

Clinical Trial Results Summary

A Study to Learn About the Effects of CSJ117 in People With Chronic Obstructive Pulmonary Disease (COPD)

Thank you!

Thank you to the participants who took part in the clinical trial for COPD. Every participant helped the researchers learn more about **CSJ117**.

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: CCSJ117B12201

Drug studied: CSJ117

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.

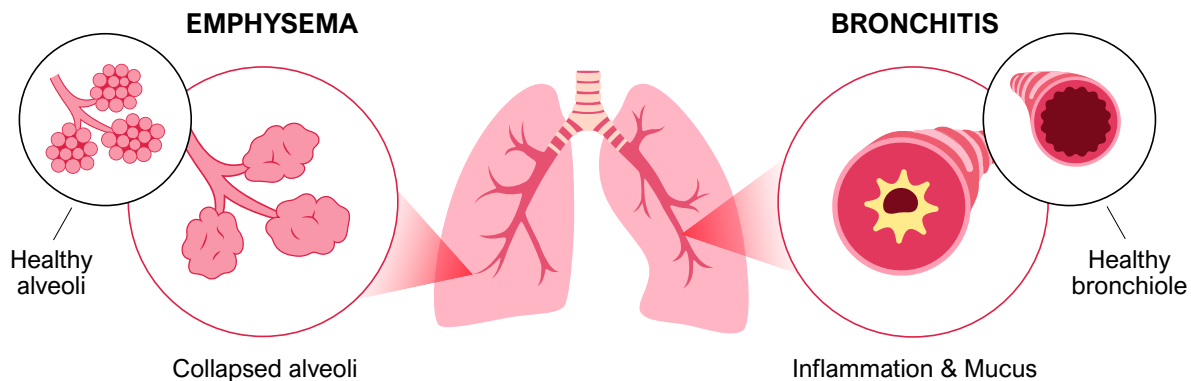
This summary only shows the results of a single clinical trial. Other clinical trials may have different findings.

What was the main purpose of this trial?

The purpose of this trial was to find out if CSJ117 can improve symptoms in participants with **chronic obstructive pulmonary disease (COPD)**.

COPD is a long-term disease that affects the lungs. There are 2 main forms of COPD:

- **Chronic bronchitis:** A condition where there is inflammation in the airways called bronchi in the lungs.
- **Emphysema:** A condition where there is damage to the walls of the air sacs called alveoli in the lungs.



Both of these conditions cause less oxygen to reach the lungs. As a result, breathing becomes difficult.

Common symptoms of COPD are:

- Coughing
- Wheezing
- Excess mucus or phlegm production
- Shortness of breath
- Lack of energy

When symptoms worsen, people with COPD may have COPD attacks. During an attack, the airways become more swollen and inflamed, making it hard to breathe.

There is no cure for COPD. Current treatments help to reduce the symptoms through opening the airways and making breathing easier. People with COPD are usually given medicines using an inhaler, which delivers the medicines directly to the lungs.

For long-term treatment, people with COPD may take a standard treatment of 3 medicines called a **triple combination therapy**. These medicines are inhaled corticosteroids (ICS), long-acting beta-agonists (LABA) and long-acting muscarinic antagonists (LAMA).

Sometimes, these treatments may not work for all patients or may stop working for some patients. As a result, there is a need to find new treatments.

A protein called **thymic stromal lymphopoietin (TSLP)** is thought to cause COPD symptoms. High amounts of TSLP are usually found in the lungs of patients with COPD. The trial drug, CSJ117, is designed to block TSLP, which may reduce COPD symptoms. CSJ117 is not currently approved to treat COPD.



The main questions that researchers wanted to answer were:

- How did the participants' COPD symptoms improve after 12 weeks of treatment?
- What adverse events did participants have during this trial?

↳ An **adverse event** is any sign or symptom that participants have during a trial.

How long was this trial?



The trial began in September 2021 and ended in September 2022. The entire duration was about 1 year. The trial was designed so that each participant would take part for up to 24 weeks.

The trial ended earlier than planned due to a strategic decision made by the sponsor.

When the trial ended, researchers created a report of the trial results. This summary is based on that report.

Who was in this trial?



37 participants with COPD received treatment in this trial.

Participants' ages ranged from 54 to 86 years. Their average age was 68 years.

The number of participants by gender and race are shown below.

Gender

18 Men

19 Women

Race

30 White

4 Black or African American

3 Asian

37 participants from **6 countries** received treatment. The map below shows the number of participants who took part in each country.



Participants **could take part** in this trial if they:

- Were at least 40 years of age or older
- Had a diagnosis of COPD at least 1 year before their first trial visit
- Were treated with LABA/LAMA/ICS for at least 3 months before their first trial visit
- Were current smokers or had a long history of smoking

Participants **could not take part** in this trial if they:

- Had asthma or a history of asthma
- Had other long-term or severe lung diseases

What treatments did the participants receive?

Researchers studied the following treatments:



CSJ117: Participants received one of the following doses: **4 or 8 milligrams (mg)**. Participants were given an inhaler along with capsules of CSJ117 which had to be placed into the device. The drug could then be inhaled directly into the lungs through the inhaler.



Placebo: Looks like the trial drug but does not have any active drug in it. Using a placebo helps researchers better understand the effect of the trial drug.

Participants would continue to take their regular COPD medicines, which was a triple combination of LABA, LAMA, and ICS, along with the trial drugs. People experiencing COPD attacks usually take rescue medicines for immediate relief. A **rescue inhaler** contains a medicine that quickly opens the airways. It was provided to participants to take in case immediate relief was needed.

In this trial, the participants, trial doctors, and trial staff did not know which doses of **CSJ117** or **placebo** that participants received. Doing a trial this way helps to make sure that the results are looked at with fairness across all treatments.

What happened during this trial?

Before treatment

Up to 2 weeks



At the start of the trial, all participants were checked to make sure they could take part.

Before Treatment: Observation Period

Up to 2 weeks



Participants continued taking their regular COPD triple combination medicines, and rescue medications if needed. Participants were observed for 2 weeks, and they recorded their COPD symptoms in the electronic diaries provided to them.

During treatment

Up to 12 weeks



Participants received CSJ117 or placebo, once a day for 12 weeks. Participants were assigned to 1 of 3 treatment groups. Neither trial staff nor participants knew which treatment the participants received.



CSJ117, 8 mg
11 participants



CSJ117, 4 mg
16 participants



Placebo
10 participants

Participants continued to record their COPD symptoms in their electronic diaries.

After treatment

Up to 8 weeks



Participants remained in the trial for an additional 8 weeks after their last dose of the trial drug. During this period, researchers checked participants' overall health and recorded adverse events.

What were the main results of this trial?

How did the participants' COPD symptoms improve after 12 weeks of treatment?

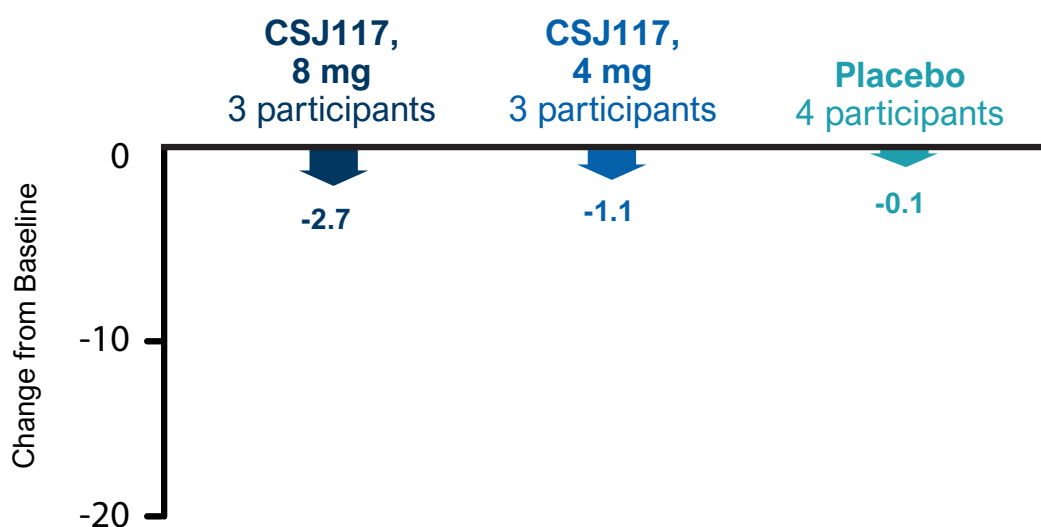


There were not enough participants for researchers to make a meaningful conclusion about the results.

To answer this question, researchers analyzed the data collected in the electronic diaries. They compared the severity of the symptoms before the 1st CSJ117 dose to the severity at the end of the 12 weeks of treatment.

The chart below shows the results for 10 participants who took at least one dose of study treatment and recorded their COPD symptoms in the electronic diary before treatment and at Week 12.

Decrease in the Severity of COPD Symptoms at Week 12



What adverse events did the participants have?

Trial doctors keep track of all **adverse events** that happen in trials, 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 during the treatment plus 8 weeks after the 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.



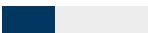
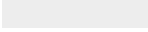
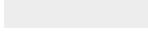
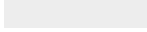
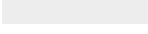
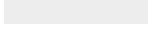
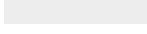
A total of 21 of 37 participants had adverse events.

- 3 participants had adverse events that were considered serious.
- None of the participants died or left the trial due to adverse events.

The researchers concluded there were no new unexpected safety concerns for CSJ117 for this trial.

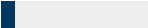
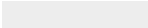
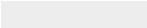
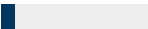
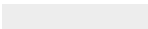
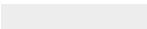
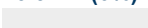
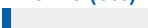
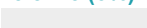
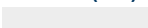
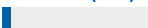
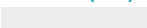
How many participants had adverse events?

The table below shows how many participants had adverse events at any time during the trial.

Summary of adverse events			
Participants who:	CSJ117, 8 mg 11 participants	CSJ117, 4 mg 16 participants	Placebo 10 participants
Had at least 1 adverse event	4 of 11 (36%) 	10 of 16 (63%) 	6 of 10 (60%) 
Had at least 1 serious adverse event	1 of 11 (9%) 	2 of 16 (13%) 	0 of 10 (0%) 
Left the trial due to an adverse event	0 of 11 (0%) 	0 of 16 (0%) 	0 of 10 (0%) 
Died	0 of 11 (0%) 	0 of 16 (0%) 	0 of 10 (0%) 

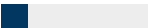
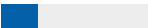
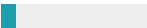
What serious adverse events did the participants have?

A total of 3 participants who received at least 1 dose of trial drug had serious adverse events. One participant from the CSJ117, 8mg group had more than one serious adverse event. The table below shows how many participants had serious adverse events.

Serious adverse events			
	CSJ117, 8 mg 11 participants	CSJ117, 4 mg 16 participants	Placebo 10 participants
Low red blood cell count Anemia	1 of 11 (9%) 	0 of 16 (0%) 	0 of 10 (0%) 
Low red blood cell count due to low iron Iron deficiency anemia	1 of 11 (9%) 	0 of 16 (0%) 	0 of 10 (0%) 
Pain and inflammation in the joints caused by a bacterial infection Arthritis bacterial	0 of 11 (0%) 	1 of 16 (6%) 	0 of 10 (0%) 
Worsening of COPD Chronic obstructive pulmonary disease	0 of 11 (0%) 	1 of 16 (6%) 	0 of 10 (0%) 

What other adverse events did the participants have?

A total of 18 participants who received at least 1 dose of trial drug had other adverse events. The only adverse event that happened in more than 1 participant was worsening of COPD that was not considered serious.

Other adverse events			
	CSJ117, 8 mg 11 participants	CSJ117, 4 mg 16 participants	Placebo 10 participants
Worsening of COPD Chronic obstructive pulmonary disease	2 of 11 (18%) 	4 of 16 (25%) 	1 of 10 (10%) 

What was learned from this trial?

This trial helped researchers learn about the effects of CSJ117 in people with COPD.



The researchers concluded that after 12 weeks of treatment:

- Due to the small number of participants, no meaningful conclusions could be drawn.
- No new unexpected safety concerns were found.

The trial ended earlier than planned due to a strategic decision made by the sponsor. Currently, there are no further studies with CSJ117 planned.

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:



Go to
www.novctrd.com



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Clinical Trial Results



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Search for
CCSJ117B12201

For more information about this trial go to any of the following websites:

- clinicaltrials.gov – search using the number **NCT04882124**
- clinicaltrialsregister.eu/ctr-search/search – search using the number **2019-004905-29**

Full clinical trial title: A 12-week, Randomized, Participant-and Investigator-blinded, Placebo-controlled, Parallel Group Study to Explore the Efficacy, Pharmacodynamics, Safety, and Pharmacokinetics of Two Doses of Inhaled CSJ117 in Adults with Chronic Obstructive Pulmonary Disease (COPD).



Novartis is a global healthcare company based in Switzerland that provides solutions to address the evolving needs of patients worldwide.

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