

CQGE031C2302E1 Study of Efficacy and Safety of Ligelizumab in Chronic Spontaneous Urticaria Patients Who Completed a Previous Study With Ligelizumab

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Primary registry identifying number

LBCTR2020094573

MOH registration number

Study registered at the country of origin

Type of registration

Prospective

Date of registration in national regulatory agency

Primary sponsor

Novartis Pharmaceuticals

Date of registration in primary registry

11/11/2021

Public title

CQGE031C2302E1 Study of Efficacy and Safety of Ligelizumab in Chronic Spontaneous Urticaria Patients Who Completed a Previous Study With Ligelizumab

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

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 H1antihistamine (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 posttrial access to patients who have completed studies CQGE031C2302, CGQE031C2303, CQGE031C2202 or CQGE031C1301

Brief summary of the study: Arabic

دراسة تمديد متعدّدة المراكز ومزدوجة التعمية ومفتوحة اللصاقة لتقييم فعاليّة وسلامة ليجيليزوماب كإعادة معالجة وعلاج يُعطي ذاتيًا ومعالجة أو CQGE031C2302، CQGE031C2303، CQGE031C2202 أحاديّة لدى مرضى الشرى التلقائي المزمن الذين أنجزوا دراسات CQGE031C1301

Protocol number CQGE031C2302E1

Study registered at the country of origin: Specify

Type of registration: Justify

N/A

Primary sponsor: Country of origin

Novartis Pharmaceuticals

Date of registration in national regulatory agency

Acronym

Acronym



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 Key inclusion and exclusion criteria: Specify gender

Both

Key inclusion and exclusion criteria: Age minimum

Key inclusion and exclusion criteria: Age maximum

12 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 Type of intervention: Specify type

Pharmaceutical

Trial scope Trial scope: Specify scope

Therapy N/A

Study design: AllocationStudy design: MaskingNon-randomized controlled trialBlinded (masking used)

Study design: ControlStudy phaseN/A3

Study design: Purpose Study design: Specify purpose

Treatment

Study design: Assignment Study design: Specify assignment

Parallel

IMP has market authorization IMP has market authorization: Specify

No

Name of IMP Year of authorization Month of authorization

Ligelizumab





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: Specify model

Time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Number of groups/cohorts

Biospecimen retention

Samples without DNA

Target sample size

Date of first enrollment: Type

Anticipated

Date of study closure: Type

Anticipated

Recruitment status

Recruiting

Date of completion

20/04/2022

Study model: Explain model

N/A

Time perspective: Explain time perspective

N/A

Target follow-up duration: Unit

Biospecimen description

Samples will be sent to Q2 central Lab for analysis

Actual enrollment target size

Date of first enrollment: Date

30/09/2020

Date of study closure: Date

16/12/2026

Recruitment status: Specify



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



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	Carla Irani	Ashrafieh	Lebanon	961349549 6	iranica@yahoo.c om	Hotel Dieu De France
Public	Alfred Ammoury	Ashrafieh	Lebanon	961788208 21	docalf@yahoo.co m	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 Ammoury	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	