



# 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

19/10/2020

### 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, 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  $\geq 12$  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](http://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
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