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
27/02/2023

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، عشوائيّة التوزيع، مزدوجة التعمية، مرتكزة على المقارنة بدواء وهمي للبحث في فعاليّة وسلامة ليجليزوماب(QGE031) في علاج الشرى المزمن المحرّض لدى مراهقين وبالغين حالتهم غير مضبوطة بشكل كافٍ بواسطة مضادات الهيستامين H1

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 dermographism, cold urticaria or cholinergic urticaria for ≥ 4 months.

Diagnosis of CINDU (symptomatic dermographism, 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 dermographism
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

21/06/2022

Recruitment status

Suspended

Recruitment status: Specify

Date of completion

06/04/2022

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
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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 dermographism	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 dermographism 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 dermographism	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