Clinical Study Results

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Study Sponsor: UCB Biopharma SRL

Treatment Studied: Bimekizumab

Protocol Number: PS0008

Study Purpose: A study to learn how well bimekizumab works in participants with moderate to severe plaque psoriasis

Thank you

UCB thanks all the participants of this study. All the participants helped the researchers learn more about using bimekizumab to treat moderate to severe plaque psoriasis. Bimekizumab is also called UCB4940.

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. This study is sometimes called the BE SURE study.

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 the study staff.

Overview of this study

Why was the research needed?

Researchers are looking for better ways to treat moderate to severe 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 either bimekizumab or adalimumab. The participants were given these treatments through injections just under the skin.

What were the results of the study?

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

- **Did bimekizumab improve the participants' plaque psoriasis symptoms compared to adalimumab?**

  Yes. Overall, the researchers found that the participants who received bimekizumab had significant improvements in their plaque psoriasis symptoms compared to those who received adalimumab.

- **What medical problems did the study doctors report as possibly related to the study treatments?**

  ○ During the first 24 weeks, participants received either bimekizumab or adalimumab, **26.2%** of participants had medical problems that the study doctors reported as possibly being related to the study treatments. This was 125 out of 478 participants.

  ○ During the entire time, participants received bimekizumab (about 56 weeks), **35.7%** of participants had medical problems that the study doctors reported as possibly being related to the study treatments. This was 167 out of 468 participants.

More details about the study periods and 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 plaque psoriasis compared to another treatment called adalimumab. They also wanted to learn if the participants had any medical problems during the study.

Plaque psoriasis is a disease of the immune system where inflammation 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. Plaque psoriasis is a chronic disease, which means it lasts for a long time and can come and go.

Treatments exist for plaque psoriasis, including a commonly used drug called adalimumab. **Adalimumab** is designed to work by stopping certain proteins in the body that cause inflammation. But, currently available treatments like adalimumab do not work well enough for everyone.

The drug that researchers are studying, **bimekizumab**, is also designed to work by stopping different proteins in the body that cause inflammation. In this study, researchers wanted to learn how well bimekizumab works compared to adalimumab and how safe bimekizumab is in adults with moderate to severe 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' plaque psoriasis symptoms compared to adalimumab?
- What medical problems did the study doctors report as possibly related to the study treatments?

Who participated in the study?

There were 328 males and 150 females with moderate to severe plaque psoriasis who participated in this study. A total of 478 people participated in the study. They were 18 to 83 years old when they joined.

The study included participants in 9 countries:

Country	Number of Participants
Australia	21
Canada	77
Germany	50
Hungary	38
Korea	5

Country	Number of Participants
Poland	126
Russian Federation	14
Taiwan	6
United States	141

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

- Had plaque psoriasis for at least 6 months before joining the study.
- Had plaque psoriasis that was considered moderate to severe by the study doctors, based on certain grading systems for plaque psoriasis.
- Might have benefited from systemic treatments for their plaque psoriasis. **Systemic treatments** are treatments that enter the bloodstream and affect the whole body. Systemic treatments can be taken by mouth, given as an injection just under the skin, or given through a needle directly into a vein over a period of time (IV infusion).

Each participant who completed the study was in the study for up to about 81 weeks from the screening period before receiving study treatment to the end of the safety follow-up period. Additionally, participants were able to join another study (PS0014) to continue taking bimekizumab once they completed treatment in this study.

The whole study lasted for about 2 years. This is because not all of the participants joined the study at the same time.

The study started in January 2018 and ended in February 2020.

What treatments did the participants receive?

For the first 16 weeks, the participants in this study received either bimekizumab or adalimumab. This was called the initial treatment period. After the initial treatment period, the participants were able to enter a 40-week maintenance treatment period. In this period, all participants either continued receiving bimekizumab or switched from adalimumab to bimekizumab (on Week 24). Doses of bimekizumab and adalimumab were measured in milligrams (mg). The participants were given these treatments through injections just under the skin.

None of the participants, study doctors, or study staff knew what treatment each participant was receiving during the initial treatment period and first 8 weeks of the maintenance treatment period (24 total weeks). 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 adalimumab. This helped make sure the treatments were chosen fairly and comparing the results for the treatments was as accurate as possible.

From week 24 until the end of the study, the participants, study doctors, and study staff knew that all the participants were receiving bimekizumab, but they did not know how often they were receiving it.

Bimekizumab and adalimumab were given to the participants on different schedules (more information in the table below). Because of the different dosing schedules, some participants may have received the placebo injections at some visits so that the participant and the researchers could not figure out what treatment they were receiving. A placebo looks like a drug but does not have any medicine in it.

Initial Treatment Period (16 Weeks)

	Bimekizumab Group	Adalimumab Group
	319 participants	159 participants
	320 mg of bimekizumab	40 mg of adalimumab
	Once every 4 weeks with placebo injections every 2 weeks	2 doses (80 mg) at their first visit and then once every 2 weeks with placebo injections every 4 weeks when participants would receive bimekizumab

28 participants stopped participating in the trial by week 24, so the maintenance treatment period only includes 450 participants.

Maintenance Treatment Period (40 weeks)

	Bimekizumab Group		
	450 participants		
	Participants who received **bimekizumab** in the initial treatment period:		Participants who received **adalimumab** in the initial treatment period:
	320 mg of bimekizumab once every 4 weeks	320 mg of bimekizumab once every 8 weeks with a placebo injection every 4 weeks	40 mg of adalimumab every 2 weeks until Week 24, then 320 mg of bimekizumab once every 4 weeks

What happened during this study?

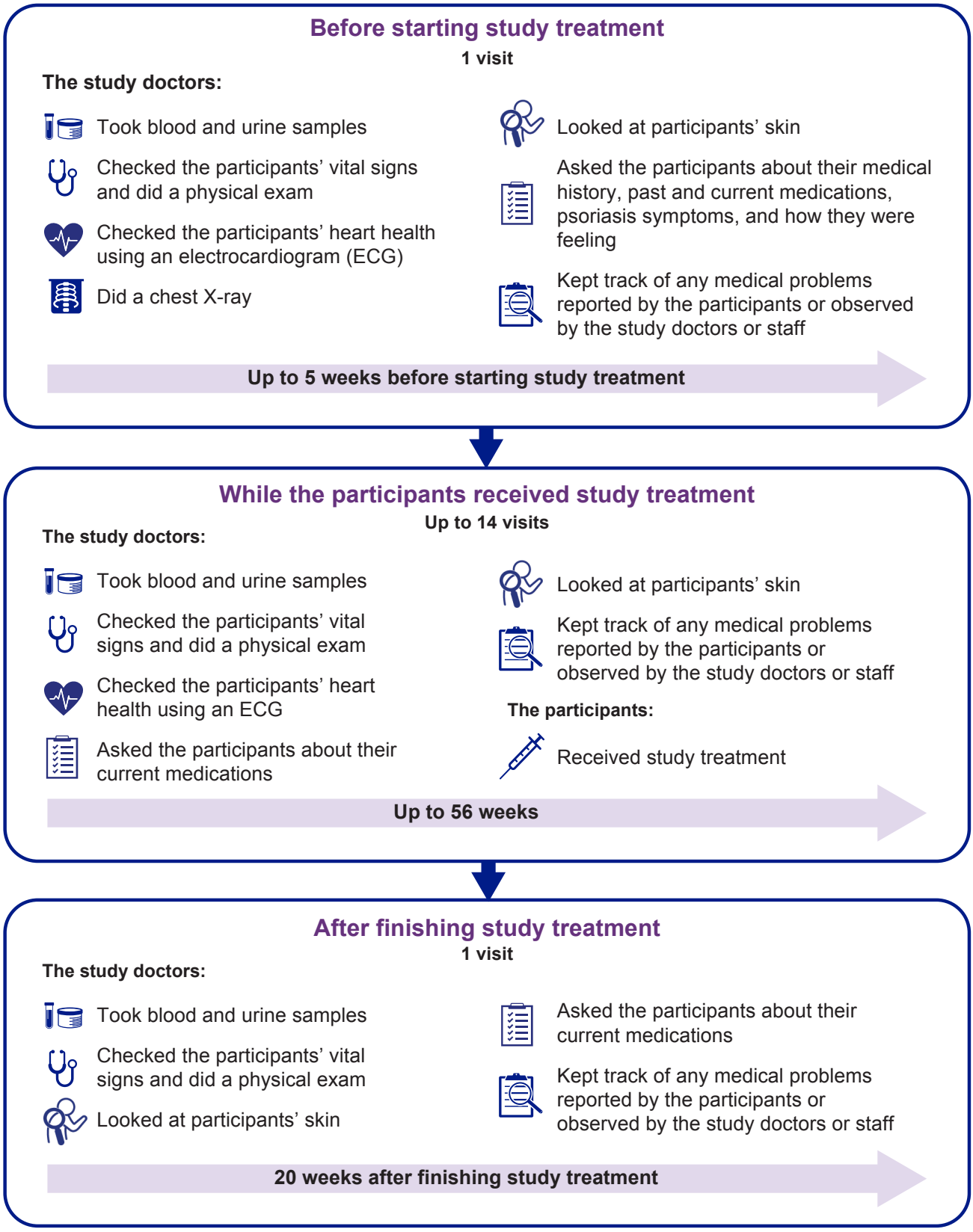
This section shows how the study was planned to be done.

Before joining the study, the participants visited their study center 1 time. All the participants first learned about the study and then decided to join. This is called the "informed consent procedure". Then, the study doctors and staff asked the participants about their medical history and checked their health to make sure they could join the study.

During this time, the doctors asked the participants to stop taking certain medications. This part is called a "washout period". It was done so that these medications could leave the participants' bodies before they took any study treatment. This part lasted up to 5 weeks.

While receiving and after receiving study treatment, the participants visited the study center regularly. At these visits, the doctors gave them their study treatment and checked their health. The study doctors kept track of any medical problems reported by the participants or observed by doctors or study staff.

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



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' plaque psoriasis symptoms?

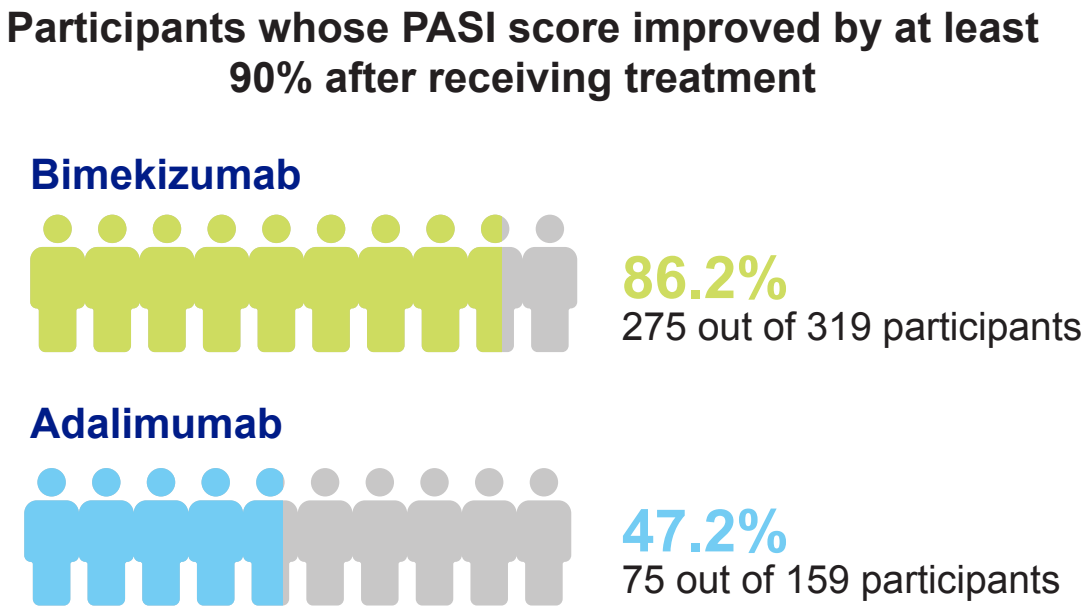
Yes. In this study, the participants who received bimekizumab had a significant improvement in their psoriasis symptoms compared to the participants who received adalimumab.

The researchers answered this question by looking at the participants' skin at every visit and assessing the severity of their psoriasis 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 the study to after receiving study treatment (Week 16).

- **86.2%** of the participants (275 out of 319) who received **bimekizumab** had at least a 90% improvement in their PASI score after receiving study treatment.
- **47.2%** of the participants (75 out of 159) who received **adalimumab** had at least a 90% improvement in their PASI score after receiving study treatment.

The image below shows these results.



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

- **0** means **clear skin** or **no signs** of psoriasis
- **1** means **very mild** signs of psoriasis on the skin
- **2** means **mild** signs of psoriasis on the skin
- **3** means **moderate** signs of psoriasis on the skin
- **4** means **severe** signs of psoriasis on the skin

In this study, researchers looked at how many participants had an IGA score that improved by at least 2 points from before starting the study to after receiving study treatment, and who had no signs or very mild signs of psoriasis after receiving study treatment (Week 16).

- **85.3%** of the participants (272 out of 319) who received **bimekizumab** had an IGA score that improved by at least 2 points and had no signs or very mild signs of psoriasis after receiving study treatment.
- **57.2%** of the participants (91 out of 159) who received **adalimumab** had an IGA score that improved by at least 2 points and had no signs or very mild signs of psoriasis after receiving study treatment.

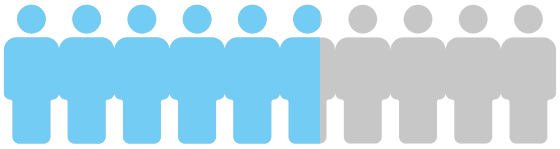
The image below shows these results.

Participants whose IGA score improved by at least 2 points and who had no or very mild psoriasis symptoms after receiving treatment

Bimekizumab

85.3%
272 out of 319 participants

Adalimumab



57.2%
91 out of 159 participants

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

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 treatments. These medical problems are called "**adverse reactions**".

In this study, the doctors did not know whether the participants were receiving bimekizumab or adalimumab 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.

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 treatments. 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 the study?

Since some of the participants received adalimumab for up to 24 weeks, the results below are presented in 2 ways: during the first 24 weeks and during both treatment periods together.

Adverse reactions during the first 24 weeks of the study

	Bimekizumab (out of 319 participants)	**Adalimumab** (out of 159 participants)
How many participants had serious adverse reactions?	0.3% (1 participant)	0.6% (1 participant)
How many participants had adverse reactions?	27.3% (87 participants)	23.9% (38 participants)
How many participants stopped receiving study treatment due to adverse reactions?	0.9% (3 participants)	none

The results below include 468 participants because 10 participants taking adalimumab stopped participating in this study before switching to bimekizumab.

Adverse reactions during both treatment periods of the study

	Bimekizumab (out of 468 participants)
How many participants had serious adverse reactions?	0.4% (2 participants)
How many participants had adverse reactions?	35.7% (167 participants)
How many participants stopped receiving study treatment due to adverse reactions?	1.1% (5 participants)

What serious adverse reactions did the participants have?

The serious adverse reactions during the **first 24 weeks** of this study were:

- A bacterial skin infection called cellulitis in 0.3% of participants who received **bimekizumab**. This was 1 out of 319 participants.
- An infection of a fluid-filled bump on the skin (Infected dermal cyst) in 0.6% of participants who received **adalimumab**. This was 1 out of 159 participants.

The serious adverse reactions participants taking bimekizumab had during **both treatment periods** of this study were:

- A bacterial skin infection called cellulitis in 0.2% of participants who received **bimekizumab**. This was 1 out of 468 participants.
- Collection of pus in the tissue underneath the skin in 0.2% of participants who received **bimekizumab**. This was 1 out of 468 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 treatment group was yeast infection in the mouth, also known as oral thrush (Oral candidiasis).

The tables below show the adverse reactions that happened in 5.0% or more of participants in either treatment group. There were other adverse reactions, but those happened in fewer participants.

Adverse reactions during the first 24 weeks in 5.0% or more of participants

Adverse reaction	Bimekizumab (out of 319 participants)	Adalimumab (out of 159 participants)
Yeast infection in the mouth, also known as oral thrush (Oral candidiasis)	10.0% (32)	none
Common cold	5.3% (17)	7.5% (12)

Adverse reactions during both treatment periods in 5.0% or more of participants

Adverse reaction	Bimekizumab (out of 468 participants)
Yeast infection in the mouth, also known as oral thrush (Oral candidiasis)	14.3% (67)
Common cold	5.1% (24)

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 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 ongoing.

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/NCT03412747
- www.clinicaltrialsregister.eu/ctr-search/search?query=2016-003392-22

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

Study Information

Protocol Number: PS0008

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

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

National Clinical Study Number: NCT03412747

EudraCT Number: 2016-003392-22

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 02 October 2024.
The final clinical study report is dated 28 September 2020.