



# Study of Safety of QAW039 in Patients With Asthma Inadequately Controlled on Standard-of-care Asthma Treatment

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## Main Information

**Primary registry identifying number**

LBCTR2019121309

**Protocol number**

CQAW039A2315

**MOH registration number**

23137/2018

**Study registered at the country of origin**

Yes

**Study registered at the country of origin: Specify**

**Type of registration**

Retrospective

**Type of registration: Justify**

This was earlier submitted as paper before implementation of LBCTR , this study still have patients ongoing until 2022

**Date of registration in national regulatory agency**

31/05/2018

**Primary sponsor**

Novartis Pharma Services Inc.

**Primary sponsor: Country of origin**

Novartis Pharma Services Inc.

**Date of registration in primary registry**

20/03/2020

**Date of registration in national regulatory agency**

31/05/2018

**Public title**

Study of Safety of QAW039 in Patients With Asthma Inadequately Controlled on Standard-of-care Asthma Treatment

**Acronym**

**Scientific title**

A 2-treatment Period, Randomized, Placebo-controlled, Multicenter Parallel-group Study to Assess the Safety of QAW039 When Added to Existing Asthma Therapy in GINA Steps 3, 4 and 5 Patients With Uncontrolled Asthma.

**Acronym**

**Brief summary of the study: English**

This study is a 2-treatment period, randomized, multicenter parallel-group study. The overall purpose of this study is to provide long-term safety data for fevipiprant (QAW039) (Dose 1 and Dose 2), compared with placebo, when added to the Global Initiative for Asthma (GINA) steps 3, 4, and 5 standard-of-care (SoC) asthma therapy (GINA 2016), in patients with moderate-to- severe asthma.

**Brief summary of the study: Arabic**

عندما QAW039 دراسة متوازنية المجموعة ومتعددة المراكز ومراقبة الدواء الوهمي وعشوائية التوزيع ذات فترتيّ علاج لتقييم سلامة دواء حسب المبادرة العالمية للربو المصابين بالربو غير المتحكم به 5 و 4 ويُضاف إلى علاج الربو الحالي لدى مرضى المراحل

**Health conditions/problem studied: Specify**

Respiratory - Asthma

**Interventions: Specify**

•Drug: QAW039 Dose 1  
QAW039 Dose 1 once daily

•Drug: QAW039 Dose 2  
QAW039 Dose 2 once daily



•Drug: Placebo  
Placebo once daily

**Key inclusion and exclusion criteria: Inclusion criteria**

Inclusion Criteria:

Patients completing a prior Phase 3 study of QAW039:  
•Informed consent and assent (if applicable).  
•Completion of the Treatment Period (on blinded study drug) of a prior Phase 3 study of QAW039.  
•Patient is able to safely continue into the study as judged by the investigator.

Patients who have not previously participated in a study of QAW039:  
•Written informed consent.  
•A diagnosis of asthma, uncontrolled on GINA 3/4/5 asthma medication.  
•Evidence of airway reversibility or airway hyper-reactivity.  
•FEV1 of  $\leq 85\%$  of the predicted normal value.  
•An ACQ score  $\geq 1.5$  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**

Exclusion Criteria:

Patients completing a prior phase 3 study of QAW039:  
•Pregnant or nursing (lactating) women.  
•Women of child-bearing potential unless they are using basic methods of contraception during dosing of study drug  
•Patients who did not complete the Treatment Period on blinded study drug of the prior QAW039 study they participated in.  
•Inability to comply with all study requirements.  
•Patient who experienced a serious and drug-related AE in the prior QAW039 study they participated in.

Patients who have not previously participated in a study of QAW039:  
•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 (i.e.-the patient was randomized in another study).  
•A QTcF (Fridericia)  $\geq 450$  msec (male) or  $\geq 460$  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 greater than 20 mg of simvastatin > 40 mg of atorvastatin, >40 mg of pravastatin, or >2 mg of pitavastatin. Statin doses less than or equal to these doses as well as other statins will be permitted during the study.

**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**

CRTh2 antagonist

**Therapeutic indication**

GINA steps 3, 4 and 5 patients with uncontrolled asthma

**Therapeutic benefit**

QAW has a function on lung function (FEV1) in patients with moderate-to-severe asthma, and an improvement in quality-of-life scores and asthma control questionnaire scores in severe patients uncontrolled at baseline. In one study, QAW039 also demonstrated a reduction in sputum eosinophils in patients with severe asthma. The overall purpose of this study is to provide long-term safety data for fevipirant (QAW039) (150 mg once daily and 450 mg once daily), compared with placebo, when added to the Global Initiative for Asthma (GINA) steps 3, 4, and 5 standard-of-care (SoC) asthma therapy (GINA 2016), in adult and adolescent ( $\geq 12$  years) patients with moderate-to-severe asthma.

**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**

A central laboratory will be used to analyze and report blood chemistry/hematology and urinalysis/ urine chemistry

**Target sample size****Actual enrollment target size**



20

**Date of first enrollment: Type**

Actual

**Date of study closure: Type**

Actual

**Recruitment status**

Complete

**Date of completion**

28/11/2019

**IPD sharing statement plan**

Yes

**Additional data URL**

<https://clinicaltrials.gov/ct2/show/record/NCT03052517?cond=Asthma&cntry=LB&rank=3>

**Admin comments**

**Trial status**

Approved

20

**Date of first enrollment: Date**

15/11/2018

**Date of study closure: Date**

10/06/2020

**Recruitment status: Specify**

**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.

This trial data availability is according to the criteria and process described on [www.clinicalstudydatarequest.com](http://www.clinicalstudydatarequest.com)

## Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
clinical trials.gov	NCT03052517

## 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	Carla Irani	Beirut	Lebanon	iranica@yahoo.com	961-3-495496	Hotel Dieu De France
Scientific	Hind Khairallah	Sinefil	Lebanon	+961 1512002#271	Hind.Khairallah@fattal.com.lb	KFF Healthcare - Khalil
Public	Zouheir Alameh	Ainwazein	Lebanon	961-70-669618	alamehclinic@gmail.com	Ainwazein Medical Village
Public	Georges Juvelikian	Beirut	Lebanon	01 441 000	juveleg@hotmail.com	Saint George Hospital University Medical Center

## Centers/Hospitals Involved in the Study

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

## Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	21/07/2018	Nancy Alam	nancy.alam@usj.edu.lb	961 (0) 1 421000 ext 2335
Saint George Hospital University Medical Center	27/07/2018	Michel Daher	mndaher@stgeorgehospital.org	961 (0)1 441 733
Ain w Zein Medical Village	20/07/2018	Khaled Abdel Baki	Khaled.abdelbaki@awmedicalvillage.org	961 (0) 5 509 001 ext 2000



## Countries of Recruitment

Name
Lebanon
Argentina
Australia
Austria
Belgium
Brazil
Bulgaria
Canada
China
Colombia
Czech Republic
Greece
Hungary
India
Japan
Kuwait
Tunisia
United Kingdom
United States of America

## Health Conditions or Problems Studied

Condition	Code	Keyword
Asthma	Asthma, unspecified (J45.9)	Respiratory , Asthma



## 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
treatment-emergent adverse events AEs	52 weeks	52 weeks
•treatment emergent serious adverse events	52 weeks	52 weeks
•treatment emergent AEs leading to study treatment discontinuation	52 weeks	52 weeks

## Key Secondary Outcomes

Name	Time Points	Measure
•Rate of patients with at least 1 treatment emergent AE by primary system organ class	52 weeks	52 weeks
•Rate of treatment emergent patient deaths and patient hospitalizations due to an asthma exacerbation	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**