



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

29/12/2021

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, CQGE031C2303, CQGE031C2202 or CQGE031C1301

Brief summary of the study: Arabic

دراسة تمديد متعددة المراكز ومزدوجة التعمية ومفتوحة اللصاقة لتقييم فعالية وسلامة ليجيليزوماب كأعادة معالجة وعلاج يُعطى ذاتيًا ومعالجة أو تمديد متعددة المراكز ومزدوجة التعمية ومفتوحة اللصاقة لتقييم فعالية وسلامة ليجيليزوماب كأعادة معالجة وعلاج يُعطى ذاتيًا ومعالجة 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

17

Date of first enrollment: Type

Actual

Date of first enrollment: Date

09/12/2020

Date of study closure: Type

Actual

Date of study closure: Date

16/12/2026

Recruitment status

Recruiting

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 |
|--------------|-------------------|------------|---------|------------------------|-------------------------------|--|
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| 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 |
| Public | Alfred Ammourey | Ashrafieh | Lebanon | 96178820821 | docalf@yahoo.com | St. Georges Hospital University Medical Center |

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 |
| St Georges Hospital University Medical Center | Alfred Ammourey | Dermatology | 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 |
| Saint George Hospital University Medical Center | 24/09/2020 | Michel Daher | mndaher@stgeorgehospital.org | 9611581714 |



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