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
Sponsor	Eli Lilly and Company
Registrierung in anderen Studienregistern	EudraCT 2019-002933-12 ClinicalTrials.gov NCT04178967 (primäres Register)