ForPatients
by Roche

Prurigo nodularis

Study to Assess the Efficacy, Safety, and Tolerability of Vixarelimab in Reducing Pruritus in Prurigo Nodularis

Trial Status	Trial Runs In	Trial Identifier
Completed	13 Countries	NCT03816891 GS45044 KPL-716-C201

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase 2a/b, Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy, Safety, Tolerability and Pharmacokinetics of KPL-716 in Reducing Pruritus in Subjects With Prurigo Nodularis

Trial Summary:

Study of the efficacy, safety, tolerability, pharmacokinetics (PK), and immunogenicity of Vixarelimab (KPL-716) in subjects with prurigo nodularis (PN).

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT03816891 GS45044 KPL-716-C201
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 80 Years	No

Inclusion Criteria:

Inclusion Criteria (apply to both Phase 2a and Phase 2b unless otherwise specified):

- Male or female aged 18 to 75 years (Phase 2a), 18 to 80 years (Phase 2b)
- Have clinical diagnosis of prurigo nodularis for at least 6 months
- Have at least 10 nodules (Phase 2a), 20 nodules (Phase 2b) at the Screening Visit and Day 1
- Moderate to severe pruritus (Phase 2a); severe pruritus (Phase 2b)

- Female subjects of childbearing potential must have a negative pregnancy test, be nonlactating, and having agreed to use a highly effective method of contraception, as specified in the protocol, from the Screening Visit until 16 weeks after final study drug administration
- Able to comprehend and willing to sign an Informed Consent Form and able to abide by the study restrictions and comply with all study procedures for the duration of the study

Exclusion Criteria:

Exclusion Criteria (apply to both Phase 2a and Phase 2b unless otherwise specified):

- Use of prohibited medications within the indicated timeframe from Day 1
- Is currently using medication known to cause pruritus
- Presence of any inflammatory, pruritic, and/or fibrotic skin condition other than moderate to severe prurigo nodularis or atopic dermatitis unless approved by the Sponsor
- Laboratory abnormalities that fall outside the windows specified in the protocol at the Screening Visit
- Has an active infection, including skin infection
- Any medical or psychiatric condition which, in the opinion of the Investigator or the Sponsor, may place the subject at increased risk as a result of study participation, interfere with study participation or study assessments, affect compliance with study requirements, or complicate interpretation of study results