



A multi-center, randomized, double-blind, active and placebo-controlled study to investigate the efficacy and safety of ligelizumab (QGE031) in the treatment of Chronic Spontaneous Urticaria (CSU) in adolescents and adults inadequately controlled with H1-antihistamines

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## Main Information

**Primary registry identifying number**

LBCTR2019020192

**Protocol number**

CQGE031C2303

**MOH registration number**

37979/2018

**Study registered at the country of origin**

Yes

**Study registered at the country of origin: Specify****Type of registration**

Retrospective

**Type of registration: Justify**

LCTR was recently initiated, original file was previously submitted by Paper

**Date of registration in national regulatory agency**

13/09/2018

**Primary sponsor**

Novartis Pharma Services Inc.

**Primary sponsor: Country of origin**

Novartis Pharmaceuticals

**Date of registration in primary registry**

04/01/2022

**Date of registration in national regulatory agency**

13/09/2018

**Public title**

A multi-center, randomized, double-blind, active and placebo-controlled study to investigate the efficacy and safety of ligelizumab (QGE031) in the treatment of Chronic Spontaneous Urticaria (CSU) in adolescents and adults inadequately controlled with H1-antihistamines

**Acronym**

Pearl 2

**Scientific title**

A multi-center, randomized, double-blind, active and placebo-controlled study to investigate the efficacy and safety of ligelizumab (QGE031) in the treatment of Chronic Spontaneous Urticaria (CSU) in adolescents and adults inadequately controlled with H1-antihistamines

**Acronym****Brief summary of the study: English**



The purpose of this study is to establish efficacy and safety of ligelizumab in adolescent and adult subjects with CSU who remain symptomatic despite standard of care treatment by demonstrating better efficacy over omalizumab.

The study population will consist of approximately 1050 male and female subjects aged  $\geq 12$  years who have been diagnosed with Chronic Spontaneous Urticaria CSU and who remain symptomatic despite the use of H1-antihistamines. Of these, approximately 1000 adults and 50 adolescents are planned for inclusion in the study.

This is a multi-center, randomized, double-blind, active- and placebo-controlled, parallel-group study. There is a screening period of up to 28 days, a 52 week double-blind treatment period, and a 12 week post-treatment follow-up period.

#### Brief summary of the study: Arabic

دراسة متعددة المراكز وعشوائية التوزيع ومزدوجة التعمية ونشطة قائمة على مقارنة تأثير الدواء بدواء وهمي لدراسة فعالية وسلامة دواء ليجيليزوماب (QGE031) لدى المراهقين والبالغين H1 في علاج الشرى التلقائي المزمن غير المسيطر عليه بشكل كافٍ بمضادات الهستامين (QGE031)

#### Health conditions/problem studied: Specify

Patients with chronic spontaneous urticaria

#### Interventions: Specify

IMP: Ligelizumab

Comparators: Omalizumab and Placebo

#### Key inclusion and exclusion criteria: Inclusion criteria

- Signed informed consent must be obtained prior to participation in the study. The subject's, parent's or legal guardian's signed written informed consent and child's assent, if appropriate, must be obtained before any assessment is performed. Of note, if the subject reaches age of consent (age as per local law) during the study, they will also need to sign the corresponding study Informed Consent Form (ICF) at the next study visit.
- Male and female subjects  $\geq 12$  years of age at the time of screening.
- CSU diagnosis for  $\geq 6$  months.
- Diagnosis of CSU refractory to H1-AH at approved doses at the time of randomization, as defined by all of the following:
  - The presence of itch and hives for  $\geq 6$  consecutive weeks at any time prior to Visit 1 (Day - 28 to Day -14) despite current use of non-sedating H1-antihistamine
  - UAS7 score (range 0-42)  $\geq 16$  and HSS7 (range 0-21)  $\geq 8$  during the 7 days prior to randomization (Visit 110, Day 1)
  - Subjects must be on H1-antihistamine at only approved doses for treatment of CSU starting at Visit 1 (Day -28 to Day -14)
  - Willing and able to complete a daily symptom eDiary for the duration of the study 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 their excipients or to drugs of similar chemical classes (i.e. to murine, chimeric or human antibodies).
- Subjects having a clearly defined cause of their chronic urticaria, other than CSU. This includes, but is not limited to, the following: symptomatic dermatographism (urticaria factitia), cold-, heat-, solar-, pressure-, delayed pressure-, aquagenic-, cholinergic- or contact-urticaria.
- Diseases, other than chronic 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).
- Subjects with evidence of helminthic parasitic infection as evidenced by stools being positive for a pathogenic organism according to local guidelines. All subjects will be screened at Visit 1. If stool testing is positive for pathogenic organism, the subject will not be randomized and will not be allowed to rescreen.
- Any other skin disease associated with chronic itching that might influence the investigators opinion the study evaluations and results (e.g. atopic dermatitis, bullous pemphigoid, dermatitis herpetiformis, senile pruritus, etc.).
- Prior exposure to ligelizumab or omalizumab.
- Any H2 antihistamine, LTRA (montelukast or zafirlukast) or H1 antihistamines use at greater than approved doses after Visit 1.

#### Type of study

Interventional

#### Type of intervention

Pharmaceutical

#### Type of intervention: Specify type

N/A

|  |   |                               |
|--|---|-------------------------------|
| <b>Trial scope</b>   | <b>Trial scope: Specify scope</b>                 |                               |
| Other  |   |                               |
| <b>Study design: Allocation</b>  | <b>Study design: Masking</b>                      |                               |
| Randomized controlled trial  | Blinded (masking used)                            |                               |
| <b>Study design: Control</b>   | <b>Study phase</b>                                |                               |
| Active   | 3   |                               |
| <b>Study design: Purpose</b>   | <b>Study design: Specify purpose</b>              |                               |
| Treatment  | N/A   |                               |
| <b>Study design: Assignment</b>  | <b>Study design: Specify assignment</b>           |                               |
| Parallel   | N/A   |                               |
| <b>IMP has market authorization</b>  | <b>IMP has market authorization: Specify</b>      |                               |
| No   |   |                               |
| <b>Name of IMP</b>   | <b>Year of authorization</b>                      | <b>Month of authorization</b> |
| Ligelizumab  |   |                               |
| <b>Type of IMP</b>   |   |                               |
| Immunological  |   |                               |
| <b>Pharmaceutical class</b>  |   |                               |
| Humanized monoclonal antibody of the subtype IgG1/ (anti-IgE)                              |   |                               |
| <b>Therapeutic indication</b>  |   |                               |
| Patients with chronic spontaneous urticaria inadequately controlled with H1-antihistamines |   |                               |
| <b>Therapeutic benefit</b>   |   |                               |
| Absolute change from baseline in UAS7 at Week 12 in Chronic Spontaneous Urticaria patients |   |                               |
| <b>Study model</b>   | <b>Study model: Explain model</b>                 |                               |
| N/A  | N/A   |                               |
| <b>Study model: Specify model</b>  |   |                               |
| N/A  |   |                               |
| <b>Time perspective</b>  | <b>Time perspective: Explain time perspective</b> |                               |
| N/A  | N/A   |                               |
| <b>Time perspective: Specify perspective</b>   |   |                               |
| N/A  |   |                               |
| <b>Target follow-up duration</b>   | <b>Target follow-up duration: Unit</b>            |                               |
|  |   |                               |
| <b>Number of groups/cohorts</b>  |   |                               |
|  |   |                               |
| <b>Biospecimen retention</b>   | <b>Biospecimen description</b>                    |                               |
|  |   |                               |

|   |  |
|---|--|
| <b>Samples without DNA</b>  | Central lab name, address and contact details: Q <sup>2</sup> Solutions<br>The Alba Campus Rosebank Livingston EH54 7EG United Kingdom   |
| <b>Target sample size</b><br>22   | Lab tests to be preformed: Hematology, Clinical chemistry , Coagulation PK/PD:ligelizumab/total IgE Anti-Drug(ligelizumab) antibodies (ADA) Chronic urticaria (CU) index panel (CU index, thyroid peroxidase IgG,thyroglobulin IgG) IgE- autoantibodies,Total tryptase Urine dipstick, Urine Pregnancy Test .<br><b>Actual enrollment target size</b><br>23  |
| <b>Date of first enrollment: Type</b><br>Actual   | <b>Date of first enrollment: Date</b><br>19/02/2019  |
| <b>Date of study closure: Type</b><br>Actual  | <b>Date of study closure: Date</b><br>31/07/2022   |
| <b>Recruitment status</b><br>Complete   | <b>Recruitment status: Specify</b>   |
| <b>Date of completion</b><br>26/10/2020   |  |
| <b>IPD sharing statement plan</b><br>No   | <b>IPD sharing statement description</b><br>Novartis is committed to sharing with qualified external researchers, access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent review panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations.<br><br>This trial data availability is according to the criteria and process described on <a href="http://www.clinicalstudydatarequest.com">www.clinicalstudydatarequest.com</a> |
| <b>Additional data URL</b><br><a href="https://clinicaltrials.gov/ct2/show/record/NCT03580356?term=CQGE031C2303&amp;rank=1">https://clinicaltrials.gov/ct2/show/record/NCT03580356?term=CQGE031C2303&amp;rank=1</a> |  |
| <b>Admin comments</b>   |  |
| <b>Trial status</b><br>Approved   |  |

| Secondary Identifying Numbers                     |                              |
|---|------------------------------|
| Full name of issuing authority                    | Secondary identifying number |
| National Institute of Health (clinicaltrials.gov) | NCT03580369                  |

| 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 3 795 246          | 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       | Beirut     | Lebanon | 961 3 495 496          | iranica@yahoo.com             | Hotel Dieu De France                            |
| Public       | Alfred Ammourey   | Beirut     | Lebanon | 961 78 820 821         | docalf@yahoo.com              | Saint George 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 | Dr Hadi Hamam                   | Dermatology                        | Approved         |
| Hotel Dieu De France                       | Dr Carla Irani                  | Immunologist and Allergist         | Approved         |
| Saint Georges Hospital UMC                 | Dr Alfred Ammourey              | Dermatology                        | Approved         |

## Ethics Review

| Ethics approval obtained                        | Approval date | Contact name  | Contact email                | Contact phone             |
|---|---------------|---------------|------------------------------|---------------------------|
| Hotel Dieu de France                            | 31/07/2018    | Sami Richa    | cue@usj.edu.lb               | 961421229                 |
| Saint George Hospital University Medical Center | 23/10/2018    | Michel Daher  | mndaheh@stgeorgehospital.org | 01/441733                 |
| Hammoud Hospital University Medical Center      | 16/07/2018    | Ahmad Zaatari | zaatari@hammoudhospital.com  | 961 (0) 7 723111 ext 1160 |



## Countries of Recruitment

| Name                     |
|--------------------------|
| Australia                |
| Belgium                  |
| Japan                    |
| Germany                  |
| Norway                   |
| Russian Federation       |
| Spain                    |
| United States of America |
| Italy                    |
| France                   |
| Tunisia                  |
| 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                           |
|--|-----------------------------------|-----------------------------------|
| Absolute change from baseline in UAS7                        | Week 12                           | Week 12                           |
| Complete itch response is defined as ISS7 :average daily ISS | ISS over the preceding 7 days = 0 | ISS over the preceding 7 days = 0 |



## Key Secondary Outcomes

| Name                                  | Time Points | Measure |
|---------------------------------------|-------------|---------|
| Complete absence of hives and itch    | week 12     | Week 12 |
| Improvement of severity of itch       | week 12     | week12  |
| No impact on subjects quality of life | 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