. und wurden nicht modifiziert.

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

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