KURZPROTOKOLL
R668-AD-1924

Öffentlicher Titel	Phase III Studie zu Dupilumab bei moderater bis schwerer atopischer Hand und Fuß Dermatitis
Wissenschaftl. Titel	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
Kurztitel	R668-AD-1924
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Haut: Ekzem (Dermatitis): Neurodermitis (Atopische Dermatitis) Haut: sonstige
Einschlusskriterien	- Patients with involvement of at least 2 anatomical areas at screening and baseline - Patients need to have an IGA hand and foot score of 3 or 4 (moderate-to-severe disease) at screening and baseline - 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) - Patients meet the diagnosis criteria for atopic dermatitis (AD) - Provide informed consent/assent signed by study patient or legally acceptable representative - Patients need to have been compliant with the skin protection measures through the entire duration of the screening period - NOTE: Other protocol defined inclusion criteria apply
Ausschlusskriterien	- Treatment with dupilumab in the past - Patients with a positive patch test reaction that are deemed to be clinically relevant as the current cause of the hand and foot dermatitis - Patients with documented exposure to irritants believed to be a predominant cause of the current hand and foot dermatitis - Treatment with systemic corticosteroids or non-steroidal immunosuppressive drugs within 4 weeks prior to baseline - Known history of HIV/HBV/HCV infection - Pregnant or breastfeeding women or planning to become pregnant or breastfeed during the patient's participation in this study - 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 - NOTE: Other protocol defined exclusion criteria apply
Alter	12 - 17 Jahre
Prüfzentren	**Klinik für Dermatologie, Venerologie und Allergologie** (Nachbeobachtung) Theodor-Stern-Kai 7 60590 Frankfurt am Main Karina Tamm
Sponsor	Regeneron
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT04417894 EudraCT 2019-003088-22 (primäres Register)