

**KURZPROTOKOLL**  
**CDX0159-04**

<b>Öffentlicher Titel</b>	Phase I Studie zu CDX-0159 bei Prurigo nodularis
<b>Wissenschaftl. Titel</b>	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
<b>Kurztitel</b>	CDX0159-04
<b>Studienart</b>	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, mehrarmig
<b>Studienphase</b>	Phase I
<b>Erkrankung</b>	Haut: sonstige
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Males and females, 18 - 75 years old</li><li>- 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 <math>\geq</math> 3 at screening and Baseline (Day 1)</li><li>- Severe itch, defined as the mean of the daily worst itch NRS (WI-NRS) score of <math>\geq</math> 7 during the 7-day period immediately prior to initiation of study treatment</li><li>- Documented history of inadequate response to prescription topical medications or for whom topical medications are medically inadvisable</li><li>- Willing to apply a topical moisturizer (emollient) twice daily throughout the study</li><li>- 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</li><li>- Willing and able to complete a daily symptom electronic diary for the duration of the study and adhere to the study visit schedule</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- PN due to neuropathy, psychiatric disorders or medications</li><li>- Unilateral lesions of prurigo (eg, only one arm affected)</li><li>- Active unstable pruritic skin conditions in addition to PN</li><li>- Women who are pregnant or nursing</li><li>- Known hepatitis B or hepatitis C infection or active COVID-19 infection</li><li>- 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</li><li>- History of anaphylaxis</li></ul>
<b>Alter</b>	18 - 75 Jahre
<b>Prüfzentren</b>	<b>Klinik für Dermatologie, Venerologie und Allergologie</b> (Nachbeobachtung) Theodor-Stern-Kai 7 60590 Frankfurt am Main Daniela Hoffmann
<b>Sponsor</b>	Celldex
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT04944862 EudraCT 2021-002852-36 (primäres Register)