KURZPROTOKOLL
NB-NM026-2198-101

Öffentlicher Titel	Phase I Studie zu NM26-2198 bei Neurodermitis
Wissenschaftl. Titel	A randomized, Double-blind, Placebo-controlled, Single-and Muliple-ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, Pharmacodynamics and Exploratory Clinical Activity of NM26-2198 in Healthy Japanese and Non-Asian Volunteers and in Adult Patients with Atopic Dermatitis
Kurztitel	NB-NM026-2198-101
Studienphase	Phase I
Erkrankung	Haut: Ekzem (Dermatitis): Neurodermitis (Atopische Dermatitis)
Einschlusskriterien	- SAD: Non-Asian ethnicity with grandparents and parents of non-Asian descent or Japanese descent having all four Japanese grandparents born in Japan - SAD: Male or female aged 18 to 55 years; MAD: Male or female >=18 years of age - Weight of 45 kg to 100 kg and BMI of 18.0 to 30.0 kg/m2 - SAD: Non-childbearing, non-breastfeeding females or males willing to use double barrier contraception or abstention from sex and sperm donation during the study; MAD: Males willing to use double barrier contraception or abstention from sex and sperm donation during the study; non-childbearing females or females of childbearing potential using protocol-defined method contraception, and who is not pregnant, lactating, or breastfeeding - MAD: Diagnosis of chronic AD - MAD: EASI score >=16 - MAD: vIGA-AD™ score of >=3 - MAD: Atopic lesions cover >=10% of body surface area (BSA) - MAD: PP-NRS score >=4 - MAD: Daily use of non-prescription emollient
Ausschlusskriterien	- SAD: Any clinically-relevant medical history or lab abnormality, including positive test for SARS-CoV-2, Hepatitis B or C, or HIV; MAD: Clinically-significant, abnormal laboratory findings, or positive test for SARS-CoV-2, Hepatitis B or C, or HIV - Clinically important ECG abnormalities or history/evidence thereof - SAD: Use of prescription or non-prescription medications (except occasional use of paracetamol) - MAD: Diagnosis of protocol-specified skin diseases other than AD, or history of other significant skin condition that could interfere with study assessments - MAD: History or ongoing allergy/hypersensitivity or history, or history of hypersensitivity to biological drugs - MAD: Recent receipt of immunoglobulin or blood products - MAD: Recent treatment with protocol-specified investigational treatments, or any prior treatment with dupilumab, tralokinumab, lebrikizumab, nemolizumab, or other protocol-specified drugs - MAD: AD with recent ocular involvement requiring chronic ocular corticosteroid treatment - MAD: Chronic pruritis due to conditions other than AD - MAD: Acute AD superinfection, recent superficial skin infection, or other chronic/acute infection requiring protocol-defined treatments - MAD: Recent use of sedating antihistimines, systemic corticosteroids, cytotoxic treatments, other immunosuppressive/immunomodulating agents, and other protocol-specified prohibited medications - MAD: Recent topical corticosteroid or prescription moisturizer use
Alter	18 Jahre und älter

Prüfzentren	**Klinik für Dermatologie, Venerologie und Allergologie** (Geschlossen) Theodor-Stern-Kai 7 60590 Frankfurt am Main T. O'Connor
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT05859724 EudraCT 2023-503577-38
Links	Zu den EIn- und Ausschlusskriterien