

A multi-center, randomized, double-blind, active and placebocontrolled 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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Primary registry identifying number

LBCTR2019020192

MOH registration number

37979/2018

Study registered at the country of origin

Type of registration

Retrospective

Date of registration in national regulatory agency

13/09/2018

**Primary sponsor** 

Novartis Pharma Services Inc.

Date of registration in primary registry

08/09/2020

**Public title** 

A multi-center, randomized, double-blind, active and placebocontrolled 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

Scientific title

A multi-center, randomized, double-blind, active and placebocontrolled 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

Brief summary of the study: English

Protocol number

CQGE031C2303

Study registered at the country of origin: Specify

Type of registration: Justify

LCTR was recently initiated, original file was previously submitted

by Paper

Primary sponsor: Country of origin

**Novartis Pharmaceuticals** 

Date of registration in national regulatory agency

13/09/2018

Acronym

Pearl 2

Acronvm



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 ≥ 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 وعشوانيّة التوزيع ومزدوجة التعمية ونشطة قائمة على مقارنة تأثير الدواء بدواء وهميّ لدراسة فعاليّة وسلامة دواء ليجيليزوماب لدى المراهقين والبالغين H1 خي علاج الشرى التلقائي المزمن غير المسيطر عليه بشكل كاف 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 ≥ 12 years of age at the time of screening.
- •CSU diagnosis for ≥ 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 ≥ 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) ≥ 16 and HSS7 (range 0-21) ≥ 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

Key inclusion and exclusion criteria: Specify gender

Both

Key inclusion and exclusion criteria: Age minimum

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 dermographism (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 in the investigators opinion the study evaluations and results (e.g. atopic dermatitis, bullous pemphigoid, dermatitis herpetiformis, senile pruritus, etc.).

N/A

- •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

Type of intervention: Specify type

Pharmaceutical





Trial scope: Specify scope

Study design: Masking

Blinded (masking used)

Year of authorization

Study model: Explain model

Study design: Specify purpose

Study design: Specify assignment

IMP has market authorization: Specify

Month of authorization

Study phase

Trial scope

Study design: Allocation
Randomized controlled trial

Study design: Control

Active

Other

Study design: Purpose

Treatment

Study design: Assignment

Parallel

IMP has market authorization

No

Name of IMP

Ligelizumab

Type of IMP

Immunological

Pharmaceutical class

Humanized monoclonal antibody of the subtype IgG1/ (anti-IgE)

Therapeutic indication

Patients with chronic spontaneous urticaria inadequately controlled with H1-antihistamines

Therapeutic benefit

Absolute change from baseline in UAS7 at Week 12

Study model

N/A N/A

Study model: Specify model

N/A

Time perspective: Explain time perspective

N/A N/A

Time perspective: Specify perspective

N/A

Target follow-up duration Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention Biospecimen description



Samples without DNA

Central lab name, address and contact details: Q² Solutions The Alba Campus Rosebank Livingston EH54 7EG United Kingdom

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 .

Target sample size

22

Date of first enrollment: Type

Actual

Date of study closure: Type

Actua

Recruitment status

Recruiting

Date of completion

28/02/2020

IPD sharing statement plan

Nο

Actual enrollment target size

13

Date of first enrollment: Date

19/02/2019

Date of study closure: Date

30/07/2021

Recruitment status: Specify

### IPD sharing statement description

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.

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/NCT03580356?term=CQGE031C2303&rank=1

**Admin comments** 

Trial status

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 NA		

Contac	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@hot mail.com	Hammoud Hospital	
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Public	Alfred Ammoury	Beirut	Lebanon	961 78 820 821	docalf@yahoo.co m	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 Ammoury	Dermatology	Approved	

Ethics Review					
Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone	
Hotel Dieu de France	31/07/2018	Nancy Alam	nancy.alam@usj.edu.lb	961 1421000 ext 2335	
Saint George Hospital University Medical Center	23/10/2018	Michel Daher	mndaher@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	