

## **KURZPROTOKOLL** **ADvocate2**

<b>Öffentlicher Titel</b>	Phase III Studie zu Lebrikizumab bei mittelschwerer bis schwerer Neurodermitis
<b>Wissenschaftl. Titel</b>	A Randomized, Double-Blind, Placebo-Controlled Trial To Evaluate The Efficacy and Safety Of Lebrikizumab in Patients With Moderate-To-Severe Atopic Dermatitis
<b>Kurztitel</b>	ADvocate2
<b>Studienart</b>	multizentrisch, prospektiv, Therapiestudie, randomisiert, doppelblind, mehrarmig
<b>Studienphase</b>	Phase III
<b>Erkrankung</b>	Haut: Ekzem (Dermatitis): Neurodermitis (Atopische Dermatitis) Kinder: Hauterkrankungen
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Male or female adults and adolescents (<math>\geq 12</math> years and <math>\geq 40</math> kg)</li><li>- Chronic atopic dermatitis (according to American Academy of Dermatology Consensus Criteria) that has been present for <math>\geq 1</math> year before the screening visit</li><li>- Eczema Area and Severity Index (EASI) score <math>\geq 16</math> at the baseline visit</li><li>- Investigator Global Assessment (IGA) score <math>\geq 3</math> (scale of 0 to 4) at the baseline visit</li><li>- <math>\geq 10\%</math> body surface area (BSA) of atopic dermatitis involvement at the baseline visit</li><li>- History of inadequate response to treatment with topical medications; or determination that topical treatments are otherwise medically inadvisable</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Prior treatment with dupilumab or tralokinumab</li><li>- Treatment with topical corticosteroids, calcineurin inhibitors or phosphodiesterase-4 inhibitors such as crisaborole within 1 week prior to the baseline visit</li><li>- 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</li><li>- 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</li><li>- Treatment with a live (attenuated) vaccine within 12 weeks of the baseline visit or planned during the study</li><li>- Uncontrolled chronic disease that might require bursts of oral corticosteroids, e.g., co-morbid severe uncontrolled asthma</li><li>- Evidence of active acute or chronic hepatitis</li><li>- History of human immunodeficiency virus (HIV) infection or positive HIV serology</li><li>- 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</li><li>- Pregnant or breastfeeding women, or women planning to become pregnant or breastfeed during the study</li></ul>
<b>Alter</b>	12 Jahre und älter
<b>Prüfzentren</b>	<b>Klinik für Dermatologie, Venerologie und Allergologie</b> (Rekrutierung beendet) Theodor-Stern-Kai 7 60590 Frankfurt am Main Dr. med. Andreas Pinter Tel: 069 6301-83115 Fax: 069 6301-83175 <a href="mailto:andreas.pinter@unimedizin-ffm.de">andreas.pinter@unimedizin-ffm.de</a>
<b>Sponsor</b>	Eli Lilly and Company
<b>Registrierung in anderen Studienregistern</b>	EudraCT 2019-002933-12 ClinicalTrials.gov NCT04178967 (primäres Register)