

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

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Main Information       Protocol number         District field fie		
LBCT22019070260       CLC226082319E1         MOH registration number       Study registered at the country of origin         Yes       Study registered at the country of origin: Specify         Yes       Type of registration: Justify         Propertive       NA         Date of registration in national regulatory agency       Na         Primary sponsor       Primary sponsor: Country of origin         Novartis Pharma Services       Date of registration in national regulatory agency         Outcome of registration in primary registry       Date of registration in national regulatory agency         Outcome of registration in primary registry       Date of registration in national regulatory agency         Outcome of registration in primary registry       Date of registration in national regulatory agency         Outcome of Sacubitrill/Valastratian in Pediatic Date Mathematic Long- tem Safetry of Sacubitrill/Valastratian in Pediatic Date Mathematic Long- tem Safetry of Sacubitrill/Valastration in pediatic patients with heart faluer due (HF)       Acronym         Scientific title       Acronym         Partice title value (LC269682319)       Acronym         Brain (LC269682319)       Acronym         Scientific title       Acronym         Inpurpose of this study is to evaluate long-term safety and brain (LC269682319)       Acronym         Scinter of this study is LC269682319       Acronym	Main Information	
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Interventions: Specify Drug: sacubitril/valsartan	Health conditions/problem studied: Specify	
Drug: sacubitril/valsartan	Heart failure patients	
Drug: sacubitril/valsartan	Interventions: Specify	
Target dose 3.1 mg/kg bid		
	Target dose 3.1 mg/kg bid	

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#### Formulations:

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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)

#### Key inclusion and exclusion criteria: Inclusion criteria

Signed informed consent

Other Name: LCZ696

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
 Key inclusion and exclusion criteria: Specify gender

 Both
 Revenue of the second second

Key inclusion and exclusion criteria: Age minimum

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	Type of intervention: Specify ty	vpe	
Pharmaceutical	N/A		
Trial scope	Trial scope: Specify scope		
Safety	N/A		
Study design: Allocation	Study design: Masking		
N/A: Single arm study	Open (masking not used)		
Study design: Control	Study phase		
N/A	2		
Study design: Purpose	Study design: Specify purpose		
Study design: Purpose Treatment	Study design: Specify purpose N/A		
Treatment	N/A		
Treatment Study design: Assignment	N/A Study design: Specify assignm	ent	
Treatment Single	N/A Study design: Specify assignm N/A	ent Specify the dosage forms 50,100 and	
Treatment Study design: Assignment Single IMP has market authorization	N/A Study design: Specify assignm N/A IMP has market authorization: S Lebanon and worldwide : yes for t	ent Specify the dosage forms 50,100 and	



# Lebanon Clinical Trials Registry

Type of IMP	
Others	
Pharmaceutical class	
LCZ696, also known as Entresto® (sacubitril/valsartan) is an angiotensin rec (ARNI), providing concomitant neprilysin (neutral endopeptidase 24.11, NEP 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 (PANORAM open-label sacubitril/valsartan.	A-HF) patients receiving
Study model	Study model: Explain model
N/A	N/A
Study model: Specify model	
N/A	
Time perspective	Time perspective: Explain time perspective
N/A	N/A
Time perspective: Specify perspective	
N/A	
Target follow-up duration	Target follow-up duration: Unit
Number of groups/cohorts	
Biospecimen retention	Biospecimen description
Samples without DNA	blood and urine samples
Target sample size	Actual enrollment target size
10	1
Date of first enrollment: Type	Date of first enrollment: Date
Actual	03/01/2020
Data of study allowing Trans	
Date of study closure: Type	Date of study closure: Date
Actual	24/08/2022
Recruitment status	Recruitment status: Specify
Recruiting	
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+hea	rt+failure&rank=8&view=record
Admin comments	
<b>Trial status</b> 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	

Contac	t for Public/Scientific Queries	5				
Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Linda Daou	Beirut	Lebanon	961604976	drlindadaou@gm ail.com	Hotel Dieu
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Public	Ghassan Chehab	Beirut	Lebanon	961338858 1	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



## REPUBLIC OF LEBANON MINISTRY OF PUBLIC HEALTH Lebanon Clinical Trials Registry

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		

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	