

## **KURZPROTOKOLL** **R668-AD-1924**

<b>Öffentlicher Titel</b>	Phase III Studie zu Dupilumab bei moderater bis schwerer atopischer Hand und Fuß Dermatitis
<b>Wissenschaftl. Titel</b>	A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel- Group Study to Evaluate the Efficacy and Safety of Dupilumab in Adult and Adolescent Patients With Moderate-to-Severe Atopic Hand and Foot Dermatitis
<b>Kurztitel</b>	R668-AD-1924
<b>Studienart</b>	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, zweiarmig
<b>Studienphase</b>	Phase III
<b>Erkrankung</b>	Haut: Ekzem (Dermatitis): Neurodermitis (Atopische Dermatitis) Haut: sonstige
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Patients with involvement of at least 2 anatomical areas at screening and baseline</li><li>- Patients need to have an IGA hand and foot score of 3 or 4 (moderate-to-severe disease) at screening and baseline</li><li>- Patients with documented recent history (within 6 months before the screening visit) of inadequate response of atopic hand and foot dermatitis to topical medication(s)</li><li>- Patients meet the diagnosis criteria for atopic dermatitis (AD)</li><li>- Provide informed consent/assent signed by study patient or legally acceptable representative</li><li>- Patients need to have been compliant with the skin protection measures through the entire duration of the screening period</li><li>- NOTE: Other protocol defined inclusion criteria apply</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Treatment with dupilumab in the past</li><li>- Patients with a positive patch test reaction that are deemed to be clinically relevant as the current cause of the hand and foot dermatitis</li><li>- Patients with documented exposure to irritants believed to be a predominant cause of the current hand and foot dermatitis</li><li>- Treatment with systemic corticosteroids or non-steroidal immunosuppressive drugs within 4 weeks prior to baseline</li><li>- Known history of HIV/HBV/HCV infection</li><li>- Pregnant or breastfeeding women or planning to become pregnant or breastfeed during the patient's participation in this study</li><li>- Women of childbearing potential (WOCBP) who are unwilling to practice highly effective contraception prior to the initial dose/start of the first treatment and during the study</li><li>- NOTE: Other protocol defined exclusion criteria apply</li></ul>
<b>Alter</b>	12 - 17 Jahre
<b>Sponsor</b>	Regeneron
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT04417894 EudraCT 2019-003088-22 (primäres Register)