



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

12/09/2025 08:41:48

## 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

09/12/2022

### 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 للبطن 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  $\geq 36$ -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**

9

**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**

30/12/2022

**Recruitment status**

Complete

**Recruitment status: Specify****Date of completion**

13/12/2021

**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       | Nasser Audi       | Beirut     | Lebanon | +961 76 708060         | dr.nasser.audi@gmail.com      | Rafic 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 | Nasser Audi                     | Pediatric 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         |
|                |



|                                     |
|-------------------------------------|
| 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