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 متوازية المجموعة ومتعددة المراكز ومراقبة الدواء الوهمي وعشوائيّة التوزيع ذات فترتيّ علاج لتقييم سلامة دواء حسب المبادرة العالميّة للربو المصابين بالربو غير المتحكم به5 و4 و3يُضاف 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 ≤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

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

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 fevipiprant (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-tosevere 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

10/06/2020

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