



# 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 وجزئية ومزدوجة التعمية ومراقبة الدواء الوهمي لتقييم فعالية وسلامة دواء 52 دراسة 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**

Fevipirant

**Year of authorization**

**Month of authorization**

**Type of IMP**

Cell therapy

**Pharmaceutical class**



CRT<sub>h2</sub> 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	mndaheer@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