



# Study of Efficacy and Safety of Ligelizumab in Adolescents and Adults With Chronic Inducible Urticaria Who Remain Symptomatic Despite Treatment With H1- Antihistamines

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## Main Information

### Primary registry identifying number

LBCTR2022014919

### Protocol number

CQGE031E12301

### MOH registration number

### Study registered at the country of origin

Yes

### Study registered at the country of origin: Specify

### Type of registration

Prospective

### Type of registration: Justify

N/A

### Date of registration in national regulatory agency

### Primary sponsor

Novartis Pharmaceuticals

### Primary sponsor: Country of origin

Novartis Pharmaceuticals

### Date of registration in primary registry

11/04/2022

### Date of registration in national regulatory agency

### Public title

Study of Efficacy and Safety of Ligelizumab in Adolescents and Adults With Chronic Inducible Urticaria Who Remain Symptomatic Despite Treatment With H1- Antihistamines

### Acronym

PEARL-PROVOKE

### Scientific title

A Multi-center, Randomized, Double-blind, Placebo Controlled Study to Investigate the Efficacy and Safety of Ligelizumab (QGE031) in the Treatment of Chronic Inducible Urticaria (CINDU) in Adolescents and Adults Inadequately Controlled With H1-antihistamines

### Acronym

### Brief summary of the study: English

This is a placebo controlled, phase 3 study designed to evaluate the efficacy and safety of ligelizumab in participants with chronic inducible urticaria who are inadequately controlled with H1-antihistamines

### Brief summary of the study: Arabic

دراسة متعددة المراكز، عشوائية التوزيع، مزدوجة التعمية، مركزة على المقارنة بدواء وهمي للبحث في فعالية وسلامة في علاج الشرى المزمن المحرض لدى مراهقين وبالغين حالتهم غير مضبوطة بشكل كافٍ بواسطة مضادات (QGE031) ليجليزوماب H1 الهيستامين

### Health conditions/problem studied: Specify

Chronic Inducible Urticaria

### Interventions: Specify

Drug: Ligelizumab

- Ligelizumab treated groups and arms
- Other Name: QGE031





Other: Placebo  
- Placebo treated groups and arms

**Key inclusion and exclusion criteria: Inclusion criteria**

Confirmed CINDU diagnosis (as per guidelines) for symptomatic dermatographism, cold urticaria or cholinergic urticaria for  $\geq 4$  months.

Diagnosis of CINDU (symptomatic dermatographism, cold urticaria or cholinergic urticaria) inadequately controlled with H1-AH at local label approved doses at the time of randomization, as defined by all of the following:

Positive response (i.e. development of symptoms) to triggers despite treatment with H1-AH

Positive response (i.e. development of symptoms) to provocation test on day of randomization

Participants must be able to physically perform the protocol defined provocation test specific to the participant's CINDU.

Cholinergic urticaria participants must show sweating in performing the pulse-controlled ergometry test on day of randomization. Participants with anhidrosis must not be included.

Willing and able to complete a daily symptom eDiary as per protocol requirement and adhere to the study visit schedules

**Key inclusion and exclusion criteria: Gender**

Both

**Key inclusion and exclusion criteria: Specify gender****Key inclusion and exclusion criteria: Age minimum**

12

**Key inclusion and exclusion criteria: Age maximum**

99

**Key inclusion and exclusion criteria: Exclusion criteria**

History of hypersensitivity to any of the study drugs or its components or to drugs of similar chemical classes or to the provocation test or items used in provocation tests

Participants who have concomitant CSU at screening

Participants who have a familial form of the target CINDU that is being considered for the participant's inclusion in this study

Participants having a more defined other form of inducible urticaria than the target CINDU that is being considered for the participant's inclusion in this study

Diseases, other than chronic inducible urticaria, with urticarial or angioedema symptoms such as urticarial vasculitis, erythema multiforme, cutaneous mastocytosis (urticaria pigmentosa) and hereditary or acquired angioedema (eg, due to C1 inhibitor deficiency).

Any other skin disease associated with chronic itching that might influence, in the investigator's opinion, the study evaluations and results (eg, atopic dermatitis, bullous pemphigoid, dermatitis herpetiformis, senile pruritus, etc.) or skin diseases associated with only wheals and no itch e.g asymptomatic dermatographism

Prior exposure to ligelizumab, omalizumab and or other anti-IgE therapies

**Type of study**

Interventional

**Type of intervention**

Pharmaceutical

**Type of intervention: Specify type**

N/A

**Trial scope**

Therapy

**Trial scope: Specify scope**

N/A

**Study design: Allocation**

Randomized controlled trial

**Study design: Masking**

Blinded (masking used)

**Study design: Control**

Placebo

**Study phase**

3

**Study design: Purpose**

Treatment

**Study design: Specify purpose**

N/A

**Study design: Assignment**

Parallel

**Study design: Specify assignment**

N/A

**IMP has market authorization**

No

**IMP has market authorization: Specify****Name of IMP**

Ligelizumab

**Year of authorization****Month of authorization**

**Type of IMP**

Immunological

**Pharmaceutical class**

Anti-IgE

**Therapeutic indication**

Patients with Chronic Inducible Urticaria

**Therapeutic benefit**

There are currently no approved therapies for patients with CINDU who remain symptomatic despite treatment with H1-antihistamines. The purpose of this study is to establish efficacy and safety of ligelizumab (QGE031) over placebo in participants with chronic inducible urticaria (CINDU) who remain symptomatic despite treatment with H1 antihistamine.

**Study model**

N/A

**Study model: Explain model**

N/A

**Study model: Specify model**

N/A

**Time perspective**

N/A

**Time perspective: Explain time perspective**

N/A

**Time perspective: Specify perspective**

N/A

**Target follow-up duration****Target follow-up duration: Unit****Number of groups/cohorts****Biospecimen retention**

Samples without DNA

**Biospecimen description**

hematology, chemistry, PK/PD/ADA will be sent to Q2 lab

**Target sample size**

8

**Actual enrollment target size****Date of first enrollment: Type**

Anticipated

**Date of first enrollment: Date**

10/04/2022

**Date of study closure: Type**

Anticipated

**Date of study closure: Date**

27/12/2024

**Recruitment status**

Pending

**Recruitment status: Specify****Date of completion**



01/07/2024

## IPD sharing statement plan

No

## IPD sharing statement description

Novartis is committed to sharing access to patient-level data and supporting clinical documents from eligible studies with qualified external researchers. Requests are reviewed and approved by an independent review panel on the basis of scientific merit. All data provided is anonymized to protect the privacy of patients who have participated in the trial in line with applicable laws and regulations.

## Additional data URL

<https://clinicaltrials.gov/ct2/show/NCT05024058?term=CQGE031E12301&draw=2&rank=1>

## Admin comments

## Trial status

Approved

## Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
ClinicalTrials.gov	NCT05024058

## Sources of Monetary or Material Support

Name
Novartis Pharma Services Inc.

## Secondary Sponsors

Name
NA

## Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Hadi Hamam	Saida	Lebanon	+961 3 795246	hadihamam@hotmail.com	Hammoud Hospital
Scientific	Hind Khairallah	Beirut	Lebanon	+961 1 512002 Ext. 271	hind.khairallah@fattal.com.lb	Khalil Fattal et Fils s.a.l
Public	Carla Irani	Beirut	Lebanon	+961 3 495496	iranica@yahoo.com	Hotel Dieu De France Hospital



## Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hammoud Hospital University Medical Center	Hadi Hamam	Dermatology	Approved
Hotel Dieu De France Hospital	Carla Irani	Dermatology	Approved

## Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hammoud Hospital University Medical Center	01/12/2021	Ibrahim Omeis	iomeis@hammoudhospital.org	+961 7 721021 ext 1160
Hotel Dieu de France	31/01/2022	Nancy Alam	nancy.alam@usj.edu.lb	+961 (0) 1 421000 ext 2335

## Countries of Recruitment

Name
Hungary
Lebanon

## Health Conditions or Problems Studied

Condition	Code	Keyword
Chronic Inducible Urticaria	Urticaria (L50)	CINDU

## Interventions

Intervention	Description	Keyword
- IMP Administration - Informed consent procedure - Visit Schedule and Assessments	- IMP Administration - Informed consent procedure - Visit Schedule and Assessments	ICF-IMP



## Primary Outcomes

Name	Time Points	Measure
Change from baseline in Total Fric Score in participants with symptomatic dermatographism	Week 12	Total Fric score (a scale from 0-4 where a positive response with all of the four pins is TFS = 4, while a positive response with only one pin - the largest pin is TFS = 1)
Change from baseline in critical temperature threshold in participants with cold urticaria	Week 12	The Temptest is used to induce itch and hives in participants with cold urticaria. Critical temperature threshold (CTT), as measured by the Temptest, determines the highest temperature sufficient for inducing symptoms.
Change from baseline in itch numerical rating scale in participants with cholinergic urticaria	Week 12	Itch numerical rating scale, a scale from 0 to 10

## Key Secondary Outcomes

Name	Time Points	Measure
Proportion of participants with symptomatic dermatographism with Total Fric score = 0	Week 12	Total Fric score, a scale from 0-4 where a positive response with all of the four pins is TFS = 4, while a positive response with only one pin - the largest pin is TFS = 1
Change from baseline in itch numerical rating scale in participants with symptomatic dermatographism	Week 12	Itch numerical rating scale, a scale from 0-10
Proportion of participants with cold urticaria with complete response (no itch or hives) to the TempTest	Week 12	The Temptest is used to induce itch and hives in participants with cold urticaria
Change from baseline in itch numerical rating scale in participants with cold urticaria	Week 12	Itch numerical rating scale, a scale from 0-10
Proportion of participants with cholinergic urticaria with itch numerical rating scale =0	Week 12	Itch numerical rating scale, a scale from 0-10
Proportion of participants with cholinergic urticaria with physician global assessment of severity of hives (PGA - hive score) =0	Week 12	Physician global assessment of severity of hives
Occurrence of treatment emergent adverse events and serious adverse events during the study	Week 24	Treatment emergent adverse events and serious adverse events are those which occur at any time only after treatment has started



## Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files