KURZPROTOKOLL
ADvocate2

Öffentlicher Titel	Phase III Studie zu Lebrikizumab bei mittelschwerer bis schwerer Neurodermitis
Wissenschaftl. Titel	A Randomized, Double-Blind, Placebo-Controlled Trial To Evaluate The Efficacy and Safety Of Lebrikizumab in Patients With Moderate-To-Severe Atopic Dermatitis
Kurztitel	ADvocate2
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, doppelblind, mehrarmig
Studienphase	Phase III
Erkrankung	Haut: Ekzem (Dermatitis): Neurodermitis (Atopische Dermatitis) Kinder: Hauterkrankungen
Einschlusskriterien	- Male or female adults and adolescents (>=12 years and >=40 kg) - Chronic atopic dermatitis (according to American Academy of Dermatology Consensus Criteria) that has been present for >=1 year before the screening visit - Eczema Area and Severity Index (EASI) score >=16 at the baseline visit - Investigator Global Assessment (IGA) score >=3 (scale of 0 to 4) at the baseline visit - >=10% body surface area (BSA) of atopic dermatitis involvement at the baseline visit - History of inadequate response to treatment with topical medications; or determination that topical treatments are otherwise medically inadvisable
Ausschlusskriterien	- Prior treatment with dupilumab or tralokinumab - Treatment with topical corticosteroids, calcineurin inhibitors or phosphodiesterase-4 inhibitors such as crisaborole within 1 week prior to the baseline visit - Treatment with any of the following agents within 4 weeks prior to the baseline visit: Immunosuppressive/immunomodulating drugs (e.g., systemic corticosteroids, cyclosporine, mycophenolate-mofetil, IFN-, Janus kinase inhibitors, azathioprine, methotrexate, etc.) Phototherapy and photochemotherapy (PUVA) for AD - Treatment with the following prior to the baseline visit: An investigational drug within 8 weeks or within 5 half-lives (if known) of baseline, whichever is longer Cell-depleting biologics, including to rituximab, within 6 months of baseline Other biologics within 5 half-lives (if known) or 16 weeks of baseline, whichever is longer - Treatment with a live (attenuated) vaccine within 12 weeks of the baseline visit or planned during the study - Uncontrolled chronic disease that might require bursts of oral corticosteroids, e.g., co-morbid severe uncontrolled asthma - Evidence of active acute or chronic hepatitis - History of human immunodeficiency virus (HIV) infection or positive HIV serology - History of malignancy, including mycosis fungoides, within 5 years before the screening visit, except completely treated in situ carcinoma of the cervix, completely treated and resolved non-metastatic squamous or basal cell carcinoma of the skin - Pregnant or breastfeeding women, or women planning to become pregnant or breastfeed during the study
Alter	12 Jahre und älter
Prüfzentren	**Klinik für Dermatologie, Venerologie und Allergologie** (Rekrutierung beendet) 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	Eli Lilly and Company
Registrierung in anderen Studienregistern	EudraCT 2019-002933-12 ClinicalTrials.gov NCT04178967 (primäres Register)