NOVARTIS

## Clinical Trial Results Summary

# A clinical trial to collect additional safety information for LCZ696 in Japanese children with heart failure

# Thank you!

Thank you to the participants who took part in the clinical trial for **heart failure**. Every participant helped the researchers learn more about the trial drug **LCZ696**, also called sacubitril/valsartan.

Novartis sponsored this trial and believes it is important to share what was learned from the results of this trial with the participants and the public. We hope this helps the participants understand their important role in medical research.

## Trial information

**Trial number:** CLCZ696B2319E2

**Novartis drug studied: LCZ696**, also called sacubitril/valsartan

**Sponsor:** Novartis

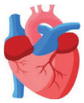
If you were a participant and have any questions about the results, please talk to the doctor or staff at the trial site.

This summary only shows the results of a single clinical trial. Other clinical trials may have different results.

# What was the main purpose of this trial?

The purpose of this trial was to collect additional safety information for **LCZ696** in Japanese children with **heart failure (HF)** who had completed a previous trial, **CLCZ696B2319E1**. This trial was a further extension of the **CLCZ696B2319E1** trial.

This trial continued until **LCZ696** was available in Japan in a formulation suitable for children to take.



**Heart failure (HF)** is a long-term condition where the heart becomes too weak to pump enough blood around the body. This reduces the oxygen supply needed for normal function, causing symptoms like shortness of breath, weakness, fatigue, and swollen ankles and legs.

**LCZ696** contains 2 medicines, **sacubitril** and **valsartan**. It is approved in many countries for the treatment of **HF** in adults and children. **LCZ696** works by relaxing the blood vessels which helps reduce the workload on the heart. This improves the heart's capacity to pump blood around the body.

**Trial drug**

**LCZ696** also called **sacubitril/valsartan**

**Pronounced as**

**su-KOO-bi-tril/val-SAR-tan**

**The trial's purpose was to answer this main question:**

- How many Japanese children had medical problems, also called adverse events, during this trial?

  ↳ An **adverse event** is any sign or symptom that participants have during a trial. Adverse events **may** or **may not** be caused by treatments in the trial.

# How long was this trial?

The trial began in December 2023 and ended in August 2024. The participants were in the trial for up to 9 months.

The researchers completed this trial as planned. When the trial ended, the researchers collected information from participants and created a report of the trial results. This summary is based on that report.

# Who was in this trial?

8 children with **HF** received treatment in this trial – 2 boys and 6 girls. The children's ages ranged from 3 to 16 years. Their average age was 6 years.

All the children were from Japan.

Japanese children could take part in this trial if they:

- were below 18 years of age
- had completed the previous trial and were eligible for this trial in the opinion of the trial doctor
- had not permanently discontinued **LCZ696** during the previous trial

# What treatment did the children receive?

The treatment in this trial was:

**LCZ696**, also called sacubitril/valsartan, given orally twice daily. It was used in 3 forms: tablets, capsules containing granules, and a liquid suspension. The weight of a child and the dose of **LCZ696** determined the form of **LCZ696** the child received.

The starting dose of **LCZ696** was decided by the trial doctor based on the children's condition.

The dose of **LCZ696** was gradually increased until it reached the target dose of 3.1 milligrams for every kilogram of body weight given twice daily.

The participants, researchers, and trial staff knew what treatment the participants were receiving. All participants took **LCZ696.**

# What happened during the trial?

## Before treatment — 1 Day

The trial staff checked to make sure the children could be in this trial.

## During treatment — Up to 8 months

- 8 children received **LCZ696** in this trial.
- The trial staff checked on the children's health via a phone call 3 months after the start of treatment and again at the trial site, either 6 months after the start of treatment and/or when the trial ended.
- Children could receive **LCZ696** until it was available in Japan in the form of granules inside capsules. Once it was available, they could continue receiving it as part of their regular healthcare, outside of this trial.

## After treatment — Up to 30 days

Trial staff checked the children's general health and for any medical problems for up to 30 days after the children received the last dose of trial treatment.

# What were the main results of this trial?

## How many Japanese children had medical problems, also called adverse events, during this trial?

Trial doctors keep track of all medical problems, also called **adverse events**, that happen in trials. They track adverse events even if they think the adverse events are not related to the trial treatments.

Many trials are needed to know if a drug or treatment causes an adverse event.

This section is a summary of the adverse events that happened from the start of treatment until 30 days after the last treatment.

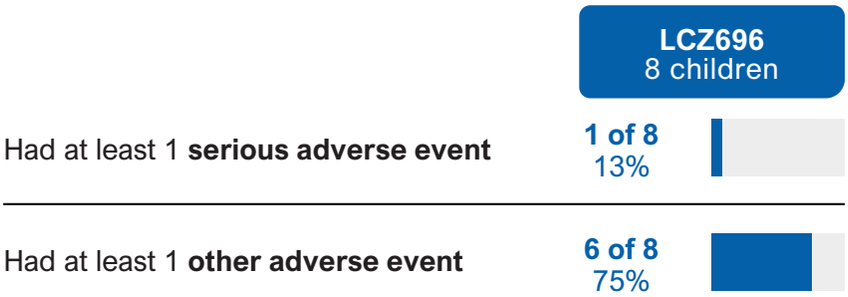
An **adverse event** is:

- Any **sign or symptom** that the participants have during a trial
- Considered **serious** when it is life-threatening, causes lasting problems, the participant needs hospital care, or results in death

Adverse events **may** or **may not** be caused by treatments in the trial.

## How many children had adverse events?

A total of 6 out of 8 children had adverse events. 1 child had adverse events that were considered serious. None of the children left the trial due to an adverse event or died. The researchers concluded there were no new safety concerns for **LCZ696** in this trial.



## What serious adverse events did the children have?

The 2 serious adverse events that happened in 1 of the 8 children (13%) were:

- **Infection of nose and throat** (upper respiratory tract infection)
- **Disease of the lung causing difficulty in breathing** (asthma)

## What other (not including serious) adverse events did the children have?

The most common other adverse event that happened in 2 of the 8 children (25%) was **common cold** (nasopharyngitis).

Other adverse events that happened during the trial were:

- **Bacterial infection** (streptococcal infection)
- **COVID-19**
- **Flu** (influenza)
- **Infection of nose and throat** (upper respiratory tract infection)
- **Inflammation of the inner lining of the nose due to an allergy** (rhinitis allergic)
- **Itchy skin rash** (eczema)
- **Low blood sugar** (hypoglycaemia)
- **Middle ear infection** (otitis media)
- **Muscle tightness**
- **Seasonal allergy**
- **Stomach flu** (gastroenteritis)
- **Urine infection** (urinary tract infection)
- **Vomiting**

# What was learned from this trial?

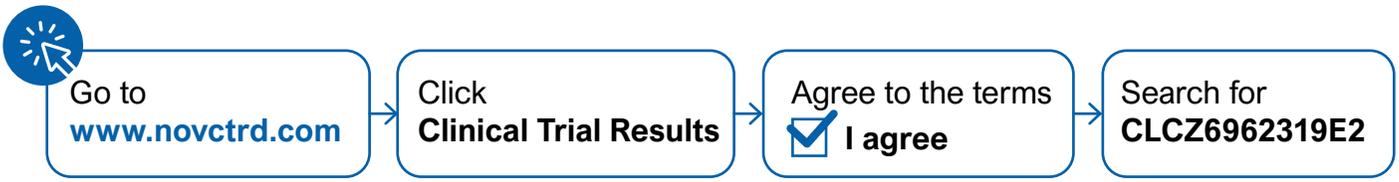
Researchers learned additional safety information for **LCZ696** in Japanese children with **heart failure (HF)**. Researchers did not find any new safety concerns with the use of **LCZ696** in this trial.

When this summary was written, the sponsor had no plans for future trials of **LCZ696** in children with **HF**.

# Where can I learn more about this trial?

More information about the results and adverse events in this trial can be found in the scientific summary of the results available on the Novartis Clinical Trial Results website, www.novctrd.com.

Follow these steps to find the scientific summary of **this trial**:




Follow these steps to find the scientific summary of the **previous trial:**


For more information about this trial, go to the following website:

- www.clinicaltrials.gov– search using the number **NCT06149104**

Other trials of **LCZ696** may appear on the public websites above. When there, search for **LCZ696** or sacubitril/valsartan.

**Full clinical trial title:** A multicenter, open-label study to collect the safety information of sacubitril/valsartan in Japanese pediatric patients with heart failure due to systemic left ventricle systolic dysfunction who have completed CLCZ696B2319E1 study

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