Clinical Study Results

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Study Sponsor: UCB Biopharma SRL

Treatment Studied: Bimekizumab

Protocol Number: PS0013

Short Study Title: A study to learn how well bimekizumab works and how safe it is in adults with moderate to severe chronic plaque psoriasis

Thank you

UCB thanks all the participants of this study. All the participants helped the researchers learn more about using bimekizumab in people living with moderate to severe chronic plaque psoriasis.

This study is also called the BE READY study. This is a summary of the main results of this study. An independent, non-profit organization helped prepare this summary of the study results, which included feedback from patients.

We think it is important to share the results with the participants and the public. We hope this summary helps the participants understand their important role in medical research.

The purpose of this summary is only to share information. If you need medical advice, please contact your doctor. If you participated in this study and have questions about the results, please speak with study staff.

Overview of this study

Why was the research needed?

Researchers are looking for a different way to treat moderate to severe chronic plaque psoriasis. Before a treatment is available for all patients, researchers do clinical studies to find out how the treatment works and how safe it is.

What treatments did the participants receive?

The participants in this study received bimekizumab or a placebo. The placebo looked like bimekizumab but did not have any drug in it.

What were the results of the study?

The main questions the researchers wanted to answer in this study were:

- **Did bimekizumab improve the participants' psoriasis symptoms?**

  Yes. Overall, the researchers found that the participants who received bimekizumab had improved psoriasis symptoms after 16 weeks compared to the participants who received the placebo.

- **What medical problems did the study doctors report as possibly related to the study treatment?**
  - During **Part 1** of the study, there were 16.6% of participants who had medical problems that the study doctors reported as possibly being related to the study treatment. This was 72 out of 435 participants.
  - During **Part 2** of the study, there were 23.7% of participants who had medical problems that the study doctors reported as possibly being related to the study treatment. This was 74 out of 312 participants.

  More details about the results of this study are included later in this summary.

Where can I learn more about this study?

You can find more information about this study on the websites listed on the last page. When a full report of the study results is available, it also can be found on these websites.

Why was the research needed?

Before a treatment is available to all patients, researchers do clinical studies to get information about how well the treatment works and about how safe it is.

The researchers in this study wanted to learn if bimekizumab worked in a large number of participants living with moderate to severe chronic plaque psoriasis. They also wanted to learn if the participants had any medical problems during the study.

Chronic plaque psoriasis causes dry, red, scaly patches of skin. These patches are called plaques. They can form on any part of the body, but most often on the elbows, knees, scalp, and lower back. These plaques can also be itchy and painful, and can sometimes crack and bleed, especially around the joints.

The drug that the researchers are studying, **bimekizumab**, is designed to work by stopping certain proteins in the body that cause inflammation. In this study, researchers wanted to learn how bimekizumab works and how safe it is in adults with moderate to severe chronic plaque psoriasis.

What were the main questions studied?

The main questions the researchers wanted to answer in this study were:

- Did bimekizumab improve the participants' psoriasis symptoms?
- What medical problems did the study doctors report as possibly related to the study treatment?

Who participated in the study?

There were 313 males and 122 females with moderate to severe chronic plaque psoriasis who participated in this study. They were 18 to 81 years old when they joined.

The study included participants in 9 countries:

Country	Number of Participants
Australia	10
Canada	89
Germany	38
Hungary	31
Korea	7

Country	Number of Participants
Poland	150
Russia	19
United Kingdom	6
United States	85

In this study, the researchers planned to include participants living with moderate to severe chronic plaque psoriasis who:

- Had plaque psoriasis for at least 6 months before joining the study.
- Had psoriasis that was considered moderate to severe by the study doctors, based on certain grading systems for plaque psoriasis.
- Might benefit from systemic treatments for their plaque psoriasis. Systemic treatments are treatments that enter the bloodstream and affect the whole body.

Each participant was in the study for up to 1.5 years, but the whole study lasted for almost 2 years. The study started in February 2018 and ended in January 2020.

What treatments did the participants receive?

The participants in this study received bimekizumab or a placebo as injections just under the skin. The placebo injection looked like a bimekizumab injection but did not have any drug in it. The researchers used the placebo to help make sure the effects they found in the study were actually caused by bimekizumab. Doses of bimekizumab were measured in milligrams (mg).

None of the participants, study doctors, or study staff knew what treatment each participant was receiving. UCB staff also did not know. Some studies are done this way because knowing what treatment the participants are receiving can affect the results of the study. After the study was completed, UCB learned what treatment each participant received so they could create a report of the results.

The researchers used a computer program to randomly choose if the participants received bimekizumab or the placebo. This helped make sure the treatments were chosen fairly and comparing the results for the treatments was as accurate as possible.

This study had 2 main parts:

- **Part 1 – Initial Treatment Period**: During this part of the study, the participants were assigned to receive either bimekizumab once every 4 weeks or the placebo once every 4 weeks. This part of the study lasted 16 weeks. The participants from Part 1 who did not respond well enough to study treatment to start Part 2 finished the study by receiving bimekizumab once every 4 weeks for 12 weeks.
- **Part 2 – Withdrawal Period**: During this part of the study, the participants from Part 1 who had responded well enough to study treatment were assigned to receive either bimekizumab once every 4 weeks, bimekizumab once every 8 weeks, or the placebo once every 4 weeks. This part of the study lasted 40 weeks. If a participant stopped responding to study treatment during this part, they finished the study by receiving bimekizumab once every 4 weeks for 12 weeks.

Clinical Study Results

The chart below shows the treatments the researchers planned to study:

Part 1 – Up to 16 weeks		
	Group 1	**Group 2**
	86 participants	349 participants
	Placebo	320 mg of bimekizumab
	Once every 4 weeks	Once every 4 weeks

Part 2 – Up to 40 weeks				
	Group 1	**Group 2**	**Group 3**	**Group 4**
	1 participant who received the placebo in Part 1	105 participants who received bimekizumab in Part 1	100 participants who received bimekizumab in Part 1	106 participants who received bimekizumab in Part 1
	Placebo	Placebo	320 mg of bimekizumab	320 mg of bimekizumab
	Once every 4 weeks	Once every 4 weeks	Bimekizumab or the placebo, alternating, once every 4 weeks	Once every 4 weeks

The participants in Group 3 received bimekizumab injections once every 8 weeks and received placebo injections in between. This was so that the total number and timing of injections they received would match the other treatment groups. This helps make sure that no one accidentally learns what treatment group they are in.

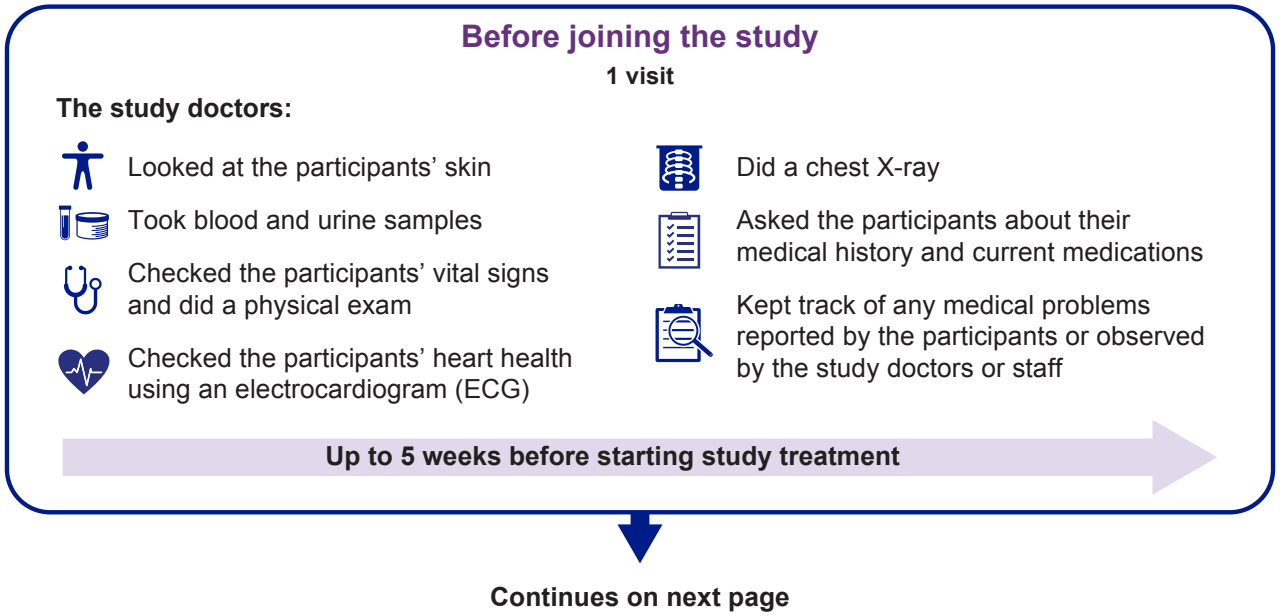
What happened during this study?

This section shows how the study was planned to be done.

Before joining the study, the participants visited their clinic 1 time. All the participants first learned about the study and then decided to join. This is called “informed consent”. Then, the study doctors and study staff asked the participants about their medical history and checked their health to make sure they could join the study. This part lasted up to 5 weeks.

While receiving and after receiving study treatment, the participants visited the clinic up to 18 times so the doctors could look at their skin, take blood and urine samples, and check their overall health. The study doctors kept track of any medical problems reported by the participants or observed by the doctors or study staff.

The chart below shows how the study was planned to be done:



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While the participants received study treatment

Part 1
7 visits

The study doctors:

- Looked at the participants' skin
- Took blood and urine samples
- Checked the participants' vital signs and did a physical exam
- Checked the participants' heart health using an electrocardiogram (ECG)
- Asked the participants about their medical history and current medications
- Kept track of any medical problems reported by the participants or observed by the study doctors or staff

The participants:

- Received bimekizumab or the placebo

16 weeks

Part 2
9 visits

The study doctors:

- Looked at the participants' skin
- Took blood and urine samples
- Checked the participants' vital signs and did physical exams
- Checked the participants' heart health using an electrocardiogram (ECG)
- Asked the participants about their current medications
- Kept track of any medical problems reported by the participants or observed by the study doctors or staff

The participants:

- Received bimekizumab or the placebo

40 weeks

After finishing study treatment
2 visits

The study doctors:

- Looked at the participants' skin
- Took blood and urine samples
- Checked the participants' vital signs and did physical exams
- Asked the participants about their current medications
- Kept track of any medical problems reported by the participants or observed by the study doctors or staff

20 weeks

What were the results of the study?

This is a summary of the main results from this study. These are the results from all the participants combined. The individual results of each participant might be different and are not in this summary.

Deciding which treatments work best usually takes results from several studies. Other studies may provide new information or different results. Always talk to a doctor before making any treatment decisions.

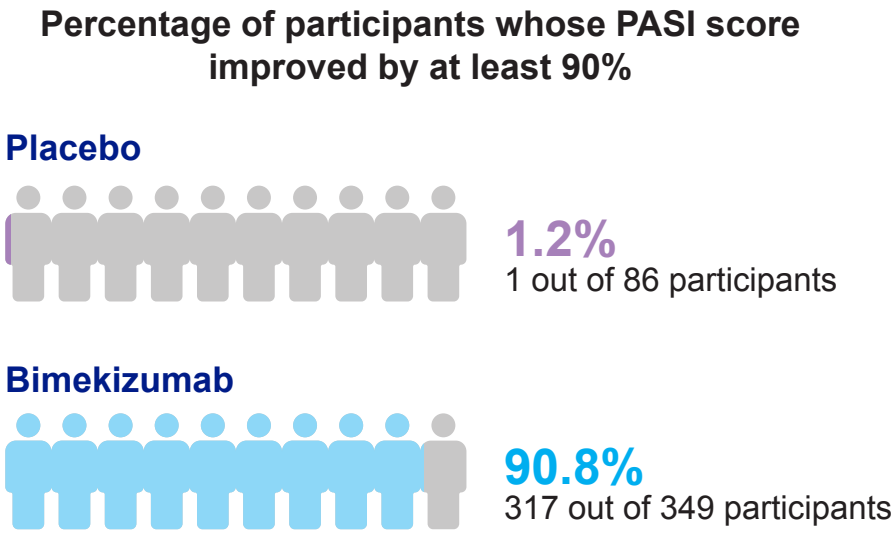
Did bimekizumab improve the participants' psoriasis symptoms?

Yes. In this study, the participants who received bimekizumab had improved psoriasis symptoms after 16 weeks compared to the participants who received the placebo.

The researchers answered this question by looking at the participants' skin at every visit and assessing their psoriasis symptoms by using 2 different scales: **PASI** and **IGA**.

The Psoriasis Area and Severity Index (**PASI**) is a scale from 0 to 72, where a lower score means less severe psoriasis symptoms. In this study, researchers looked at how many participants had at least a 90% improvement in their PASI score from before starting study treatment to 16 weeks after starting study treatment.

The image below shows these results at Week 16.

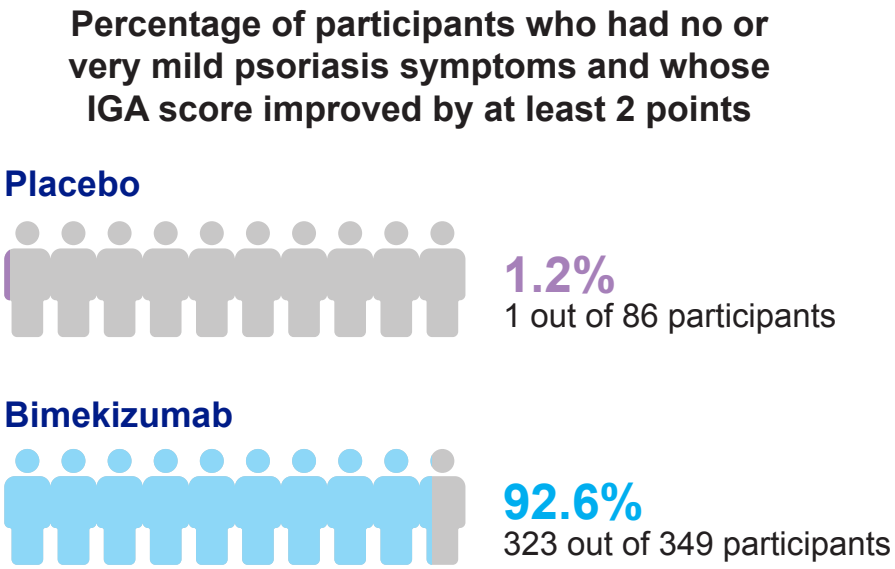


The Investigator's Global Assessment (**IGA**) is a scale from 0 to 4 points, where:

- **0** means **no** psoriasis symptoms
- **1** means **very mild** psoriasis symptoms
- **2** means **mild** psoriasis symptoms
- **3** means **moderate** psoriasis symptoms
- **4** means **severe** psoriasis symptoms

In this study, researchers looked at how many participants had **no** psoriasis symptoms or **very mild** psoriasis symptoms, and an IGA score that improved by at least 2 points from before starting study treatment to 16 weeks after starting study treatment.

The image below shows these results at Week 16.



What medical problems did the study doctors report as possibly related to the study treatment?

This section is a summary of the medical problems that the participants had during the study that the doctors reported as **possibly related** to the study treatment. These medical problems are called **adverse reactions**.

In this study, the doctors did not know whether the participants were receiving bimekizumab or the placebo when the medical problems happened. This summary does not show if the study sponsor found that any of the adverse reactions were related to the treatments in the study. Some participants had more than 1 adverse reaction.

This summary also includes information about **serious adverse reactions**. An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

Other studies may or may not show that these medical problems were related to the study treatment. The results from several studies are often needed to decide if a treatment causes an adverse reaction. Always talk to a doctor before making any treatment decisions.

Did any adverse reactions happen during this study?

Overview of the adverse reactions in Part 1 of this study		
	Group 1 (out of 86 participants)	**Group 2** (out of 349 participants)
How many participants had serious adverse reactions?	none	0.6% (2 participants)
How many participants had adverse reactions?	8.1% (7 participants)	18.6% (65 participants)
How many participants left the study due to adverse reactions?	none	0.3% (1 participant)

Overview of the adverse reactions in Part 2 of this study				
	Group 1 (out of 1 participant)	**Group 2** (out of 105 participants)	**Group 3** (out of 100 participants)	**Group 4** (out of 106 participants)
How many participants had serious adverse reactions?	none	1.0% (1 participant)	none	none
How many participants had adverse reactions?	none	21.9% (23 participants)	23.0% (23 participants)	26.4% (28 participants)
How many participants left the study due to adverse reactions?	none	1.0% (1 participant)	none	none

What serious adverse reactions did the participants have?

The serious adverse reactions in **Part 1** of this study were:

- **Inflammation of the digestive system** in 0.3% of participants in the **bimekizumab** group (Group 1). This was 1 out of 349 participants.
- A type of lung infection called **pneumonia** in 0.3% of participants in the **bimekizumab** group (Group 1). This was 1 out of 349 participants.

The serious adverse reactions in **Part 2** of this study were:

- A rare but severe form of psoriasis that covers most of the body (**Erythrodermic psoriasis**) in 1.0% of participants in the **placebo** group in **Part 2** (Group 2) who received **bimekizumab** in Part 1. This was 1 out of 105 participants.

None of the participants died due to serious adverse reactions.

What adverse reactions did the participants have?

The most common adverse reaction in the **bimekizumab** groups in both parts was a yeast infection in the mouth, also known as oral thrush (**Oral candidiasis**).

The table below shows the adverse reactions that happened in 4 or more participants in either treatment group in **Part 1**. There were other adverse reactions, but those happened in fewer participants.

Adverse reactions in 4 or more participants in Part 1 of this study

	Group 1 (out of 86 participants)	**Group 2** (out of 349 participants)
Yeast infection in the mouth, also known as oral thrush (Oral candidiasis)	none	4.9% (17 participants)
Yeast infection in the mouth and throat, also known as oral thrush (Oropharyngeal candidiasis)	none	1.1% (4 participants)
Reaction where the injection was given	none	1.1% (4 participants)
Itchy skin (Pruritus generalized)	none	1.1% (4 participants)

The table below shows the adverse reactions that happened in 4 or more participants in any treatment group in **Part 2**. There were other adverse reactions, but those happened in fewer participants.

Adverse reactions in 4 or more participants in Part 2 of this study

	Group 1 (out of 1 participant)	Group 2 (out of 105 participants)	Group 3 (out of 100 participants)	Group 4 (out of 106 participants)
Yeast infection in the mouth, also known as oral thrush (Oral candidiasis)	none	5.7% (6 participants)	7.0% (7 participants)	7.5% (8 participants)
Common cold (Nasopharyngitis)	none	4.8% (5 participants)	5.0% (5 participants)	0.9% (1 participant)

What did the researchers learn from this study?

The results of this study have helped researchers learn more about using bimekizumab in people living with moderate to severe chronic plaque psoriasis.

Deciding which treatments work best for patients almost always takes results from several studies. This summary shows only the main results from this one study. Other studies may provide new information or different results.

The purpose of this summary is only to share information. If you need medical advice about your own health or situation, please contact your doctor.

At the time this document was approved, further clinical studies with bimekizumab were planned.

Where can I learn more about this study?

You can find more information about this study at the websites listed below:

- www.clinicaltrials.gov/ct2/show/study/NCT03410992
- www.clinicaltrialsregister.eu/ctr-search/search?query=2016-003426-16

If you have questions about this study, UCB contact information is available at www.ucb.com/UCBcares.

Study Information

Protocol Number: PS0013

Study Sponsor: UCB Biopharma SPRL sponsored this study. It is referred to as UCB in this summary.

Full Study Title: A Phase 3, Multicenter, Double-Blind, Placebo-Controlled Study With an Initial Treatment Period Followed by a Randomized Withdrawal Period to Evaluate the Efficacy and Safety of Bimekizumab in Adult Subjects with Moderate to Severe Chronic Plaque Psoriasis

National Clinical Trial Number: NCT03410992

EudraCT Number: 2016-003426-16

Thank you

Participants in clinical studies belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for patients.

CISCRP REVIEW PANEL

This summary was last updated on 10 September 2024.
The final clinical study report is dated 25 July 2004.