KURZPROTOKOLL
CDX0159-04

Öffentlicher Titel	Phase I Studie zu CDX-0159 bei Prurigo nodularis
Wissenschaftl. Titel	A Randomized, Double-Blind, Placebo-Controlled, Phase 1 Single and Multiple Dose Study to Assess the Safety, Pharmacokinetics, and Clinical Effect of CDX-0159 in Patients with Prurigo Nodularis
Kurztitel	CDX0159-04
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, mehrarmig
Studienphase	Phase I
Erkrankung	Haut: sonstige
Einschlusskriterien	- Males and females, 18 - 75 years old - Diagnosis of Prurigo Nodularis by a dermatologist at least 3 months prior to Screening with: (a) At least 20 PN nodules with bilateral distribution on both arms and/or both legs and/or both sides of the trunk at screening.(b) An Investigators Global Assessment (IGA) score for PN >= 3 at screening and Baseline (Day 1) - Severe itch, defined as the mean of the daily worst itch NRS (WI-NRS) score of >= 7 during the 7-day period immediately prior to initiation of study treatment - Documented history of inadequate response to prescription topical medications or for whom topical medications are medically inadvisable - Willing to apply a topical moisturizer (emollient) twice daily throughout the study - Both males and females of child-bearing potential must agree to use highly effective contraceptives during the study and for 150 days afterwards after treatment - Willing and able to complete a daily symptom electronic diary for the duration of the study and adhere to the study visit schedule
Ausschlusskriterien	- PN due to neuropathy, psychiatric disorders or medications - Unilateral lesions of prurigo (eg, only one arm affected) - Active unstable pruritic skin conditions in addition to PN - Women who are pregnant or nursing - Known hepatitis B or hepatitis C infection or active COVID-19 infection - Vaccination with a live vaccine within 2 months prior to study drug administration (subjects must agree to avoid vaccination during the study and for four months thereafter). NOTE: Inactivated vaccines are allowed such as seasonal influenza for injection. COVID-19 vaccination is allowed - History of anaphylaxis
Alter	18 - 75 Jahre
Prüfzentren	**Klinik für Dermatologie, Venerologie und Allergologie** (Nachbeobachtung) Theodor-Stern-Kai 7 60590 Frankfurt am Main Daniela Hoffmann
Sponsor	Celldex
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT04944862 EudraCT 2021-002852-36 (primäres Register)