CQGE031C2302E1 Study of Efficacy and Safety of Ligelizumab in Chronic Spontaneous Urticaria Patients Who Completed a Previous Study With Ligelizumab

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Main Information

Primary registry identifying number
LBCTR2020094573

Protocol number
CQGE031C2302E1

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
23/09/2020

Date of registration in national regulatory agency

Public title
CQGE031C2302E1 Study of Efficacy and Safety of Ligelizumab in Chronic Spontaneous Urticaria Patients Who Completed a Previous Study With Ligelizumab

Acronym

Scientific title
A Multi-center, Double-blinded and Open-label Extension Study to Evaluate the Efficacy and Safety of Ligelizumab as Retreatment, Self-administered Therapy and Monotherapy in Chronic Spontaneous Urticaria Patients Who Completed Studies CQGE031C2302, CQGE031C2303, CQGE031C2202 or CQGE031C1301

Acronym

Brief summary of the study: English
The purpose of this extension study is to establish efficacy and safety of ligelizumab. This will be assessed in adult and adolescent chronic spontaneous urticaria (CSU) patients who have completed a preceding ligelizumab study and have relapsed, following treatment in these preceding studies, despite standard of care H1-antihistamine (H1-AH) treatment. In a subset of subjects, the safety and efficacy of ligelizumab monotherapy will be assessed.

This study will also fulfill the Novartis commitment to provide post-trial access to patients who have completed studies CQGE031C2302, CGQE031C2303, CQGE031C2202 or CQGE031C1301

Brief summary of the study: Arabic
دراسة تمديد متعدّدة المراكز ومزدوجة التعمية ومفتوحة اللصاقة لتقييم فعاليّة وسلامة ليجيليزوماب كإعادة معالجة وعلاج يُعطى ذاتيًا ومعالجة أحاديّة لدى مرضى الشرى التلقائي المزمن الذين أنجزوا دراسات CQGE031C2302، CQGE031C2303، CQGE031C2202 أو CQGE031C1301

Health conditions/problem studied: Specify

Chronic Spontaneous Urticaria

Interventions: Specify

Drug: Ligelizumab
liquid in vial 120 mg/mL Prefilled Syringe 120 mg/mL

Other Name: QGE031

Key inclusion and exclusion criteria: Inclusion criteria

Key Inclusion Criteria:
•Written informed consent
•Subjects who successfully completed all of the treatment period and the follow-up period in any of the following studies: CQGE031C2302, CQGE031C2303, CQGE031C2202 or CQGE031C1301
•Male and female, adult and adolescent subjects ≥12 years of age
•Willing and able to complete a daily symptom eDiary for the duration of the study and adhere to the study visit schedule

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

Key Exclusion Criteria:
•Use of investigational drugs, other than those in use in the preceding studies, at the time of enrollment
•Use of omalizumab within 16 weeks of Screening
•History of hypersensitivity to the study drug ligelizumab or its components, or to drugs of similar chemical classes
•New onset or signs and symptoms of any form of chronic urticarias other than CSU during the preceding studies CQGE031C2302, CQGE031C2303 or CQGE031C2202.
•Diseases with possible symptoms of urticaria or angioedema
•Subjects with evidence of helminthic parasitic infection
•Documented history of anaphylaxis
•Pregnant or nursing (lactating) women

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

Non-randomized controlled trial

Study design: Masking

Blinded (masking used)

Study design: Control

N/A

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

Ligelizumab is a high-affinity anti-human-IgE

Therapeutic indication

Patients with:
Chronic Spontaneous Urticaria

Therapeutic benefit

improvement of CSU symptoms including itch, hives, angioedema

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

Samples will be sent to Q2 central Lab for analysis

Target sample size

10

Actual enrollment target size

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

30/09/2020

Date of study closure: Type

Anticipated

Date of study closure: Date

16/12/2026

Recruitment status

Pending

Recruitment status: Specify

Date of completion

20/04/2022

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.

This trial data availability is according to the criteria and process described on www.clinicalstudydatarequest.com

Additional data URL

https://clinicaltrials.gov/ct2/show/record/NCT04210843?cond=ligelizumab&draw=3

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Clinical trials.gov	NCT04210843

Sources of Monetary or Material Support

Name
Novartis Pharma services

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 3 795 246	hadihamam@hotmail.com	Hammoud Hospital
Scientific	Hind Khairallah	Sin El Fil	Lebanon	+961 1 512002 Ext. 271	Hind.Khairallah@fattal.com.lb	Khalil Fattal et Fils s.a.l.
Public	Carla Irani	Ashrafieh	Lebanon	9613495496	iranica@yahoo.com	Hotel Dieu De France

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	Carla Irani	Allergy and Immunology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hammoud Hospital University Medical Center	28/05/2020	Ahmad Zaatari	zaatari@hammoudhospital.com	961 (0) 7 723111 ext 1160
Hotel Dieu de France	05/05/2020	Nancy Alam	nancy.alam@usj.edu.lb	961 (0) 1 421000 ext 2335

Countries of Recruitment

Name
Australia
Austria
Belgium
Canada
Czech Republic
France
Germany
Greece
Hungary
Japan
Republic of Korea
Slovakia
Spain
Thailand
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
chronic spontaneous urticaria	Urticaria, unspecified (L50.9)	chronic spontaneous urticaria

Interventions

Intervention	Description	Keyword
Informed consent, questionnaires, Lab tests, drug administration	Informed consent, questionnaires, Lab tests, drug administration	ICF, Lab, ECG, IMP

Primary Outcomes

Name	Time Points	Measure
proportion of subjects with well-controlled disease USA7	Week 12	Week 12
Reduction in number of hives and itch	week 12	week 12
Improvement of severity of itch	week 12	week 12

Key Secondary Outcomes

Name	Time Points	Measure
Complete control of chronic spontaneous urticaria (CSU)	week 12	week 12
Reduction from extension baseline in weekly itch severity score (ISS7)	ISS over the preceding 7 days	ISS over the preceding 7 days
Reduction from extension baseline in weekly Urticaria Activity Score (UAS7)	week 12	week 12
Reduction from extension baseline in weekly hives severity score HSS7	week 12	week 12
Achieving a weekly angioedema-free period (AAS7) = 0	week 12	week 12
Percentage of subjects achieving Dermatology Life Quality Index (DLQI) = 0-1	week 12	week 12
Efficacy of ligelizumab in the treatment of CSU after self administration	week 12	week 12
Safety and tolerability of ligelizumab 120 mg q4w after self administration	week 12	week 12

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