



CLCZ696B2319E1 Open Label Extension Study to Evaluate Long-term Safety of Sacubitril/Valsartan in Pediatric Patients With Heart Failure (HF).

22/11/2024 10:15:18

Main Information

Primary registry identifying number

LBCTR2019070266

Protocol number

CLCZ696B2319E1

MOH registration number

Study registered at the country of origin

Yes

Study registered at the country of origin: Specify

Type of registration

Prospective

Type of registration: Justify

N/A

Date of registration in national regulatory agency

Primary sponsor

Novartis Pharma Services

Primary sponsor: Country of origin

Novartis Pharmaceuticals

Date of registration in primary registry

11/11/2021

Date of registration in national regulatory agency

Public title

CLCZ696B2319E1 Open Label Extension Study to Evaluate Long-term Safety of Sacubitril/Valsartan in Pediatric Patients With Heart Failure (HF).

Acronym

Scientific title

A multicenter study to evaluate long-term safety and tolerability of open label sacubitril/valsartan in pediatric patients with heart failure due to systemic left ventricle systolic dysfunction who have completed study CLCZ696B2319

Acronym

Brief summary of the study: English

The purpose of this study is to evaluate long-term safety and tolerability data in eligible CLCZ696B2319 (PANORAMA-HF) patients receiving open-label sacubitril/valsartan

Brief summary of the study: Arabic

دراسة متعددة المراكز لتقييم السلامة الطويلة الأمد لدواء ساكوبيتريل / فالسارتان المفتوح اللصاقة وقدرة تحمله لدى أطفال مرضى مصابين بفشل القلب بسبب الخلل الوظيفي الانقباضي الجهازى للبطين الأيسر وقد أنجزوا دراسة CLCZ696B2319

Health conditions/problem studied: Specify

Heart failure patients

Interventions: Specify

Drug: sacubitril/valsartan

Target dose 3.1 mg/kg bid





Formulations:

Tablets (50, 100, 200 mg) Granules [12.5 mg (4 granules), 31.25 mg (10 granules), in capsules] Liquid (1 mg/ml, 4 mg/ml, prepared from tablets)

Other Name: LCZ696

Key inclusion and exclusion criteria: Inclusion criteria

Signed informed consent
On study drug at PANORAMA-HF Part 2 End of Study visit. Does not have any significant safety issue

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

1

Key inclusion and exclusion criteria: Age maximum

18

Key inclusion and exclusion criteria: Exclusion criteria

Subject only participated in PANORAMA-HF Part 1 or was a Screen Failure in PANORAMA-HF or permanently discontinued study drug in PANORAMA-HF Part 2
Use of investigational drugs within 5 half-lives of enrollment or within 30 days (longer duration); with the exception of PANORAMA-HF study drug (requires ≥ 36 -hour washout before baseline visit)
History of hypersensitivity or allergy to study treatment, its excipients or drugs of similar chemical class, ACEIs, ARBs, or NEP inhibitor and known/suspected contraindications to sacubitril/valsartan
Renal vascular hypertension (including renal artery stenosis)
Significant renal estimated glomerular filtration rate disorder (eGFR calculated using modified Schwartz formula $< 30\%$ mean GFR for age); hepatic disorder (serum aspartate aminotransferase or alanine aminotransferase > 3 times upper limit of normal); gastrointestinal disorder or biliary disorder
History of angioedema
Parents or legal guardians of subject who do not give consent or allow the child to give assent, or inability of patient or parents/legal guardians to follow instructions or comply with follow-up procedures
Any medical condition(s) that may put the patient at risk in the investigator's opinion or that the investigator deems unsuitable for the study
Other protocol defined inclusion/exclusion criteria may apply

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

N/A: Single arm study

Study design: Masking

Open (masking not used)

Study design: Control

N/A

Study phase

2

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Single

Study design: Specify assignment

N/A

IMP has market authorization

Yes, Lebanon and Worldwide

IMP has market authorization: Specify

Lebanon and worldwide : yes for the dosage forms 50,100 and 200 mg and No for 12.5 and 31.25 mg

Name of IMP

sacubitril/valsartan

Year of authorization

2015

Month of authorization

11

**Type of IMP**

Others

Pharmaceutical class

LCZ696, also known as Entresto® (sacubitril/valsartan) is an angiotensin receptor neprilysin inhibitor (ARNI), providing concomitant neprilysin (neutral endopeptidase 24.11, NEP) inhibition and angiotensin II type 1 (AT1) receptor blockade

Therapeutic indication

Pediatric patients with heart failure

Therapeutic benefit

long-term safety and tolerability data in eligible CLCZ696B2319 (PANORAMA-HF) patients receiving open-label sacubitril/valsartan.

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**

Samples without DNA

Biospecimen description

blood and urine samples

Target sample size

10

Actual enrollment target size

1

Date of first enrollment: Type

Actual

Date of first enrollment: Date

03/01/2020

Date of study closure: Type

Actual

Date of study closure: Date

24/08/2022

Recruitment status

Recruiting

Recruitment status: Specify**Date of completion**

21/04/2021

**IPD sharing statement plan**

No

IPD sharing statement description

Undecided

Additional data URL

<https://clinicaltrials.gov/ct2/show/record/NCT03785405?cond=pediatric+heart+failure&rank=8&view=record>

Admin comments**Trial status**

Approved

Secondary Identifying Numbers

| Full name of issuing authority | Secondary identifying number |
|--------------------------------|------------------------------|
| Clinicaltrials.gov | NCT03785405 |

Sources of Monetary or Material Support

| Name |
|--------------------------|
| Novartis Pharma Services |

Secondary Sponsors

| Name |
|------|
| NA |

Contact for Public/Scientific Queries

| Contact type | Contact full name | Address | Country | Telephone | Email | Affiliation |
|--------------|-------------------|------------|---------|------------------------|-------------------------------|----------------------------------|
| Public | Linda Daou | Beirut | Lebanon | 961604976 | drlindadaou@gmail.com | Hotel Dieu |
| Scientific | Hind Khairallah | Sin El Fil | Lebanon | +961 1 512002 Ext. 271 | Hind.Khairallah@fattal.com.lb | Khalil Fattal et Fils s.a.l. |
| Public | Ghassan Chehab | Beirut | Lebanon | 9613388581 | ghassanchehab@yahoo.com | Rafik Hariri UNiversity Hospital |



Centers/Hospitals Involved in the Study

| Center/Hospital name | Name of principles investigator | Principles investigator speciality | Ethical approval |
|----------------------------------|---------------------------------|------------------------------------|------------------|
| Hotel Dieu de France | Linda Daou | Pediatric Cardiology | Approved |
| Rafik Hariri University Hospital | Ghassan Chehab | Cardiology | Approved |

Ethics Review

| Ethics approval obtained | Approval date | Contact name | Contact email | Contact phone |
|----------------------------------|---------------|--------------|--------------------------|--------------------|
| Hotel Dieu de France | 06/06/2019 | Sami Richa | cue@usj.edu.lb | 961421229 |
| Rafic Hariri University Hospital | 28/01/2019 | Rawan Yamout | rawan.yamout@crurhuh.com | 018300000 ext 2037 |

Countries of Recruitment

| Name |
|----------------|
| Austria |
| Argentina |
| Canada |
| Croatia |
| Czech Republic |
| Egypt |
| Finland |
| France |
| Germany |
| Hungary |
| India |
| Japan |
| Jordan |
| Poland |



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|-------------------------------------|
| Portugal |
| Romania |
| Russian Federation |
| Saudi Arabia |
| Singapore |
| South Africa |
| Democratic People Republic of Korea |
| Spain |
| Sweden |
| Switzerland |
| Thailand |
| Turkey |
| United Kingdom |
| United States of America |
| Lebanon |

Health Conditions or Problems Studied

| Condition | Code | Keyword |
|---------------|---------------------|---------|
| Heart Failure | Heart failure (I50) | HF |

Interventions

| Intervention | Description | Keyword |
|------------------------------------|------------------------------------|------------------------------------|
| ICF, Physical Exam, ECG, Lab tests | ICF, Physical Exam, ECG, Lab tests | ICF, Physical Exam, ECG, Lab tests |



Primary Outcomes

| Name | Time Points | Measure |
|--|--------------------------------|-------------------------|
| Number of participants with Adverse Events (AEs) as a measure of safety and tolerability | to end of study, up to 3 years | safety and tolerability |
| .Number of participants with Serious Adverse Events (SAEs) as a measure of safety and tolerability | to end of study, up to 3 years | safety and tolerability |

Key Secondary Outcomes

| Name | Time Points | Measure |
|-------------------------|-------------|---------|
| No secondary objectives | NA | NA |

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