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 trial - 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) Theodor-Stern-Kai 7 60590 Frankfurt am Main Dr. med. Andreas Pinter Tel: 069 6301-83115 Fax: 069 6301-83175 andreas.pinter@unimedizin-ffm.de
Sponsor	Leo Pharma GmbH
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03587805 (primäres Register) EudraCT 2018-000746-19