LUSTER-Study of Efficacy and Safety of QAW039 in Patients With Severe Asthma Inadequately Controlled With Standard of Care Asthma Treatment.

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Main Information

Primary registry identifying number
LBCTR2020011378

Protocol number
CQAW039A2314

MOH registration number
37148/2017

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Retrospective

Type of registration: Justify
Trial previously submitted before LBCTR initiation

Date of registration in national regulatory agency
02/10/2017

Primary sponsor
Novartis Pharmaceuticals

Primary sponsor: Country of origin
Novartis Pharmaceuticals

Date of registration in primary registry
07/01/2020

Date of registration in national regulatory agency
02/10/2017

Public title
LUSTER-Study of Efficacy and Safety of QAW039 in Patients With Severe Asthma Inadequately Controlled With Standard of Care Asthma Treatment.

Acronym

Scientific title
A 52-week, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy and Safety of QAW039 When Added to Existing Asthma Therapy in Patients With Uncontrolled Severe Asthma.

Acronym

Brief summary of the study: English
This study aims to determine the efficacy and safety of QAW039 (Dose 1 and Dose 2), compared with placebo, when added to GINA steps 4 and 5 standard-of- care (SoC) asthma therapy (GINA 2015) in each of the groups (patients with severe asthma and high eosinophil counts and all patients with severe asthma)

Brief summary of the study: Arabic
عندما يُضاف QAW039 أسبوعًا متعددة المراكز وجُزافيّة ومزدوجة التعمية ومراقبة الدواء الوهمي لتقييم فعاليّة وسلامة دواء52دراسة من إلى علاج الربو الحالي لدى المرضى المصابين بالربو الحاد غير المتحكم به

Health conditions/problem studied: Specify
Respiratory - Asthma

Interventions: Specify
•Drug: QAW039
QAW039 Dose 1 once daily

•Drug: QAW039

QAW039 Dose 2 once daily

•Drug: Placebo
Placebo once daily

Key inclusion and exclusion criteria: Inclusion criteria

•Written informed consent.
•Male and female patients aged more than or equal 12 years.
•A diagnosis of severe asthma, uncontrolled on GINA 4 over 5 asthma medication.
•Evidence of airway reversibility or airway hyper- reactivity.
•FEV1 less than or equal 80 percent of the predicted normal value for patients aged more than or equal 18 years; FEV1 of less than or equal 90 percent for patients aged 12 to less than 18 years
•An ACQ score more than or equal 1.5
•A history of 2 or more asthma exacerbations within the 12 months prior to entering the study.

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

•Use of other investigational drugs within 5 half-lives of study entry, or within 30 days, whichever is longer.
•Subjects who have participated in another trial of QAW039.
•A QTcF (Fridericia) more than or equal 450 msec (male) or more than or equal 460 msec (female).
•History of malignancy with the exception of local basal cell carcinoma of the skin.
•Pregnant or nursing (lactating) women.
•Serious co-morbidities.
•Patients on more than 20 mg of simvastatin, more than 40 mg of atorvastatin, more than 40 mg of pravastatin, or more than 2 mg of pitavastatin.

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Safety

Trial scope: Specify scope

N/A

Study design: Allocation

Randomized controlled trial

Study design: Masking

Blinded (masking used)

Study design: Control

Placebo

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

Fevipiprant

Year of authorization

Month of authorization

Type of IMP

Cell therapy

Pharmaceutical class

CRTh2 antagonist

Therapeutic indication

GINA steps 3, 4 and 5 patients with uncontrolled asthma

Therapeutic benefit

Reduction in the rate of moderate-to-severe asthma exacerbations

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

None retained

Biospecimen description

NA

Target sample size

9

Actual enrollment target size

9

Date of first enrollment: Type

Actual

Date of first enrollment: Date

28/02/2018

Date of study closure: Type

Actual

Date of study closure: Date

28/02/2020

Recruitment status

Complete

Recruitment status: Specify

Date of completion

31/05/2018

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.

Additional data URL

https://clinicaltrials.gov/ct2/show/record/NCT02563067?term=QAW039&cond=A+52-week%2C+multicenter%2C+randomized%2C+double-blind%2C+placebocontrolled&cntry=LB&draw=1&rank=1

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
clinicaltrials.gov	NCT02563067

Sources of Monetary or Material Support

Name
Novartis Pharmaceuticals

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Zouheir Alameh	El Chouf	Lebanon	70-669618	alamehclinic@gmail.com	Ain Wazein Medical Village
Scientific	Hind Khairallah	Sin Elfil	Lebanon	961 1512002#271	Hind.Khairallah@fattal.com.lb	Khalil Fattal et Fils s.a.l.
Public	Carla Irani	Beirut	Lebanon	03-495496	iranica@yahoo.com	Hotel Dieu De France
Public	Georges Juvelikian	Beirut	Lebanon	03-497 574	gsjuvelekian@stgeorgehospital.org	Saint George Hospital University Medical Center
Public	Carole Youakim	Beirut	Lebanon	961-925 722	caroleyou@hotmail.com	Mount Lebanon Hopsital

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Ain Wazein Medical Village	Zouheir Alameh	Pulmonary Medicine	Approved
Hotel Dieu de France	Carla Irani	Allergy Clinical Immunology	Approved
Saint George Hospital University Medical Center	Georges Juvelikian	Pulmonary Medicine	Approved
Mount Lebanon Hopsital	Carole Youakim	Pulmonary Medicine	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	21/07/2017	Nancy Alam	nancy.alam@usj.edu.lb	961 (0) 1 421000 ext 2335
Saint George Hospital University Medical Center	05/09/2017	Michel Daher	mndaher@stgeorgehospital.org	01/581714
Ain w Zein Medical Village	21/07/2017	Khaled Abdel Baki	Khaled.abdelbaki@awmedicalvillage.org	(0) 5 509 001 ext 2000
Mount Lebanon Hospital	25/04/2017	Marie Merheb	Marie.merheb@mlh.com.lb	(0) 5 957 000 exr 1200

Countries of Recruitment

Name
Lebanon
Argentina
Canada
Greece
India
Italy
Japan
Mexico
Spain
United States of America

Health Conditions or Problems Studied

Condition	Code	Keyword
Asthma	Asthma, unspecified (J45.9)	Asthma/ respiratory

Interventions

Intervention	Description	Keyword
Informed Consent, Physical Exam, Vital Signs, ePROs questionnaire, Study drug/placebo administration , lab tests, spirometry, Lab tests, ECG	Informed Consent, Physical Exam, Vital Signs, ePROs questionnaire, Study drug/placebo administration , lab tests, spirometry, Lab tests, ECG	Informed Consent, Physical Exam, Vital Signs, ePROs questionnaire, Study drug/placebo administration , lab tests, spirometry, Lab tests, ECG

Primary Outcomes

Name	Time Points	Measure
Moderate-to-severe asthma exacerbations	52 weeks	52 weeks

Key Secondary Outcomes

Name	Time Points	Measure
•Asthma Quality of Life Questionnaire	52 weeks	52 weeks
•Pre-dose Forced Expiratory Volume in 1 second (FEV1)	52 weeks	52 weeks

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