NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn about the effects and safety of LTP001 in people with idiopathic pulmonary fibrosis

Thank you!

Thank you to the participants who took part in the clinical trial for idiopathic pulmonary fibrosis. Every participant helped the researchers learn about the trial drug **LTP001**.

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: CADPT09A12201

Novartis drug studied: **LTP001**

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 and safety of **LTP001** for people with idiopathic pulmonary fibrosis.

Idiopathic pulmonary fibrosis, also called **IPF**, is a long-term lung condition that causes scarring in the lungs and has no known cause. **Fibrosis**, or scarring means that thick, scar tissue replaces healthy lung tissue. The scarring gets worse over time and makes it harder to breathe. Currently, there is no cure for IPF, but there are treatments for the symptoms.

LTP001 is a trial drug designed to block a protein that may play a role in IPF. Researchers think blocking this protein could stop fibrosis from getting worse and make breathing easier.

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

- Could participants breathe easier after taking LTP001?
- 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 November 2022 and ended in September 2024. The participants started the trial on different dates.

In July 2024, the sponsor decided to end this trial early. The decision to stop this trial early was a business decision and not related to the safety of **LTP001**.

Who was in this trial?

46 participants with IPF received treatment in this trial – 33 men and 13 women. Participants' ages ranged from 54 to 82 years. Their average age was 70 years.

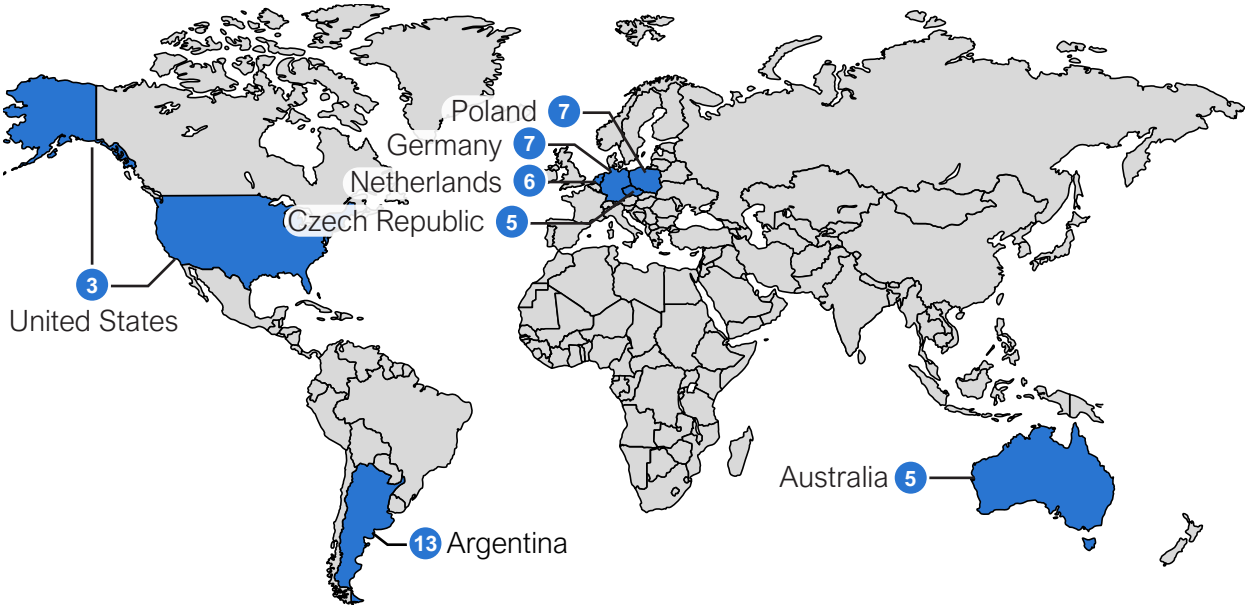
The number of participants by race is shown below.

Race	
White	46

The participants could take part in this trial if they had IPF and:

- They were not likely to need a lung transplant
- Their IPF did not get worse in the last 3 months
- They did not have certain other medical conditions

46 participants from 7 countries took treatment. The map below shows the number of participants who took part in each country.



What treatments did the participants receive?

The treatments in this trial were:

LTP001 – 6 milligrams (mg), which was taken by mouth as capsules once a day.

Placebo, which was taken by mouth as capsules once a day. It looks like the trial drug but does not have any drug in it. Using a placebo helps researchers better understand the effect of a trial drug.

Some participants continued taking certain medicines for IPF during the trial.

Researchers used a computer to randomly assign participants to their treatment.

The participants, researchers, and trial staff did not know what treatment the participants were taking. Some trials are done this way because knowing what treatment the participants take can affect the results of the trial. 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

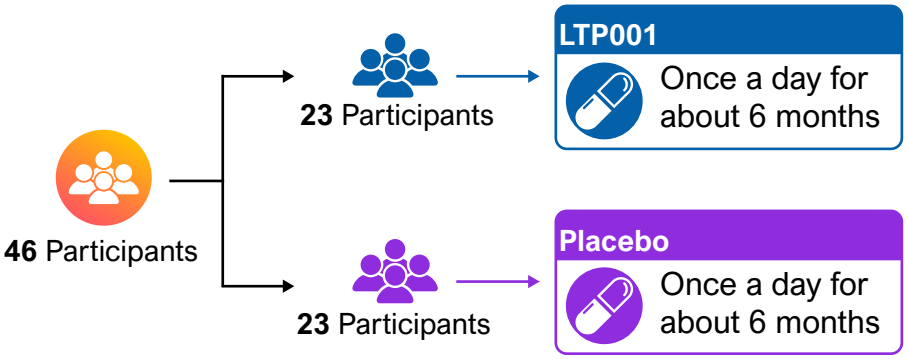
About 6 weeks

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

During treatment

About 6 months

The graphic below shows how many participants were assigned each treatment.



After treatment

About 1 month

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

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

What were the main results of this trial?

Could participants breathe easier after taking LTP001?

Researchers could not conclude if participants could breathe easier after taking **LTP001** compared to **placebo**. This was because the trial ended early and there were too few participants.

To learn this, researchers measured each participant's Forced Vital Capacity, also called FVC. **FVC** is how many milliliters (mL) of air a person can blow out. Then, the researchers calculated each participant's **percent predicted FVC**.

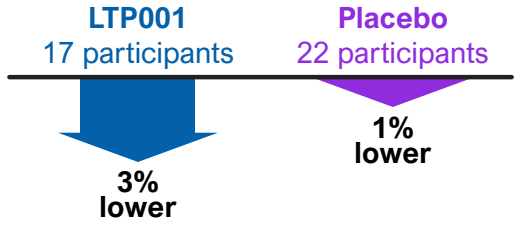
Researchers measured each participant's FVC before treatment and after about 6 months of treatment. Then, researchers compared the average change in percent predicted FVC for participants who took **LTP001** to those who took the **placebo**.

What is percent predicted FVC?

Percent predicted FVC compares a participant's FVC to the FVC researchers would expect if that same person had no lung conditions. A **lower percent** predicted FVC means it is **harder for a person to breathe**.

Change in percent predicted FVC

The results below show the change in participants' percent predicted FVC after about 6 months of treatment.



These results only include participants who had data available.

What were the other results of this trial?

Did LTP001 change participants' quality of life or other measures of their IPF?

LTP001 did not change quality of life or other measures of their IPF compared to **placebo**. However, researchers could not conclude if these results were meaningful. This was because there were too few participants in the trial.

To learn this, researchers looked at participants' answers to questions about their symptoms and how their symptoms impact their daily activities.

They also measured:

- FVC
- How well the lungs work using a test called Diffusing Capacity of the Lungs
- How far the participants could walk in 6 minutes

They looked at the changes in these measures from before treatment to after about 6 months of treatment.

The researchers also looked at:

- How many participants had their FVC go down, which means it became harder to breathe, compared to when they started the trial
- The length of time people lived until:
  - Their FVC went down compared to when they started the trial
  - They had a hospital stay for a breathing issue
  - They needed a lung transplant
  - They died

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 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 (34 of 46) had adverse events. 3 participants had adverse events that were considered serious. 1 participant died.
1 participant left the trial due to an adverse event. The researchers concluded there were no new safety concerns for **LTP001** in this trial.

How many participants had adverse events?

	LTP001 23 participants	**Placebo** 23 participants
Had **any adverse event**	**18 of 23** 78%	**16 of 23** 70%
Had at least 1 **serious adverse event**	**2 of 23** 9%	**1 of 23** 4%
Had at least 1 **other adverse event**	**14 of 23** 61%	**7 of 23** 30%
Left the trial due to an adverse event	**1 of 23** 4%	**0 of 23** 0%
Died	**1 of 23** 4%	**0 of 23** 0%

What serious adverse events did the participants have?

3 participants had serious adverse events. 1 participant in the **LTP001** group died.

The table below shows the serious adverse events.

	LTP001 23 participants	Placebo 23 participants
IPF that got worse Idiopathic pulmonary fibrosis	1 of 23 4%	1 of 23 4%
Shingles Herpes zoster	1 of 23 4%	0 of 23 0%
Infection after surgery Infection	1 of 23 4%	0 of 23 0%
Bladder problems Bladder disorder	1 of 23 4%	0 of 23 0%

What other adverse events did the participants have?

21 participants had other adverse events.

The table below shows the other adverse events that happened in **3 or more** participants. Additional adverse events happened in fewer participants.

	LTP001 23 participants	Placebo 23 participants
Frequent, loose, or watery stool Diarrhea	5 of 23 22%	1 of 23 4%
Joint pain Arthralgia	3 of 23 13%	1 of 23 4%
Cough	2 of 23 9%	1 of 23 4%
Headache	1 of 23 4%	2 of 23 9%
UTI Urinary tract infection	1 of 23 4%	2 of 23 9%

What was learned from this trial?

Researchers learned about the effects and safety of **LTP001** in people with idiopathic pulmonary fibrosis, also called IPF. The sponsor ended this trial early for business reasons and was not related to the safety of **LTP001**.

Researchers could not conclude if **LTP001** changed how easily participants could breathe compared to **placebo**. This was because the trial ended early and there were too few participants.

LTP001 did not change quality of life or other measures of their IPF compared to **placebo**. However, researchers could not conclude if these results were meaningful because there were too few participants in the trial.

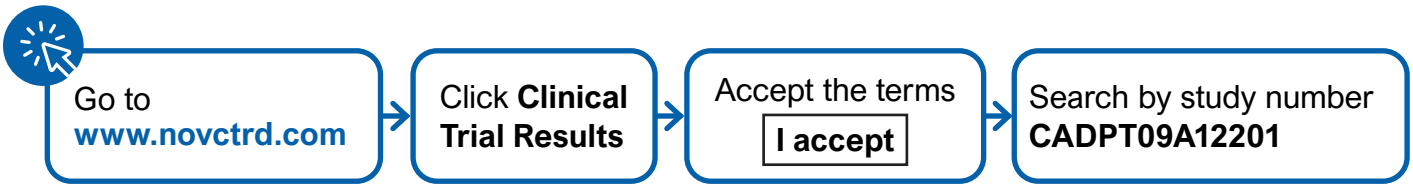
The researchers concluded there were no new safety concerns for **LTP001** in this trial.

When this summary was written, the sponsor had plans for future trials of **LTP001** in people with IPF.

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:



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

- **clinicaltrials.gov** – search using the number **NCT05497284**
- **euclinicaltrials.eu** – search using the number **2023-508729-28-00**

Other trials of **LTP001** may appear on the public websites above. When there, search for **LTP001**.

Full clinical trial title: A participant- and investigator-blinded, randomized, placebo-controlled, multicenter, platform study to investigate efficacy, safety, and tolerability of various single treatments in participants with idiopathic pulmonary fibrosis

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

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www.novartis.com/clinicaltrials