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

04/04/2025 23:39:55

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
14/10/2024

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 ساكيوبيتريل / فالسارتان المفتوح اللصاقة وقدرة تحمّله لدى أطفال مرضى مصابين بفشل القلب بسبب الخلل الوظيفي الانقباضي الجهازي للبُطين 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 PANORMA-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

6

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

29/08/2024

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	Pediatri 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