



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

07/01/2020

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 ≥ 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) ≥ 450 msec (male) or ≥ 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 (≥ 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	20
Date of first enrollment: Type Actual	Date of first enrollment: Date 15/11/2018
Date of study closure: Type Actual	Date of study closure: Date 01/11/2022
Recruitment status Complete	Recruitment status: Specify
Date of completion 28/11/2019	
IPD sharing statement plan Yes	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
Additional data URL https://clinicaltrials.gov/ct2/show/record/NCT03052517?cond=Asthma&cntry=LB&rank=3	
Admin comments	
Trial status Approved	

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
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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