



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

23/01/2020

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 أسبوعاً متتبعاً المراكز وجرّافية 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

CRTb2 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 Hospital |

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 Hospital | 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

Please reference this link about study results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

<https://www.novartis.com/news/media-releases/novartis-provides-update-luster-phase-iii-studies-patients-uncontrolled-gina-45-asthma>

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files