NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about the effects of ACZ885 in adults who had complete surgical removal of advanced non-small cell lung cancer

Thank you!

Thank you to the participants who took part in the clinical trial for advanced non-small cell lung cancer. Every participant helped the researchers learn more about the trial drug **ACZ885**, also called **canakinumab**.

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: CACZ885T2301
Drug studied: **ACZ885** also known as **canakinumab**
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 learn about the effects of **ACZ885** in people with advanced **non-small cell lung cancer** (**NSCLC**). To find this out, researchers compared the effects of **ACZ885** to a **placebo**.

NSCLC is a type of cancer that starts in the lungs. The cancer cells in the lungs divide rapidly and spread to other parts of the body. At this stage the cancer is called as 'advanced.'

There is a chemical substance in the body called interleukin-1 beta (IL-1β) that causes inflammation. IL-1β is thought to play an important role in the development of **NSCLC**. As **ACZ885** can block IL-1β, researchers believe it can help treat **NSCLC**.

Trial drug
Canakinumab.

Pronounced as
kan-a-KIN-oo-mab

ACZ885 is not approved for the treatment of cancer.

A **placebo** looks like the trial drug but does not have any trial drug in it. Using a **placebo** helps researchers better understand the effect of a trial drug.

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

- How long did the participants remain cancer-free after receiving **ACZ885** compared to **placebo**?
- **What adverse events did the 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 March 2018 and ended in February 2023. It was planned for the participants to be in the trial for about 5 years after receiving the trial treatment. However, the sponsors decided to end the trial early as the initial analysis showed that **ACZ885** did not have the expected effect on the advanced **NSCLC.**

Who was in this trial?

1382 participants with advanced **NSCLC** entered in this trial. Participants' ages ranged from 21 to 83 years. Their average age was 62 years. The number of participants by gender and race is shown below.

Gender

- 862 Men
- 520 Women

Race

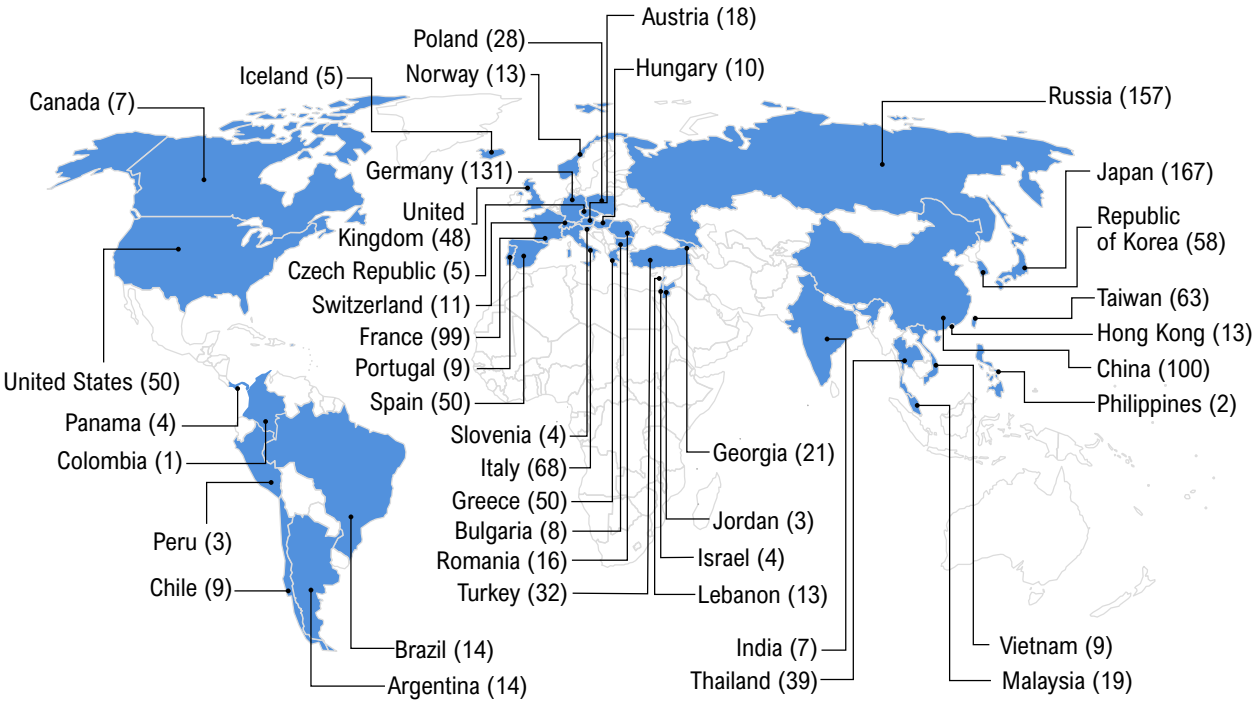
- 784 White
- 484 Asian
- 7 Black or African American
- 5 American Indian or Alaska Native
- 1 Multiple races
- 101 Missing

The participants could take part in this trial if they:

- had complete surgical removal of their cancer,
- had completed radiation or chemotherapy after the surgical removal of their cancer,
- had recovered from side effects of any medicines they took earlier, and
- could at least move and were able to carry out work of a light nature.

1382 participants from 41 countries entered this trial. The map below shows the number of participants who took part in each country.

Out of 1382 participants, 1381 participants received treatment in this trial.



What treatments did the participants receive?

The treatments in this trial were:

ACZ885, was given at a dose of 200 milligrams (mg): one 50 mg injection and one 150 mg injection under the skin. Both injections were given on Day 1 of the 21-day treatment cycle.

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

Researchers randomly assigned participants to the treatment groups using a computer.

None of the participants, trial doctors, or trial staff knew what treatment the participants were receiving. Some trials are done this way because knowing what treatment the participants receive 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 — 1 month

Trial doctors checked the participants' health and advanced **NSCLC** to make sure they could be in this clinical trial.

During treatment — 1 year

1381 patients were randomly assigned and treated with one of the following 2 treatments:

ACZ885 200 mg	Placebo
(692 participants)	(689 participants)

Participants could receive treatment for up to 18 cycles or until:

- their cancer returned,
- they had severe side effects,
- they started a new treatment,
- they left the trial by their own will or due to the trial doctor's decision, or
- they were unreachable for further follow up or died.

What is a Cycle?

A cycle is a treatment period of 21 days that can be repeated as needed. The participants received the trial drug once on Day 1 of each cycle.

As the trial was stopped earlier than planned, the treatment was also stopped earlier.

Trial doctors checked the participants' advanced **NSCLC** and general health throughout the trial.

After treatment — up to 4 years

- Participants' health was monitored for 4 months after their last dose.
- Participants were checked for return of cancer or death until the end of the trial.

What was the main result of this trial?

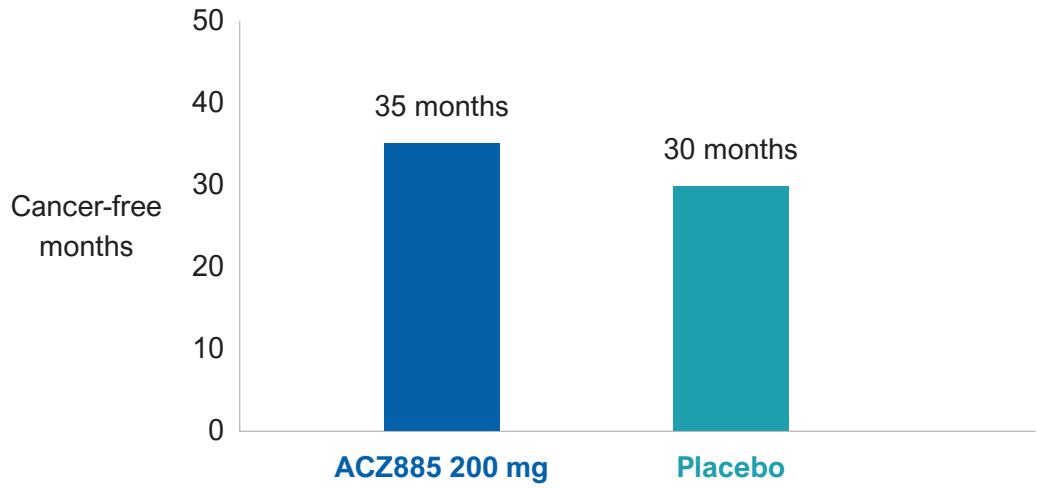
How long did the participants remain cancer-free after receiving ACZ885 compared to placebo?

The time for which the participants remained cancer-free after receiving ACZ885 was similar to those who received placebo.

To answer this question, the researchers monitored how long the participants remained cancer-free since the start of treatment.

Participants remained cancer-free on average for 35 months after receiving **ACZ885** compared to 30 months after receiving **placebo**. As the time for which the participants remained cancer-free was not notably different, researchers concluded that **ACZ885** did not increase the amount of time the participants remained cancer-free when compared to **placebo**.

The average time participants remained cancer-free



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 after the start of the trial treatments up to 4 months after last dose.

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.

87% (1207 of 1381) of the participants had adverse events. 22% (287 of 1381) participants had adverse events that were considered serious. 26 participants died. The most common cause of death was worsening of the cancer. 65 participants left the trial due to an adverse event.

The researchers concluded there were no new safety concerns for **ACZ885** for this trial.

How many participants had adverse events?

Participants who:	ACZ885 200 mg 692 participants	Placebo 689 participants
Had at least 1 serious adverse event	**141 of 692** 20%	**146 of 689** 21%
Had at least 1 other adverse event	**465 of 692** 67%	**455 of 689** 66%
Stopped treatment due to an adverse event	**34 of 692** 5%	**31 of 689** 4%
Died	**9 of 692** 1%	**17 of 689** 2%

What serious adverse events did the participants have?

287 participants had serious adverse events. 26 participants died – 9 participants in the **ACZ885** group and 17 in the **placebo** group.

The table below shows the most common serious adverse events that happened in 1% or more participants in any treatment group.

	ACZ885 200 mg 692 participants	**Placebo** 689 participants
COVID 19	**48 of 692** 7%	**48 of 689** 7%
Difficulty in breathing Dyspnea	**7 of 692** 1%	**2 of 689** <1%
Lung infection Pneumonia	**13 of 692** 2%	**9 of 689** 1%

What other adverse events did the participants have?

920 participants had other adverse events.

The table below shows the other adverse events that happened in **8% or more** participants in any treatment group.

	ACZ885 200 mg 692 participants	**Placebo** 689 participants
Back pain	**61 of 692** 9%	**56 of 689** 8%
Cough	**89 of 692** 13%	**108 of 689** 16%
Diarrhea	**57 of 692** 8%	**48 of 689** 7%
Difficulty in breathing Dyspnea	**67 of 692** 10%	**50 of 689** 7%
Extreme tiredness Fatigue	**70 of 692** 10%	**60 of 689** 9%
Headache	**31 of 692** 4%	**60 of 689** 9%
Increase in body weight Weight increased	**63 of 692** 9%	**48 of 689** 7%
Increase in liver test value of alanine aminotransferase in the blood Alanine aminotransferase increased	**65 of 692** 9%	**49 of 689** 7%
Joint pain Arthralgia	**74 of 692** 11%	**88 of 689** 13%

What was learned from this trial?

Researchers learned about the effects of **ACZ885** in people with advanced **NSCLC**.

- The sponsors decided to end the trial early as the initial analysis showed that **ACZ885** did not have the expected effect on participants who had complete surgical removal of their advanced **NSCLC**.
  The researchers found no significant difference between the effect of **ACZ885** and **placebo** in treating adults with advanced **NSCLC**.
- Researchers found no new safety concerns for **ACZ885**.

At the time of this report no new trials with **ACZ885** in advanced **NSCLC** are 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** → Click **Clinical Trial Results** → Agree to the terms ☑ **I agree** → Search for **CACZ885T2301**

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

- **clinicaltrials.gov** – search using the number **NCT03447769**
- **clinicaltrialsregister.eu/ctr-search/search** – search using the number **2017-004011-39**

Full clinical trial title: A phase III, multicenter, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of canakinumab versus placebo as adjuvant therapy in adult patients with stages American Joint Committee on Cancer (AJCC)/ Union for International Cancer Control (UICC) v. 8 II-IIIA and IIIB (T>5cm N2) completely resected (R0) non-small cell lung cancer (NSCLC)

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1-888-669-6682 (US) | +41-61-324 1111 (EU)

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