

Clinical Trial Results



Research Sponsor: Novartis
Location of Headquarters: Basel, Switzerland
Drug Studied: CJM112
Protocol #: CCJM112X2101
Full Trial Title: A randomized, double-blind, placebo and positive controlled, single and multiple dose escalation study to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of CJM112 in chronic plaque-type psoriasis patients
Full Scientific Summary: www.novctrd.com
Trial Date: June 2013 to October 2015

Thank you!

As a clinical trial patient, you belong to a large community of patients around the world. You helped researchers answer important health questions and discover new medical treatments.

Thank you for taking part in the clinical trial for the drug CJM112. You helped researchers learn more about how CJM112 works in people with chronic plaque-type psoriasis. This trial started in June 2013 and ended in October 2015.

Novartis, the sponsor of this trial, thanks you for your help and thinks it is important for you to know the results of your trial. An independent non-profit organization called CISCRP prepared this summary of the trial results for you. We hope it helps you understand your important role in medical research.

If you have questions about the results, please speak with the doctor, research nurse, or other team member at your trial site.

What's happened since the trial ended?

You were in this trial for up to about 16 weeks, but the trial took close to 2½ years to complete. The trial included 96 patients from 18 sites in the United States. When the trial ended in October 2015, the sponsor reviewed the data and created a report of the results. This is a summary of that report.



Why was the research needed?

Researchers were looking for a better way to treat chronic plaque-type psoriasis. This is the most common type of psoriasis, a long-lasting disease that affects mainly the skin. It causes areas of thick, red, raised skin called plaques. The plaques may be covered with silvery-white build-up called scales that might itch or feel sore.

Researchers have found that people with plaque-type psoriasis have higher activity of an immune system protein called interleukin-17 (IL-17). The trial drug, CJM112, is a type of antibody that blocks IL-17. Antibodies are normally made by the body's immune system to fight off infection. However, researchers are now able to use antibodies as medications to treat a variety of conditions, including chronic plaque-type psoriasis. Researchers wanted to see if CJM112 was safe to use and if it helped decrease psoriasis. Researchers compared CJM112 with secukinumab (AIN457) and a placebo. Secukinumab is a different type of antibody that is already available as a treatment option for psoriasis. A placebo looks like medicine, but does not have any real medicine in it.

The main questions researchers asked in the trial were:

- What medical problems did patients have during the trial?
- How much CJM112 got into the blood?
- Did CJM112 help treat psoriasis better than secukinumab, a placebo, or both?
- Did patients' immune systems have a reaction to CJM112?

To answer these questions, researchers asked for the help of men and women like you. The patients in this trial were 20 to 65 years old and had chronic plaque-type psoriasis.

What kind of trial was this?

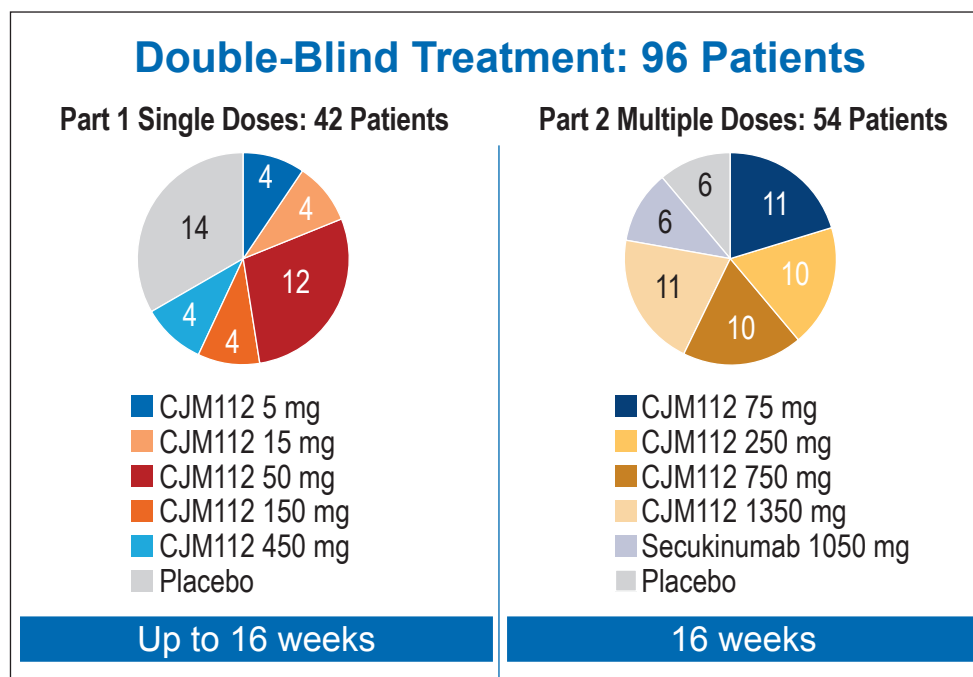
This trial was "double-blind". This means that none of the patients, trial doctors, or staff knew what treatment each patient received. Patients in this trial took either CJM112, secukinumab, or placebo.

Some trials are done this way because knowing what treatment each patient is getting can affect the results of the trial. This way, it ensures that the results are looked at fairly. When the trial ended, the research sponsor found out which treatment patients received so they could create a report of the trial results.

What happened during the trial?

This trial had 2 parts. Patients were enrolled in either Part 1, Part 2, or both.

The figure below shows how the trial was done.



Trial doctors did a full checkup of all patients to make sure they could join the trial. Patients were randomly assigned, like flipping a coin, to take either CJM112 or placebo (Part 1) or CJM112, secukinumab, or placebo (Part 2). Throughout the trial, doctors took blood samples from the patients as well as checked their weight, temperature, blood pressure, and pulse rate.

Part 1 lasted up to 16 weeks.

- Patients got 1 injection of either 5 milligrams (mg), 15 mg, 50 mg, 150 mg, or 450 mg CJM112 or placebo.
- At Week 4, patients returned to the doctor's office to record if their symptoms of chronic plaque-type psoriasis had lessened or not. About 1 month later, patients returned to the doctor's office again for a final visit.

Part 2 lasted 16 weeks.

- Patients got 9 different injections over a 12 week period. Some received CJM112, some received secukinumab, and some received placebo. The total doses over the 12-week period for the 4 groups of CJM112 were 75 mg, 250 mg, 750 mg, and 1350 mg. The total dose of secukinumab was 1050 mg.
- At Week 12, patients returned to the doctor's office to record if their symptoms of chronic plaque-type psoriasis had improved or not improved. About 1 month later, patients returned to the doctor's office again for a final visit.

What were the results of the trial?

This is a summary of the overall results of your trial, not your individual results. The results presented here are for a single trial. Researchers look at the results of many studies to decide which drugs work best and are safest for patients. Other trials may provide new information or different results. You should not make changes to your treatment based on the results of a single trial without first talking to your doctor.

What medical problems did patients have during the trial?

A lot of research is needed to know whether a drug causes a medical problem. So, when new drugs are being studied, researchers keep track of all medical problems that patients have. These medical problems are called “adverse events”. An adverse event is any sign or symptom during the trial that may or may not be caused by the trial drug.

How many patients had adverse events during the trial?

The tables below show how many patients had adverse events during this trial. The tables include all patients who took CJM112, no matter which dose they got, as well as all patients who took the placebo.

Adverse Events in Part 1

	CJM112 Total Out of 28 patients	Placebo Out of 14 patients	Total Out of 42 patients
How many patients had adverse events?	13 (46.4%)	8 (57.1%)	21 (50.0%)
How many patients had serious adverse events?	1 (3.5%)	1 (7.1%)	2 (4.8%)
How many patients stopped taking the trial drug because of adverse events?	0 (0%)	0 (0%)	0 (0%)

Adverse Events in Part 2

	CJM112 Total Out of 42 patients	Secukinumab Out of 6 patients	Placebo Out of 6 patients	Total Out of 54 patients
How many patients had adverse events?	23 (54.8%)	2 (33.3%)	5 (83.3%)	30 (55.6%)
How many patients had serious adverse events?	1 (2.4%)	0 (0%)	0 (0%)	1 (1.9%)
How many patients stopped taking the trial drug because of adverse events?	2 (4.8%)	0 (0%)	0 (0%)	2 (3.7%)

Did any patients have serious adverse events?

An adverse event is called “serious” when it is life-threatening, causes lasting problems, or leads to hospitalization. No patients died during the trial. However, some patients experienced serious adverse events.

In Part 1, 2 patients experienced a serious adverse event - 1 patient in the 150 mg CJM112 group and 1 patient in the placebo group. The serious adverse events were high blood pressure and back pain. Trial doctors did not think that any of the serious adverse events were related to the trial drug.

In Part 2, 1 patient experienced 2 serious adverse events. The patient was in the 1350 mg CJM112 group and experienced breathing problems and kidney failure after surgery for another health problem. The trial doctors did not consider either of these serious adverse events to be related to the trial drug.

What were the most common non-serious adverse events?

The tables below show the most common non-serious adverse events (in at least 2 patients) in this trial.

Most Common Non-Serious Adverse Events in Part 1

Non-Serious Adverse Event	CJM112 Total Out of 28 patients	Placebo Out of 14 patients	Total Out of 42 patients
Infection in the nose, throat, and upper airways (upper respiratory tract infection)	3 (10.7%)	1 (7.1%)	4 (9.5%)
Increased levels of the protein alanine aminotransferase in the blood (indicating liver problems)	1 (3.6%)	1 (7.1%)	2 (4.8%)
Back pain	1 (3.6%)	1 (7.1%)	2 (4.8%)
Stomach flu	2 (7.1%)	0 (0.0%)	2 (4.8%)
Headache	2 (7.1%)	0 (0.0%)	2 (4.8%)
Pain in the mouth or upper throat	1 (3.6%)	1 (7.1%)	2 (4.8%)
Itching	1 (3.6%)	1 (7.1%)	2 (4.8%)
Toothache	1 (3.6%)	1 (7.1%)	2 (4.8%)

Most Common Non-Serious Adverse Events in Part 2

Non-Serious Adverse Event	CJM112 Total Out of 42 patients	Secukinumab Out of 6 patients	Placebo Out of 6 patients	Total Out of 54 patients
Headache	3 (7.1%)	0 (0%)	1 (16.7%)	4 (7.4%)
Back pain	3 (7.1%)	0 (0%)	0 (0%)	3 (5.6%)
Itching	2 (4.8%)	0 (0%)	1 (16.7%)	3 (5.6%)
Infection in the nose, throat, and upper airways (upper respiratory tract infection)	1 (2.4%)	0 (0%)	1 (16.7%)	2 (3.7%)
Diarrhea	2 (4.8%)	0 (0%)	0 (0%)	2 (3.7%)
Stomach flu from a virus	2 (4.8%)	0 (0%)	0 (0%)	2 (3.7%)
Insomnia	1 (2.4%)	0 (0%)	1 (16.7%)	2 (3.7%)
General itching	2 (4.8%)	0 (0%)	0 (0%)	2 (3.7%)
Worsening of psoriasis	2 (4.8%)	0 (0%)	0 (0%)	2 (3.7%)
Sinus congestion	1 (2.4%)	0 (0%)	1 (16.7%)	2 (3.7%)
Infection in the nose, throat, and upper airways from a virus (viral upper respiratory tract infection)	2 (4.8%)	0 (0%)	0 (0%)	2 (3.7%)

For a full list of the adverse events that occurred in this trial, please refer to the full scientific summary of the results available on the Novartis Clinical Trial Results website (www.novctrd.com).

How much CJM112 got into the blood?

Researchers wanted to know if patients who took higher doses of CJM112 had more CJM112 stay in the blood. This was true for both Part 1 and Part 2, where the amount of CJM112 in the blood was higher for patients who took more CJM112.

Did CJM112 help treat psoriasis better than secukinumab, a placebo, or both?

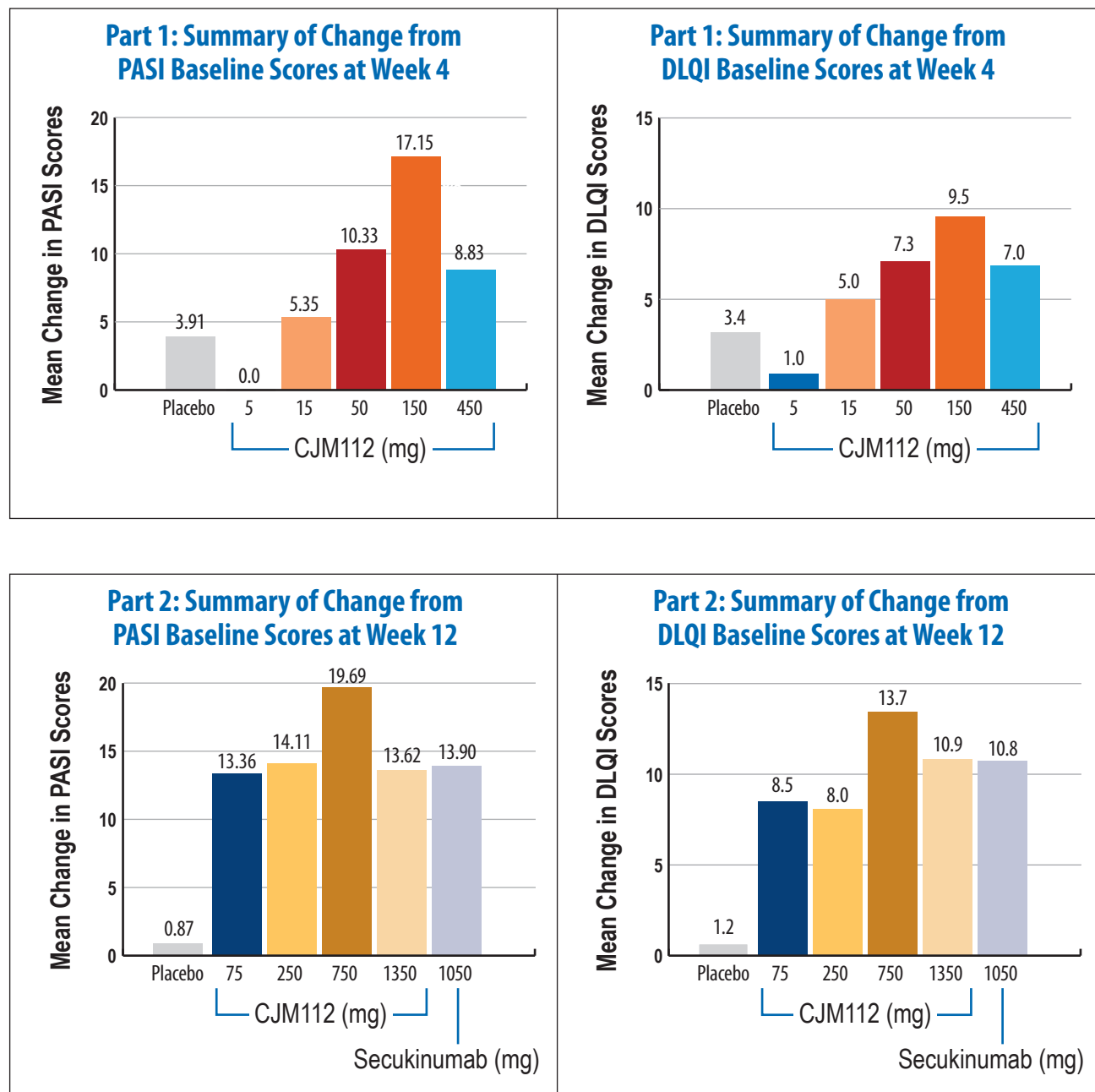
Yes. In Part 1, researchers found that the 15 mg, 50 mg, 150 mg, and 450 mg doses of CJM112 helped treat chronic plaque-type psoriasis better than placebo. The dose of 5 mg CJM112 did not help treat chronic plaque-type psoriasis better than placebo.

In Part 2, researchers found that the 75 mg, 250 mg, 750 mg, and 1350 mg total doses of CJM112 helped treat chronic plaque-type psoriasis better than placebo. Researchers found that the 3 higher doses of CJM112 helped treat chronic plaque-type psoriasis similarly to secukinumab.

Researchers used different tests to measure the extent and severity of the psoriasis. One test is called the Psoriasis Area and Severity Index or PASI. It measures thickness, redness, and scaling of the skin, as well as the amount of skin involved in different areas covering the entire body. The higher the PASI response, the more patients' psoriasis symptoms decreased.

Another test is called the Dermatology Life Quality Index or DLQI. The DLQI is a questionnaire that trial doctors use to ask patients about changes in how they feel, also known as their quality of life, since starting trial medication. The higher the DLQI response, the more patients' quality of life increased.

The graphs below show the PASI and DLQI results for each group in Part 1 and Part 2.



As displayed in the graph, in Part 1 of the study, patients had less severe symptoms and a better quality of life with increasing single doses of CJM112. In Part 2, the total CJM112 dose of 750 mg appeared to provide the best results.

How did patients' immune systems react to CJM112?

Researchers wanted to see if patients' immune systems made antibodies against CJM112 in the blood. If antibodies against CJM112 form, the drug may not work as well, or it may cause an allergic reaction to the drug - both may happen, or nothing may happen. Some patients in this trial formed antibodies against CJM112, but these antibodies were not linked to any adverse events or how well CJM112 worked in patients.

Where can I learn more about this trial?

Researchers look at the results of many trials to decide which drugs work best and are safest for patients. It takes many volunteers in many trials all around the world to advance medical science.

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). Once on the site, click “**Clinical trial results**” at the bottom of the page. After agreeing to enter the Novartis website, type **CCJM112X2101** into the keyword search box and click “**Search**”. If you have questions about the results, please speak with the doctor or staff at your trial site.

This trial was also registered on the following websites:

Clinicaltrials.gov - **National Clinical Trial # NCT01828086**

<https://www.clinicaltrialsregister.eu/ctr-search> - **EU Clinical Trial # 2012-004507-12**

Thank you

It is said that the greatest gift is one which is given anonymously, giving when you do not know whether you will get direct personal benefit.

This is the gift that you have given by taking part in a clinical trial. It is a brave and selfless act, one that advances medical knowledge and benefits public health.

Thank you for the gift of your participation in clinical research.



The Center for Information & Study on Clinical Research Participation (CISCRP) is a non-profit organization focused on educating and informing the public about clinical research participation. CISCRP is not involved in recruiting participants for clinical trials, nor is it involved in conducting clinical trials.

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