

## Clinical Trial Results Summary

### A clinical trial to learn about the effects of LOU064 on blood pressure in people with chronic spontaneous urticaria

#### Thank you!

Thank you to the participants who took part in the clinical trial for trial drug **LOU064**, also called remibrutinib. Every participant helped the researchers learn more about the effects of **LOU064** on blood pressure in people with chronic spontaneous urticaria.

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:** CLOU064A2305

**Novartis drug studied:** **LOU064**,  
also called remibrutinib

**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 learn about the effects of **LOU064** on blood pressure in people with chronic spontaneous urticaria. None of the participants had high blood pressure before they joined this trial. Some health authorities, such as the U.S. Food and Drug Administration (FDA), recommend this type of trial for drugs that are designed to be taken long term. This trial was not designed to look at the effects of **LOU064** on chronic spontaneous urticaria.



**Chronic spontaneous urticaria (CSU)** is a type of allergic disease in which the immune system becomes active even when there is no trigger (cause). When active, a protein called Bruton's Tyrosine Kinase (BTK) sends signals to release proteins that can cause inflammation in the body. This causes the chronic (long-lasting) hives and itching symptoms of CSU.

Sometimes, medicines used long term to treat diseases may cause side effects like high blood pressure. High blood pressure can raise the chance of serious health conditions, such as heart attack and stroke.



**LOU064**, also called remibrutinib, is a trial drug designed to bind to the protein BTK on certain cells in the immune system and lower the activity of these cells. By lowering the activity of these cells, researchers think **LOU064** could lessen symptoms of CSU.

## Hives from CSU



**Trial drug**  
**LOU064** also called  
remibrutinib  
**Pronounced as**  
rem-ee-bru-tih-nib



### The trial's purpose was to answer these main questions:

- Did participants' systolic blood pressure go up after taking LOU064 for 1 month?
  - ↳ **Systolic blood pressure** is the highest pressure in the arteries when the heart is pumping.
- What medical problems, also called adverse events, happened 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 April 2023 and ended in April 2024. Each participant was in the trial for up to about 5 months.

# Who was in this trial?



144 participants with CSU received treatment in this trial – 39 men and 105 women. Participants' ages ranged from 18 to 75 years. Their average age was 42 years.

The number of participants by race is shown below.



The participants could take part in this trial if they:

- Had CSU for at least 6 months before joining the trial
- Continued to have CSU while taking H1-antihistamines
- Had normal blood pressure before joining the trial
- Could wear a device that measured blood pressure for 24 hours

## What are H1-antihistamines?

**H1-antihistamines** are medicines to treat allergic reactions. H1-antihistamines, such as cetirizine, are the usual treatment for CSU.

144 participants from 10 countries received treatment. The map below shows the number of participants who took part in each country.



## What treatments did the participants receive?

The treatment in this trial was:



**LOU064**, also called remibrutinib, 25 milligrams, which was taken by mouth as tablets twice a day.

Along with the treatment above, all participants took H1-antihistamines for CSU.

The participants, researchers, and trial staff knew what treatment each participant took. All participants took **LOU064**.

# What happened during this trial?

## Before treatment

## Up to 1 month



The trial staff checked to make sure the participants could be in this trial. Participants wore a device for one day to continuously measure their blood pressure over 24 hours before starting treatment.

## During treatment

## 3 months



144 participants took **LOU064** twice a day for up to 3 months. Trial staff measured participants' blood pressure at trial visits.

After taking **LOU064** for a month, participants wore the device again for one day to continuously measure their blood pressure over 24 hours.

## After treatment

## About 1 month



Trial staff checked participants for any medical problems for up to about 1 month after participants' last dose of trial treatment.

At the end of this trial, participants who completed treatment in this trial were invited to join another trial called CLOU064A2303B to learn more about the effects of **LOU064**.

Trial staff checked the participants' general health throughout the trial.

# What were the main results of this trial?

## Did participants' systolic blood pressure go up after taking LOU064 for 1 month?



Participants' systolic blood pressure stayed about the same, on average, after taking **LOU064** for 1 month.

To learn this, participants wore a device that measured their blood pressure continually for 24 hours.

They wore the device 2 times:

- One time before they started taking **LOU064**
- Again after taking **LOU064** for a month

Researchers looked at the difference in the average **systolic blood pressure** between the 2 times they wore the device.

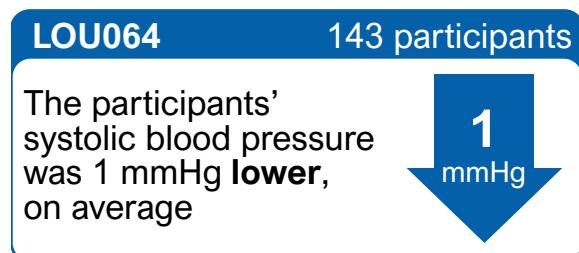
### What is systolic blood pressure?

**Systolic blood pressure** is the highest pressure in the arteries when the heart is pumping. It is the first, or top, number in a blood pressure measurement. Doctors often focus more on keeping systolic blood pressure in a safe range to prevent heart disease.

The other number in a blood pressure measurement is **diastolic blood pressure**. It is the lowest pressure in the arteries while the heart rests between beats. It is the second, or bottom, number in a blood pressure measurement and should also be kept within a safe range.

## Participants' systolic blood pressure stayed about the same, on average, after taking LOU064 for 1 month

This graph includes participants who had the required blood pressure results available.



# What were the other results of this trial?

## Did other measures of participants' blood pressure change after taking LOU064 for 1 month?



After taking **LOU064** for 1 month, other measures of participants' blood pressure stayed the same on average, including:

- Blood pressure while participants were asleep
- Diastolic blood pressure

## What medical problems, also called adverse events, happened 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 about 1 month after the last dose of trial 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.



More than half of the participants (86 of 144) had adverse events, which included serious and other (not including serious) adverse events. 4 participants had adverse events that were considered serious. 2 participants left the trial due to an adverse event. No participants died.

The researchers concluded there were no new safety concerns for **LOU064** in this trial.

## How many participants had adverse events?

LOU064  
144 participants

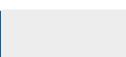
Had at least 1 **adverse event, including serious and non-serious**

86 of 144



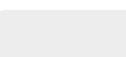
Had at least 1 **serious adverse event**

4 of 144



**Left the trial**  
due to an adverse event

2 of 144



## What serious adverse events did the participants have?

4 participants had serious adverse events. No participants died.

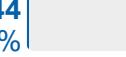
The table below shows the serious adverse events that happened in the trial. No serious adverse event happened in **more than 1** person.

LOU064  
144 participants

**Chronic hives that got worse**  
Chronic spontaneous urticaria

1 of 144

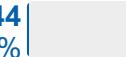
1%



**Feeling dizzy**  
Dizziness

1 of 144

1%



**Inflammation of the gallbladder**  
Cholecystitis acute

1 of 144

1%



**Tear in the inner layer of the large blood vessel that branches off the heart**  
Aortic dissection

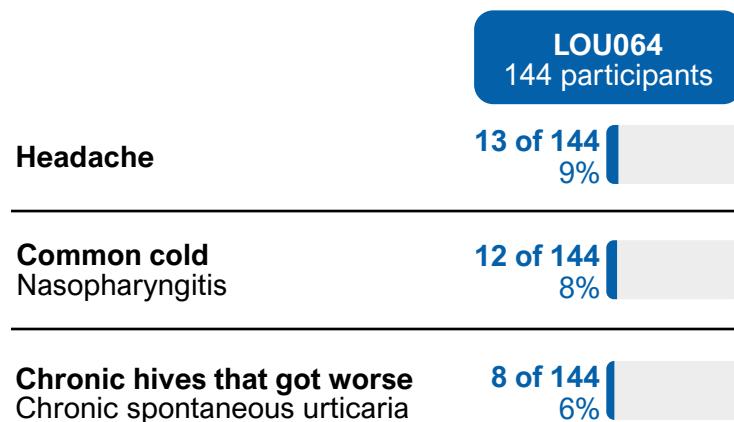
1 of 144

1%



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

The table below shows the 3 most common other adverse events. Additional adverse events happened in fewer participants.



## What was learned from this trial?

Researchers learned about the effects of **LOU064** on blood pressure in people with chronic spontaneous urticaria.



The researchers concluded that:

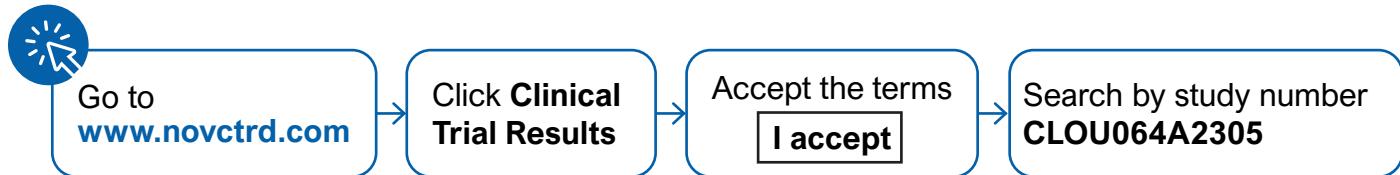
- Participants' blood pressure stayed about the same, on average, after taking **LOU064** for 1 month. This included participants' systolic and diastolic blood pressure while asleep.
- There were no new safety concerns for **LOU064** in this trial.

When this summary was written, an extension trial CLOU064A2303B was ongoing for some participants who completed this and other trials of **LOU064**.

# 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](http://www.novctrd.com)

Follow these steps to find the scientific summary:



For more information about this trial, go to any of these websites:

- [clinicaltrials.gov](https://clinicaltrials.gov) – search using the number **NCT05795153**
- [clinicaltrialsregister.eu](https://clinicaltrialsregister.eu) – search using the number **2022-002838-13**

Other trials of **LOU064** may appear on the public websites above. When there, search for **LOU064** or remibrutinib.

**Full clinical trial title:** A multicenter, open-label Phase 3 study: ambulatory blood pressure monitoring in adult patients with chronic spontaneous urticaria inadequately controlled by H1-antihistamines treated with remibrutinib up to 12 weeks.



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