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
23/04/2019

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 ≥ 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 وعشوائيّة التوزيع ومزدوجة التعمية ونشطة قائمة على مقارنة تأثير الدواء بدواء وهميّ لدراسة فعاليّة وسلامة دواء ليجيليزوماب
(QGE031) لدى المراهقين والبالغين H1- في علاج الشرى التلقائي المزمن غير المسيطر عليه بشكل كافٍ بمضادات الهستامين

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

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 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.).
•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

Trial scope
Other

Trial scope: Specify scope

Study design: Allocation
Randomized controlled trial

Study design: Masking
Blinded (masking used)

Study design: Control
Active

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
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

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

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

Actual enrollment target size

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

28/02/2019

Date of study closure: Type

Anticipated

Date of study closure: Date

30/07/2021

Recruitment status

Recruiting

Recruitment status: Specify

Date of completion

31/01/2020

IPD sharing statement plan

No

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

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
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Public	Alfred Ammoury	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 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