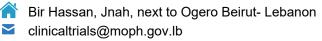
# REPUBLIC OF LEBANON Lebanon Clinical Trials Registry

## Study of Efficacy and Safety of Ligelizumab in Adolescents and Adults With Chronic Inducible Urticaria Who Remain Symptomatic Despite Treatment With H1- Antihistamines

12/09/2025 08:27:17

lain Information	
Primary registry identifying number	Protocol number
LBCTR2022014919	CQGE031E12301
MOH registration number	
Study registered at the country of origin	Study registered at the country of origin: Specify
Yes	
Type of registration	Type of registration: Justify
Prospective	N/A
Date of registration in national regulatory agency	
Primary sponsor	Primary sponsor: Country of origin
Novartis Pharmaceuticals	Novartis Pharmaceuticals
Date of registration in primary registry	Date of registration in national regulatory agency
11/04/2022	
Public title	Acronym
Study of Efficacy and Safety of Ligelizumab in Adolescents and Adults With Chronic Inducible Urticaria Who Remain Symptomatic Despite Treatment With H1- Antihistamines	PEARL-PROVOKE
Scientific title	Acronym
A Multi-center, Randomized, Double-blind, Placebo Controlled Study to Investigate the Efficacy and Safety of Ligelizumab (QGE031) in the Treatment of Chronic Inducible Urticaria (CINDU) in Adolescents and Adults Inadequately Controlled With H1- antihistamines	
Brief summary of the study: English	
This is a placebo controlled, phase 3 study designed to evaluate the efficacy and safety of ligelizumab in participants with chronic inducible urticaria who are inadequately controlled with H1- antihistamines	
Brief summary of the study: Arabic	
ىراكز، عشوائيَّة التوزيع، مزدوجة التعمية، مرتكزة على المقارنة بدواء وهمي للبحث في فعاليَّة وسلامة ل لدى مراهقين وبالغين حالتهم غير مضبوطة بشكل كافٍ بواسطة مضادات  (QGE031)ليجليزوماب H1 الهيستامين	در اسة متعددة الم في علاج الشّر ى المز من المحرَّض
Health conditions/problem studied: Specify	
Chronic Inducible Urticaria	
Interventions: Specify	
Drug: Ligelizumab - Ligelizumab treated groups and arms - Other Name: QGE031	



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Other: Placebo

- Placebo treated groups and arms

### Key inclusion and exclusion criteria: Inclusion criteria

Confirmed CINDU diagnosis (as per guidelines) for symptomatic dermographism, cold urticaria or cholinergic urticaria for ≥ 4 months.

Diagnosis of CINDU (symptomatic dermographism, cold urticaria or cholinergic urticaria) inadequately controlled with H1-AH at local label approved doses at the time of randomization, as defined by all of the following: Positive response (i.e development of symptoms) to triggers despite treatment with H1-AH Positive response (i.e. development of symptoms) to provocation test on day of randomization Participants must be able to physically perform the protocol defined provocation test specific to the participant's CINDU. Cholinergic urticaria participants must show sweating in performing the pulse-controlled ergometry test on day of randomization. Participants with anhidrosis must not be included. Willing and able to complete a daily symptom eDiary as per protocol requirement 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 12 99 Key inclusion and exclusion criteria: Exclusion criteria History of hypersensitivity to any of the study drugs or its components or to drugs of similar chemical classes or to the provocation test or items used in provocation tests Participants who have concomitant CSU at screening Participants who have a familial form of the target CINDU that is being considered for the participant's inclusion in this study Participants having a more defined other form of inducible urticaria than the target CINDU that is being considered for the participant's inclusion in this study Diseases, other than chronic inducible 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). Any other skin disease associated with chronic itching that might influence, in the investigator's opinion, the study evaluations and results (eg, atopic dermatitis, bullous pemphigoid, dermatitis herpetiformis, senile pruritus, etc.) or skin diseases associated with only wheals and no itch e.g asymptomatic dermographism Prior exposure to ligelizumab, omalizumab and or other anti-IgE therapies Type of study Interventional Type of intervention Type of intervention: Specify type Pharmaceutical N/A Trial scope Trial scope: Specify scope N/A Therapy Study design: Allocation Study design: Masking Randomized controlled trial Blinded (masking used) Study design: Control Study phase Placebo 3 Study design: Purpose Study design: Specify purpose Treatment N/A Study design: Assignment Study design: Specify assignment Parallel N/A IMP has market authorization IMP has market authorization: Specify No Name of IMP Year of authorization Month of authorization

Ligelizumab

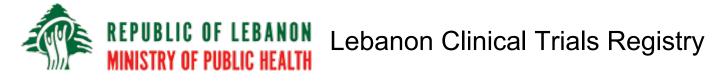


Type of IMP

# Lebanon Clinical Trials Registry

Parmaceutical class         Anti-IgE         Patients         Frequenti Indication         Patients with Chronic Indicatible Urticaria         Therapeutic Anometic         Therapeutic Anometic         Therapeutic Anometic         Therapeutic Anometic         Therapeutic Anometic Anometi	Anti-IgE Therapeutic indication Patients with Chronic Inducible Urticaria Therapeutic benefit Thera are currently no approved therapies for patients with CINDU who remains symptomatic despite treatment with H1-antihistamine. The purpose of this study is to establish efficacy and safety of ligelizumab (QGE 031) over placebo in participants with chronic inducible urticaria (CINDU) who remain symptomatic despite treatment with H1 antihistamine. Study model N/A Study model N/A Time perspective N/A Time perspective: Specify perspective
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Anticipated 27/12/2024	
	Anticipated 27/12/2024
Recruitment status: Specify	Recruitment status Recruitment status: Specify
Pending	Pending
	Date of completion
	Date of completion

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01/07/2024

### 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.

### Additional data URL

https://clinicaltrials.gov/ct2/show/NCT05024058?term=CQGE031E12301&draw=2&rank=1

Admin comments

### Trial status

Approved

Secondary Identifying Numbers		
Full name of issuing authority	Secondary identifying number	
ClinicalTrials.gov	NCT05024058	

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 795246	hadihamam@hot mail.com	Hammoud Hospital
Scientific	Hind Khairallah	Beirut	Lebanon	+961 1 512002 Ext. 271	hind.khairallah@f attal.com.lb	Khalil Fattal et Fils s.a.l
Public	Carla Irani	Beirut	Lebanon	+961 3 495496	iranica@yahoo.c om	Hotel Dieu De France Hospital





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 Hospital	Carla Irani	Dermatology	Approved	

Ethics Review					
Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone	
Hammoud Hospital University Medical Center	01/12/2021	Ibrahim Omeis	iomeis@hammoudhospital.org	+961 7 721021 ext 1160	
Hotel Dieu de France	31/01/2022	Nancy Alam	nancy.alam@usj.edu.lb	+961 (0) 1 421000 ext 2335	

Countries of Recruitment
Name
Hungary
Lebanon

Health Conditions or Problems Studied			
Condition	Code	Keyword	
Chronic Inducible Urticaria	Urticaria (L50)	CINDU	

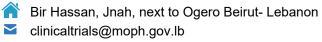
Interventions		
Intervention	Description	Keyword
- IMP Administration - Informed consent procedure - Visit Schedule and Assessments	- IMP Administration - Informed consent procedure - Visit Schedule and Assessments	ICF-IMP





Primary Outcomes					
Name	Time Points	Measure			
Change from baseline in Total Fric Score in participants with symptomatic dermographism	Week 12	Total Fric score (a scale from 0-4 where a positive response with all of the four pins is TFS = 4, while a positive response with only one pin - the largest pin is TFS = 1)			
Change from baseline in critical temperature threshold in participants with cold urticaria	Week 12	The Temptest is used to induce itch and hives in participants with cold urticaria. Critical temperature threshold (CTT), as measured by the Temptest, determines the highest temperature sufficient for inducing symptoms.			
Change from baseline in itch numerical rating scale in participants with cholinergic urticaria	Week 12	Itch numerical rating scale, a scale from 0 to 10			

Key Secondary Outcomes		
Name	Time Points	Measure
Proportion of participants with symptomatic dermographism with Total Fric score = 0	Week 12	Total Fric score, a scale from 0-4 where a positive response with all of the four pins is TFS = 4, while a positive response with only one pin - the largest pin is TFS = 1
Change from baseline in itch numerical rating scale in participants with symptomatic dermographism	Week 12	Itch numerical rating scale, a scale from 0-10
Proportion of participants with cold urticaria with complete response (no itch or hives) to the TempTest	Week 12	The Temptest is used to induce itch and hives in participants with cold urticaria
Change from baseline in itch numerical rating scale in participants with cold urticaria	Week 12	Itch numerical rating scale, a scale from 0-10
Proportion of participants with cholinergic urticaria with itch numerical rating scale =0	Week 12	Itch numerical rating scale, a scale from 0-10
Proportion of participants with cholinergic urticaria with physician global assessment of severity of hives (PGA - hive score) =0	Week 12	Physician global assessment of severity of hives
Occurrence of treatment emergent adverse events and serious adverse events during the study	Week 24	Treatment emergent adverse events and serious adverse events are those which occur at any time only after treatment has started





# Trial Results Summary results Study results globally Date of posting of results summaries 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