Clinical Trial Results Summary

NOVARTIS

The breathing effects and safety of CJM112 for people with asthma

Thank you!

Thank you to the participants who took part in the clinical trial for the drug **CJM112**. All of the participants helped the researchers learn more about how CJM112 works and how safe it is to take.

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. An independent organization prepared this summary of the trial results.

We hope this helps the participants understand their important role in medical research.

Trial information

Trial number: CCJM112X2204
Drug studied: CJM112
Sponsor: Novartis

You can find **more information** about this trial by going to the websites listed on **pages 11-12** of this summary.

? If you participated in the trial and have **questions** about the results, please speak with the trial doctors or staff at your trial site.

This trial at a glance

What was the purpose of this trial?

Read more on **page 3**

The purpose of this trial was to learn if the trial drug CJM112 could change how easily people with moderate to severe asthma could breathe. This trial focused on people with asthma that wasn't well treated with typical asthma medicines.

The main questions this trial was designed to answer:

- Did CJM112 change how easily the participants could breathe?
- What medical problems did the participants have in this trial? Keeping track of the medical problems helped to learn about the safety of CJM112.

Who was in this trial?

Read more on **pages 3-4**

- 118 men and women were in this trial
- The participants were 22 to 76 years old and had moderate to severe asthma that wasn't well treated with typical asthma medicines

What treatments did the participants receive?

Read more on **page 4**

Each participant was assigned one of these treatments:

- CJM112
- Placebo – looks like the trial drug but has no trial drug in it. Using a placebo helps researchers better understand the actual effects of a trial drug.

Each participant received their assigned treatment as an injection under the skin. They also continued taking their regular medicines for asthma.

What were the main results of this trial?

Read more on **pages 5-9**

On average, participants who received CJM112 could breathe slightly easier compared to those who received the placebo. The clinical trial team concluded this difference was not meaningful.

Most of the participants had an adverse event during this trial. The participants who received CJM112 had a similar number of adverse events as those who received the placebo. The most common adverse event was asthma that got worse.

This trial had other results along with the main results. Read more on **page 10**

What was the purpose of this clinical trial?

Researchers are looking for better ways to treat asthma. **Asthma** is a disease that causes the airways of the lungs to swell, making it hard to breathe. The symptoms of asthma include:

- Shortness of breath: feeling like you can't breathe fast enough or deeply enough
- Wheezing: a high-pitched whistling sound while breathing
- Coughing
- Chest tightness

There is currently no cure for asthma. Different types of medicines can help some people with asthma breathe easier. For certain people with moderate to severe asthma, typical asthma medicines do not always work as well.

People with more severe asthma may have higher levels of an immune system protein called **IL-17A** in the airways of their lungs. The trial drug **CJM112** is designed to block IL-17A. The purpose of this trial was to learn if CJM112 could change how easily people with moderate to severe asthma could breathe.

What is the immune system?
The immune system is made of cells and proteins that protect the body from disease and infection.

Before a drug can be approved for doctors to prescribe, researchers do many trials to find out how safe it is and how well it works.

The main questions this trial was designed to answer:

- Did CJM112 change how easily the participants could breathe?
- What medical problems did the participants have in this trial? Keeping track of the medical problems helped to learn about the safety of CJM112.

Who was in this trial?

118 participants received a trial treatment – 71 women and 47 men. They were 22 to 76 years old. Their average age was 57.

Every participant in this trial had moderate to severe asthma that wasn't well treated with typical asthma medicines.

The participants also:

- Took at least 2 typical asthma medicines regularly for at least 3 months before the trial
- Had no serious changes in their breathing or asthma symptoms during the 4 weeks before the trial
- Were in otherwise good overall health

This trial took place in Argentina, Belgium, Germany, Denmark, France, Israel, Slovakia, and the United States.

Visit novctrd.com for more information about:

- Who could and could not be in this trial
- The participants in this trial, such as their age, gender, and race

Use trial number **CCJM112X2204** to find the scientific summary.

What treatments did the participants receive?

A computer program was used to randomly assign each participant the treatment they received:

- **CJM112**, 300 milligrams (mg)
- **Placebo** – looks like the trial drug but has no trial drug in it. Using a placebo helps researchers better understand the actual effects of a trial drug.

Using a computer program to assign the treatments helped make sure the team compared the results as fairly as possible.

The participants received their assigned treatment as injections under the skin for 12 weeks. They received 9 total doses: the first 5 doses once a week, and the last 4 doses every other week.

The participants and trial staff did not know what treatment each participant received during the trial. Some trials are done this way because knowing what treatment participants receive can influence the results. Not knowing what treatment participants receive helps make sure the results are looked at fairly.

Each participant also continued taking their regular medicines for asthma and could use a rescue inhaler, if needed.

What happened during this trial?

The trial began in November 2017 and ended in July 2019. 16 participants did not complete this trial.

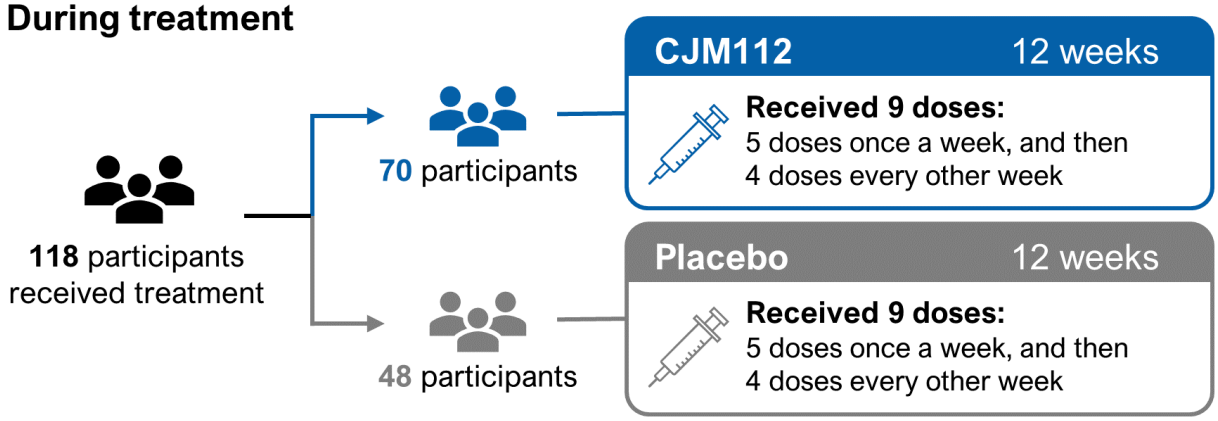
The chart below shows how the trial was done.

Here's how this trial was done:

Before treatment

- The trial doctors checked each participant's health and asthma symptoms to make sure they could be in this trial
- The trial staff measured how well each participant could breathe

During treatment



- Each participant also continued taking their regular medicines for asthma and could use a rescue inhaler, if needed
- The trial staff measured each participant's breathing and asthma symptoms during certain trial visits

After treatment

- At 1, 7, and 13 weeks after their last dose, each participant returned to the trial site for the trial doctors to check their health and asthma symptoms

What were the main results of this trial?

This is a summary of the overall results of this trial. Individual results from each participant may be different and are not included in this summary. Researchers need many trials to learn if a drug or other treatment is safe and works well. Other trials may provide new information or different results. Always talk to a doctor before making any changes to your health care.

Did CJM112 change how easily participants could breathe?

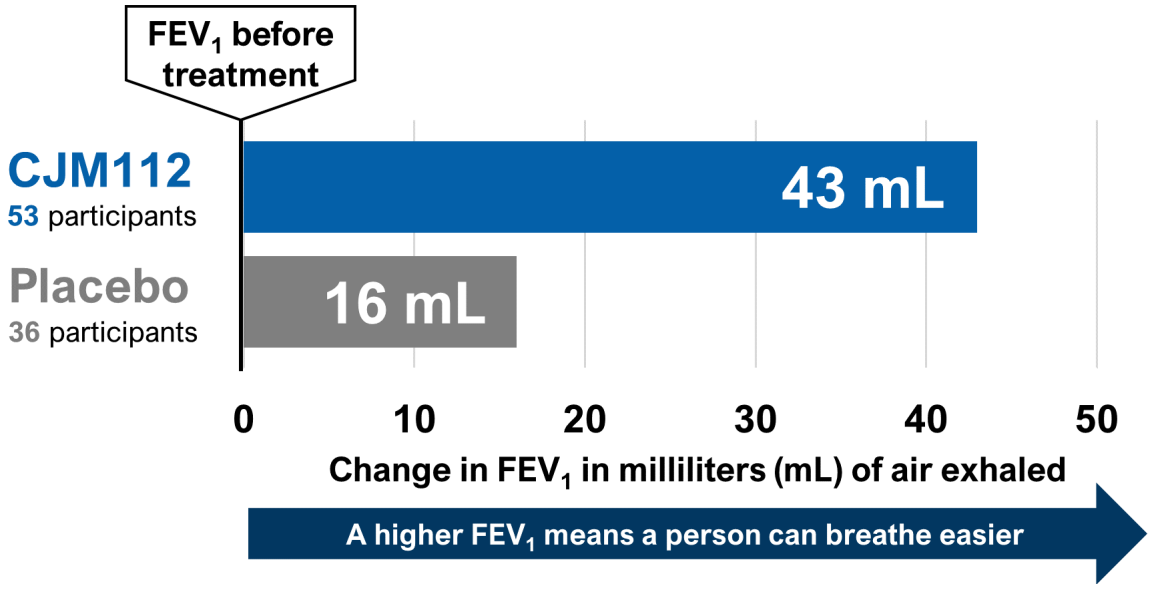
On average, participants who received CJM112 could breathe slightly easier compared to those who received the placebo. The clinical trial team concluded this difference was not meaningful.

To find this out, the clinical trial team used a measurement called Forced Expiratory Volume during 1 second, also called **FEV_1**. This is how many milliliters (mL) of air a person can blow out (exhale) with force in 1 second. Asthma narrows the airways in the lungs and lowers the amount of air a person can exhale.
A higher FEV_1 means that a person can breathe easier.

The clinical trial team compared the average of participants' FEV_1 before treatment to their FEV_1 after treatment.

On average, the participants who received CJM112 had their FEV_1 change about 27 mL more than those who received the placebo. The team concluded this difference was too small to be meaningful.

Change in FEV_1 from before treatment to after 12 weeks of treatment



Note: This graph doesn't include results from all participants, such as those who left the trial early or took medicines that could change their breathing.

What medical problems did the participants have during the trial?

Medical problems that happen during trials are called “adverse events”. An **adverse event** is any unwanted sign or symptom that participants have during a trial. An adverse event is 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. Many trials are needed to know if a drug or treatment causes an adverse event. Trial doctors keep track of all adverse events that happen in trials, even if they do not think the adverse events might be related to the trial treatments.

Most of the participants had an adverse event during this trial. The participants who received CJM112 had a similar number of adverse events as those who received the placebo. The most common adverse event was asthma that got worse.

Trial doctors looked for adverse events when they checked the participants’ health at the trial site. The participants also reported adverse events. This section includes the adverse events that happened during and after trial treatment.

Participants who had adverse events

Participants who had:	CJM112 Out of **70** participants	Placebo Out of **48** participants
Serious adverse events	**4%** 3 of 70	**4%** 2 of 48
Non-serious adverse events	**80%** 56 of 70	**79%** 38 of 48
Left this trial due to adverse events	**11%** 8 of 70	**8%** 4 of 48

What serious adverse events did participants have?

CJM112
70 participants

3 participants who received CJM112 had a total of 4 serious adverse events. These were:

- Lack of energy and strength (asthenia)
- UTI (urinary tract infection)
- Worsening depression
- Moderate asthma attack (asthmatic crisis)

Placebo
48 participants

2 participants who received the placebo had a total of 2 serious adverse events. These were:

- Heart muscle disease (stress cardiomyopathy)
- Pneumonia

During and after trial treatment, no other serious adverse events were reported, including deaths.

What non-serious adverse events did participants have?

80% of the participants (94 of 118 participants) had adverse events that were not serious. The table on the next page shows the adverse events that happened to **at least 5% of the participants** in either treatment group. Other adverse events were reported by fewer participants.

Non-serious adverse events

	CJM112 out of 70 participants	Placebo out of 48 participants
Asthma that got worse	23% 16 of 70	27% 13 of 48
The common cold Nasopharyngitis	23% 16 of 70	13% 6 of 48
Headache	11% 8 of 70	13% 6 of 48
Back pain	4% 3 of 70	10% 5 of 48
Infection in the lung airways Bronchitis	7% 5 of 70	6% 3 of 48
Cough	6% 4 of 70	8% 4 of 48
Feeling tired Fatigue	6% 4 of 70	6% 3 of 48
Diarrhea	4% 3 of 70	6% 3 of 48
Throat pain Oropharyngeal pain	4% 3 of 70	6% 3 of 48
Upper respiratory tract infection Such as the common cold or flu	6% 4 of 70	4% 2 of 48
Dizziness	6% 4 of 70	0% 0 of 48
Yeast infection in the mouth Oral candidiasis or thrush	6% 4 of 70	0% 0 of 48
Rash	1% 1 of 70	6% 3 of 48

For more information about the adverse events the participants in this trial had, visit novctrd.com. Use trial number **CCJM112X2204** to find the scientific summary.

What other results were learned?

Did CJM112 change participants' percent of predicted FEV_1?

Percent of predicted FEV_1 compares someone's FEV_1 to the average FEV_1 for people of a similar age, sex, height, and race. If this percent goes up, it means that the participants can breathe easier. The clinical trial team measured the average changes in percent of predicted FEV_1 from before and after 12 weeks of treatment.

CJM112 had no meaningful effect on the participants' percent of predicted FEV_1 compared to those who received the placebo.

Did CJM112 change participants' scores on the Asthma Control Questionnaire?

The Asthma Control Questionnaire, also called **ACQ**, is a set of questions used to measure how well people are able to control their asthma during the past week. A lower score means better control and fewer asthma symptoms. The clinical trial team measured the average change in participants' ACQ scores from before and after 12 weeks of treatment.

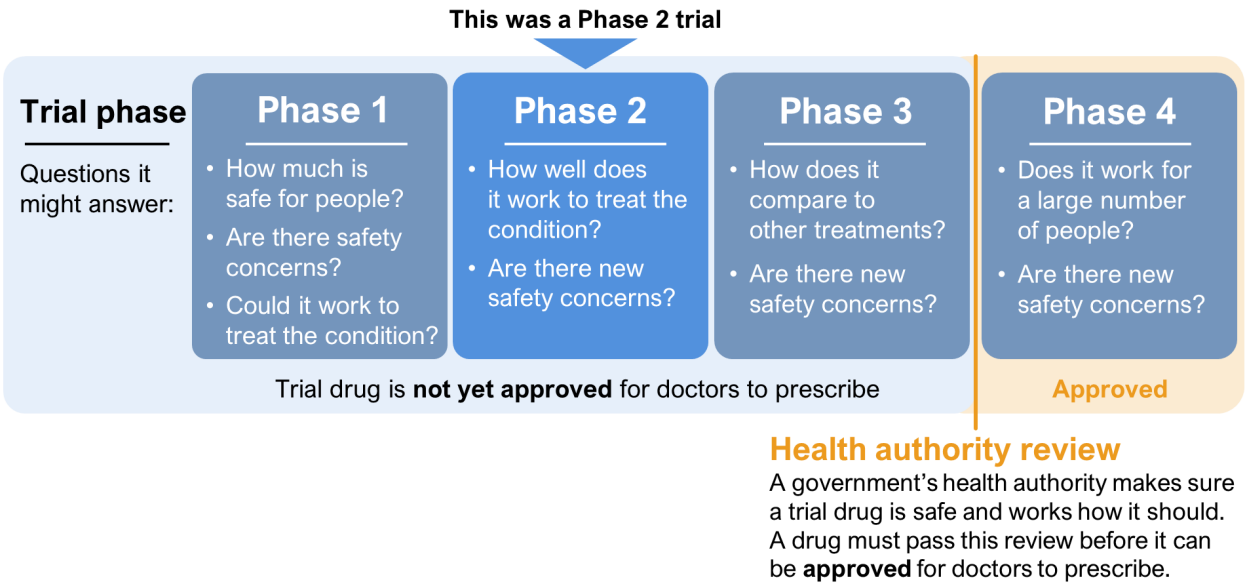
The participants who received CJM112 had slightly lower ACQ scores compared to those who received the placebo. A similar percentage of participants in both groups had a meaningful change in their ACQ scores.

What was learned from this trial?

This was the first trial to learn about how well CJM112 works to treat asthma. It focused on people with moderate to severe asthma that wasn't well treated with typical asthma medicines. The clinical trial team found:

- On average, CJM112 did not meaningfully change how easily participants could breathe compared to the placebo
- The participants who received CJM112 had a similar number of adverse events as those who received the placebo

This was a Phase 2 trial that was designed to learn about the safety of a trial drug and how well it works in a small number of participants. This was one of many trials a drug must go through before it can be approved for doctors to prescribe. The chart on the next page shows these phases and the questions they might answer.



The results presented here are for one trial. One trial cannot give a complete picture of the benefits and risks of a trial drug. The results of many trials are needed to find out which treatments can be used for people with asthma. This summary shows only the main results from this trial. Other trials may provide new information or different results.

Where can I learn more about this and future clinical trials?

This is a summary of the results for one trial.

You can find detailed results and more information about this clinical trial on the Novartis Clinical Trial Results website:

1. Visit novctrd.com
2. Click on "Clinical trial results and trial summary for patients" at the top right of the page
3. Read and scroll down, then click "I accept" to agree to use the information and the website
4. Select "Search by study number" on the bottom left of the page
5. Type **"CCJM112X2204"** in the search box and click search

If you would like to view the website in a language other than English, you can click the “Google Translate” button on the top right of the page.

If you were in this trial and have questions about the results, please speak with the doctor or staff at your trial site.

This trial was registered on the following websites:

- ClinicalTrials.gov – https://clinicaltrials.gov/
  To find this trial, type **CCJM112X2204** in the **Other terms** search box
- European Union Clinical Trials Register – https://www.clinicaltrialsregister.eu/ctr-search
  To find this trial, type **CCJM112X2204** in the search box

Full trial title:

A randomized, subject- and investigator-blinded, placebo-controlled, multi-center, multiple dose study to assess the efficacy and safety of CJM112 in patients with inadequately controlled moderate to severe asthma

If more trials are planned, they will appear on the public websites listed above. When there, search for **CJM112.**

Thank you!

Novartis would like to thank all of the people who participated in this clinical trial. The participants made this clinical trial possible and helped researchers answer important health questions and learn about a possible medical treatment. Many volunteers and many clinical trials are needed to advance medical science.

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