Study to Evaluate Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of LCZ696 Followed by a 52-week Study of LCZ696 Compared With Enalapril in Pediatric Patients With Heart Failure- PANORAMA

08/08/2025 10:17:38

Main Information

Primary registry identifying number
LBCTR2019040224

Protocol number
CLCZ696B2319

MOH registration number
22659/2018

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Retrospective

Type of registration: Justify
LCTR was recently initiated, original file was previously submitted by Paper

Date of registration in national regulatory agency
29/05/2018

Primary sponsor
Novartis Pharma Services Inc.

Primary sponsor: Country of origin
Novartis Pharmaceuticals

Date of registration in primary registry
17/08/2020

Date of registration in national regulatory agency
29/05/2018

Public title
Study to Evaluate Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of LCZ696 Followed by a 52-week Study of LCZ696 Compared With Enalapril in Pediatric Patients With Heart Failure- PANORAMA

Acronym
PANORAMA

Scientific title
Multicenter, Open-label Study to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of LCZ696 Followed by a 52-week Randomized, Double-blind, Parallel Group, Active-controlled Study to Evaluate the Efficacy and Safety of LCZ696 Compared With Enalapril in Pediatric Patients From 1 Month to < 18 Years of Age With Heart Failure Due to Systemic Left Ventricle Systolic Dysfunction

Acronym

Brief summary of the study: English
This study consist of two parts (Part 1 and Part 2). The purpose of Part 1 is to evaluate the way the body absorbs, distributes and removes the drug LCZ696. This will help determine the proper dose of LCZ696 for Part 2 of the study.

The purpose for Part 2 is to compare the effectiveness and safety of LCZ696 with enalapril in pediatric heart failure patients over 52 weeks of treatment.

Brief summary of the study: Arabic

52تليها دراسة لمدة LCZ696 دراسة متعددة المراكز، مفتوحة العنوان؛ لتقييم الأمان والتحمل والحركيات الدَّوائية والديناميكيات الدَّوائية لعقار LCZ696 مقارنة بعقار LCZ696 أسبوعًا عشوائية، مزدوجة التَّعمية، من مجموعات علاج متوازية، مُضبَطة بعقار فعَّال، ؛ لتقييم أمان وفعالية عقار سنة و يعانون من فشل القلب بسبب قصور جهازي بوظائف18إنالابريل في الأطفال المرضى الذين تتراوح أعمارهم بين شهر واحد إلى أقل من انقباض البطين الأيسر

Health conditions/problem studied: Specify

Cardiovascular / Pediatric Heart Failure

Interventions: Specify

Drug: LCZ696
LCZ696: 3.125 mg granules (packaged in capsules containing 4 or 10 granules), 50 mg, 100 mg, 200 mg dosage strengths
Drug: Enalapril
Enalapril will be open label in Part 1 and double blind in Part 2
Drug: Placebo of LCZ696
Drug: Placebo of Enalapril

Key inclusion and exclusion criteria: Inclusion criteria

Chronic heart failure resulting from left ventricular systolic dysfunction, and receiving chronic HF therapy (if not newly diagnosed)
NYHA classification II-IV (older children: 6 to <18 years old) or Ross CHF classification II-IV (younger children: < 6 years old)
Systemic left ventricular ejection fraction ≤ 40% or fractional shortening ≤20%
For Part 1 study: Patients must be treated with an ACEI or ARB prior to screening. Patients in Group 1 and 2 must be currently treated with the dose equivalent of at least enalapril 0.2 mg/kg prior to the LCZ696 3.1 mg/kg administration. Group 3 patients will participate in LCZ696 0.8 mg/kg and not LCZ696 3.1 mg/kg.
Biventricular physiology with systemic left ventricle

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

17

Key inclusion and exclusion criteria: Exclusion criteria

Patient with single ventricle or systemic right ventricle
Patients listed for heart transplantation (as United Network for Organ Sharing status 1A) or hospitalized waiting for transplant (while on inotropes or with ventricular assist device)
Sustained or symptomatic dysrhythmias uncontrolled with drug or device therapy
Patients that have had cardiovascular surgery or percutaneous intervention to palliate or correct congenital cardiovascular malformations within 3 months of the screening visit. Patients anticipated to undergo corrective heart surgery during the 12 months after entry into Part 2
Patients with unoperated obstructive or severe regurgitant valvular (aortic, pulmonary, or tricuspid) disease, or significant systemic ventricular outflow obstruction or aortic arch obstruction
Patients with restrictive or hypertrophic cardiomyopathy
Active myocarditis
Renal vascular hypertension (including renal artery stenosis)
Moderate-to severe obstructive pulmonary disease
Serum potassium > 5.3 mmol/L
History of angioedema
Allergy or hypersensitivity to ACEI / ARB

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Therapy

Trial scope: Specify scope

N/A

Study design: Allocation

Randomized controlled trial

Study design: Masking

Blinded (masking used)

Study design: Control

Active

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

Yes, Lebanon and Worldwide

IMP has market authorization: Specify

Approved for Adults use only : France, Germany, Belgium, UK, USA, KSA, UAE, Turkey

Name of IMP

LCZ696 Entresto

Year of authorization

2016

Month of authorization

3

Type of IMP

Others

Pharmaceutical class

angiotensin receptor neprilysin inhibitor

Therapeutic indication

Chronic Heart Failure

Therapeutic benefit

Global Rank endpoint through 52 weeks of Treatment

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

Biological samples : Urine, Hematology, Chemistry will be sent to Clinical Reference Laboratory, Europe Ltd.
7310 Cambridge Research Park
Beach Drive, Waterbeach
Cambridge, CB25 9TN
United Kingdom

Target sample size

8

Actual enrollment target size

8

Date of first enrollment: Type

Actual

Date of first enrollment: Date

17/08/2018

Date of study closure: Type
Actual

Date of study closure: Date
29/10/2021

Recruitment status
Recruiting

Recruitment status: Specify

Date of completion
30/04/2020

IPD sharing statement plan
No

IPD sharing statement description
Not provided

Additional data URL
https://clinicaltrials.gov/ct2/show/record/NCT02678312?term=pediatric&cond=Cardiovascular+Diseases&cntry=LB&rank=1

Admin comments

Trial status
Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Clinicaltrials.gov	NCT02678312

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	Ghassan Chehab	Beirut	Lebanon	009613388581	ghassanchehab@yahoo.com	Rafik Hariri University Hospital
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Public	Linda Daou	Beirut	Lebanon	009613524424	drlindadaou@gmail.com	Hotel Dieu De France

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hotel Dieu De France	Dr Linda Daou	Pediatric Cardiologist	Approved
Rafik Hariri University Hospital	Dr Ghassan Chehab	Pediatric Cardiologist	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Hotel Dieu de France	27/02/2018	Nancy Alam	nancy.alam@usj.edu.lb	+961 (0) 1 421000 ext 2335
Rafic Hariri University Hospital	09/01/2018	Rawan Yamout	rawan.yamout@crurhuh.com	018300000 ext 2036

Countries of Recruitment

Name
Lebanon
Argentina
Bulgaria
Canada
China
Croatia
Finland
France
Hungary
Japan
Jordan
Turkey
United States of America

Health Conditions or Problems Studied

Condition	Code	Keyword
Heart Failure	Heart failure, unspecified (I50.9)	HF

Interventions

Intervention	Description	Keyword
Physical Exam, Vital signs, ECG, Echocardiography, Urinalysis, Serum/ urine pregnancy test, lab test, completion of QoL questionnaires	Physical Exam, Vital signs, ECG, Echocardiography, Urinalysis, Serum/ urine pregnancy test, lab test, completion of QoL questionnaires	ICF, Lab, IMP, radiology

Primary Outcomes

Name	Time Points	Measure
Percentage of patients falling into each category based on global ranking	52 weeks	52 weeks
The global ranking is based on clinical events such as death, listing for urgent heart transplant, mechanical life support requirement at end of study, worsening heart failure (HF), New York Heart Association (NYHA)/Ross, Patient Global Impression of Severity (PGIS), Pediatric Quality of Life Inventory (PedsQL) physical functioning domain. The primary endpoint will be derived based on 5 categories ranking worst to best outcome	52 weeks	52 weeks

Key Secondary Outcomes

Name	Time Points	Measure
Time to first occurrence of Category 1 or Category 2 event	52 weeks	52 weeks
Change from baseline in NYHA/Ross functional class	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