## KURZPROTOKOLL LP0162-1337

Öffentlicher Titel

Phase III Studie zur Langzeit-Sicherheit von Tralokinumab bei Neurodermitis

Wissenschaftl. Titel

An open-label, single-arm, multi-centre, long-term extension trial to evaluate the safety and efficacy of tralokinumab in subjects with atopic dermatitis who participated in previous tralokinumab clinical trials

Kurztitel

LP0162-1337

**Studienart** 

multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig

Studienphase

Phase III

**Erkrankung** 

Haut: Ekzem (Dermatitis): Neurodermitis (Atopische Dermatitis)

Einschlusskriterien

- Completed the treatment period(s) of one of the parent trials
- Complied with the clinical trial protocol in the parent trial to the satisfaction of the investigator
- Able and willing to self-administer tralokinumab treatment (or have it administered by a caregiver) at home after the initial 3 injection visits at the trial site (in this trial)
- Stable dose of emollient twice daily (or more, as needed) for at least 14 days before baseline

**Ausschlusskriterien** 

- Any condition that required permanent discontinuation of trial treatment in the parent
- More than 26 weeks have elapsed since the subject received the last injection of investigational medicinal product (IMP) in the parent trial (to be assessed at baseline)
- Subjects who, during their participation in the parent trial, developed a serious adverse event (SAE) deemed related to tralokinumab by the investigator, which in the opinion of the investigator could indicate that continued treatment with tralokinumab may present an unreasonable safety risk for the subject
- Subjects who, during their participation in the parent trial, developed an AE that was deemed related to tralokinumab by the investigator and led to temporary discontinuation of trial treatment, which in the opinion of the investigator could indicate that continued treatment with tralokinumab may present an unreasonable safety risk for the subject
- Treatment with systemic immunosuppressive/immunomodulating drugs and/or systemic corticosteroid within 4 weeks prior to baseline
- Treatment with topical phosphodiesterase 4 inhibitors or topical JAK inhibitors within 2 weeks prior to baseline
- Clinically significant infection within 4 weeks prior to baseline
- A helminth parasitic infection within 6 months prior to the date when informed consent is obtained
- Tuberculosis requiring treatment within 12 months prior to screening
- Known primary immunodeficiency disorder

Alter

12 Jahre und älter

Prüfzentren

Klinik für Dermatologie, Venerologie und Allergologie (Geschlossen)

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**Sponsor** 

Leo Pharma GmbH

Registrierung in anderen Studienregistern

ClinicalTrials.gov NCT03587805 (primäres Register)

EudraCT 2018-000746-19