KURZPROTOKOLL
RD.06.SPR.118169

Öffentlicher Titel	Phase III Studie zu Nemolizumab bei moderater bis schwerer Neurodermitis
Wissenschaftl. Titel	A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of Nemolizumab (CD14152) in Subjects with Moderate-to-Severe Atopic Dermatitis
Kurztitel	RD.06.SPR.118169
Studienart	prospektiv, Therapiestudie, randomisiert, doppelblind, mehrarmig
Studienphase	Phase III
Erkrankung	Haut: Ekzem (Dermatitis): Neurodermitis (Atopische Dermatitis)
Einschlusskriterien	- Male or female subjects aged >= 12 years at the screening visit Note: Enrollment of subjects aged 12 to 17 years will begin after an IDMC has assessed interim safety data from the phase 2 study (Protocol 116912) and provided recommendations to the sponsor, who will then determine the eligibility of this age group for enrollment in the study - Chronic AD that has been documented for at least 2 years - EASI score >= 16 - IGA score >= 3 - AD involvement >= 10% of BSA - Documented recent history of inadequate response to topical medications (TCS with or without TCI) - Female subjects of childbearing potential must agree either to be strictly abstinent throughout the study and for 12 weeks after the last study drug injection, or to use an effective and approved method of contraception throughout the study and for 12 weeks after the last study drug injection, or to use an effective and approved method of contraception throughout the study and for 12 weeks after the last study drug injection
Ausschlusskriterien	- Body weight < 30 kg - Pregnant women, breastfeeding women, or women planning a pregnancy during the clinical study - Cutaneous infection within 1 week or any infection requiring treatment with oral or parenteral antibiotics, antivirals, antiparasitics, or antifungals within 1 week - History of hypersensitivity (including anaphylaxis) to an immunoglobulin product (plasma-derived or recombinant, eg, monoclonal antibody) - Any clinically significant issue, based investigator judgement
Alter	12 Jahre und älter
Prüfzentren	**Universitätsklinikum Frankfurt** (Nachbeobachtung) Klinik für Dermatologie, Venerologie und Allergologie 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	Galderma
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03985943 (primäres Register) EudraCT 2019-001888-75