Chronic Inducible Urticaria (CINDU)

A Phase 3 Study of Efficacy and Safety of Ligelizumab in Adolescents and Adults With Chronic Inducible Urticaria Who Remain Symptomatic Despite Treatment With H1- Antihistamines (PEARL-PROVOKE)

Sponsor: Novartis

Trial Link: https://clinicaltrials.gov/ct2/show/NCT05024058

Medication: Ligelizumab or placebo

Participants who complete the study prior to the investigational treatment becoming available may receive post-trial access.

Dosing: Subcutaneous injection dosing every 4 weeks

Age: ≥ 12

Gender: All

Compensation: $60 per visit

Duration: 40 weeks. There will be monthly visits in total for the entire duration of the trial.

About Ligelizumab: Ligelizumab is a humanized, IgG1-subtype monoclonal antibody, which is a highly potent inhibitor of human IgE. Participants will continue their background H1-AH (at local-approved doses) with a stable regimen during the study.

INCLUSIONS	EXCLUSIONS
☐ Confirmed CINDU diagnosis ≥ 4 months (symptomatic dermographism, cold urticaria or cholinergic urticaria) with documented evidence (e.g., medical history, photos) ☐ Inadequately controlled with H1-AH at local label approved doses (positive response to triggers/provocation despite H1-AH)	☐ Participants who have concomitant CSU ☐ Participants who have a familial form (e.g familial cold autoinflammatory syndrome, familial cold urticaria) to the target CINDU ☐ Participants with a different and more defined form of inducible urticaria other than the target CINDU ☐ Any other skin disease associated with chronic itching that might influence the study evaluations or diseases with urticaria or angioedema symptoms. ☐ Prior exposure to **ligelizumab**, **omalizumab** or other **anti-IgE therapies**. ☐ Documented history of anaphylaxis ☐ History of HIV, chronic hepatitis B virus (HBV) infection and/or hepatitis C virus (HCV) infection. ☐ Malignancy of any organ system within the past 5 years ☐ Clinically significant cardiovascular neurological, psychiatric, metabolic or other pathological conditions