Clinical Study Results

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Study Sponsor:	UCB Biopharma SRL
Treatment Studied:	Bimekizumab
Protocol Number:	PS0032
Short Study Title:	A study to learn how well bimekizumab works and how safe it is in Korean adults 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 in people living with moderate to severe plaque psoriasis.

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?

Page 3

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

What treatments did the participants receive?

Page 4

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

What were the results of the study?

Page 7

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?**
  There were no participants who had medical problems that the study doctors reported as possibly being related to the study treatment. This was 0 out of 47 participants.

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

Where can I learn more about this study?

Page 12

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

Protocol number: PS0032

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 participants living with moderate to severe plaque psoriasis. They also wanted to learn if the participants had any medical problems during the study.

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 researchers are studying, bimekizumab, is designed to work by stopping certain proteins in the body that cause inflammation. Bimekizumab is already approved for adults with plaque psoriasis in certain countries. In this study, researchers wanted to learn how bimekizumab works and how safe it is in Korean 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' psoriasis symptoms?
- What medical problems did the study doctors report as possibly related to the study treatment?

Protocol number: PS0032

Who participated in the study?

There were 47 Korean males and females with moderate to severe plaque psoriasis who participated in this study. There were 38 males and 9 females. They were 22 to 62 years old when they joined.

The study only included participants in South Korea.

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 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 about 37 weeks, but the whole study lasted for about 1 year. The study started in September 2021 and ended in September 2022.

What treatments did the participants receive?

The participants in this study received bimekizumab or the placebo through an injection just under the skin. The placebo injection looked like a bimekizumab injection but did not have any bimekizumab 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.

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

	Group 1 The placebo	**Group 2** 320 mg of bimekizumab
	15 participants	32 participants
	Injection just under the skin	Injection just under the skin
	Once every 4 weeks for 16 weeks	Once every 4 weeks for 16 weeks

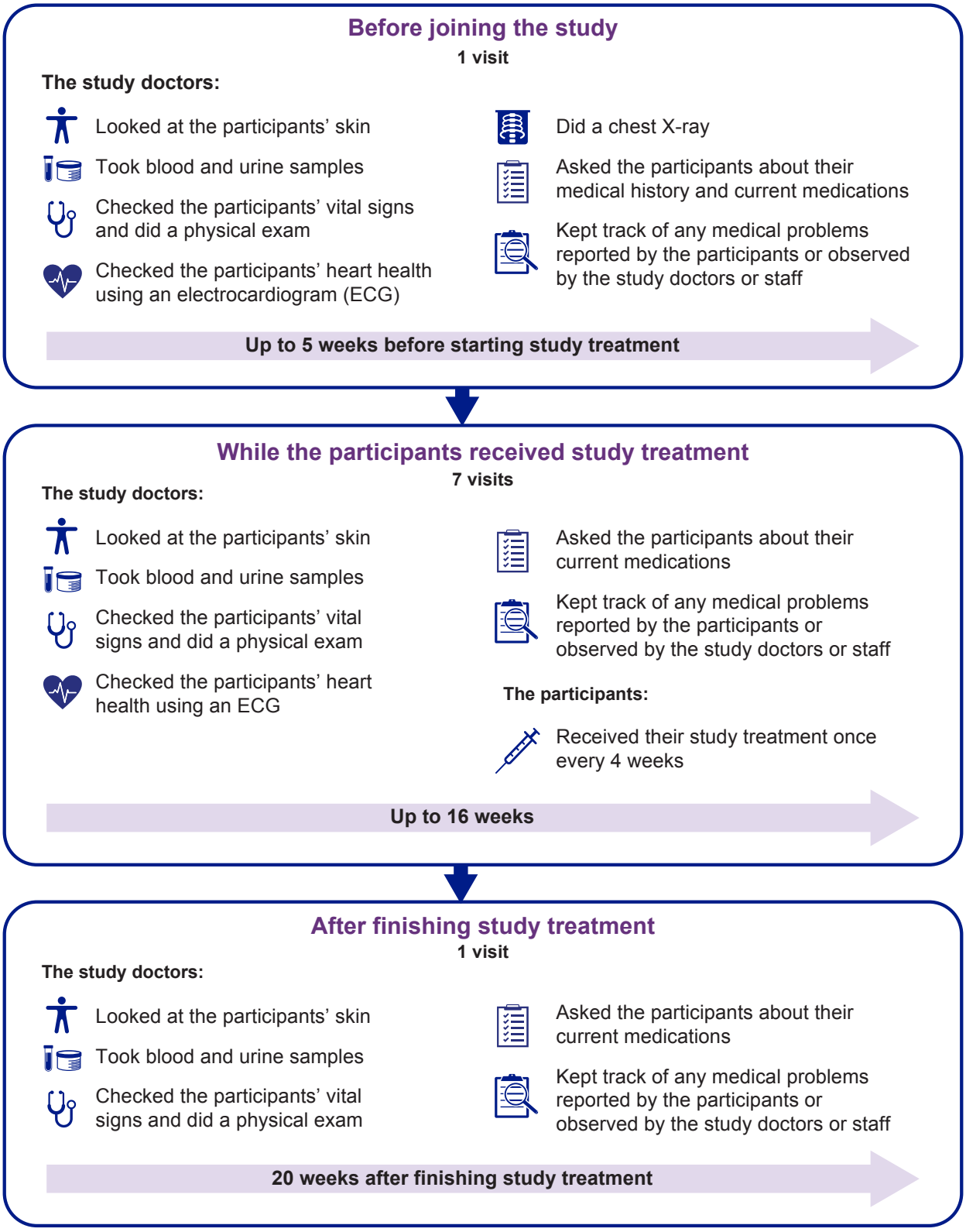
What happened during the study?

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.

During the study, the participants visited the clinic 7 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:



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 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 the study to after finishing study treatment (Week 16).

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

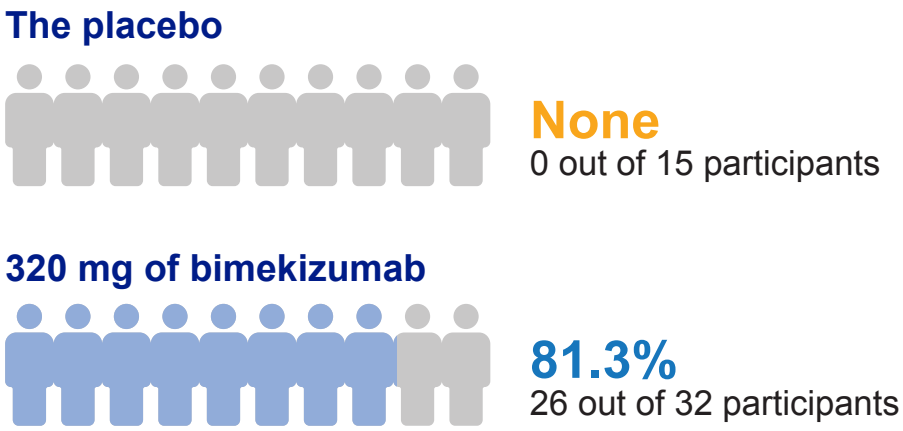
In this study, researchers looked at how many participants had an IGA score that improved by at least 2 points from before starting the study to after study treatment and had no or very mild psoriasis symptoms after finishing study treatment (Week 16).

Results using the PASI scale:

- None of the participants (0 out of 15) who received the placebo had at least a 90% improvement in their PASI score after finishing study treatment.
- 81.3% of the participants (26 out of 32) who received 320 mg of bimekizumab had at least a 90% improvement in their PASI score after finishing study treatment.

The image below shows these results.

Percentage of participants whose PASI score improved by at least 90% after finishing treatment



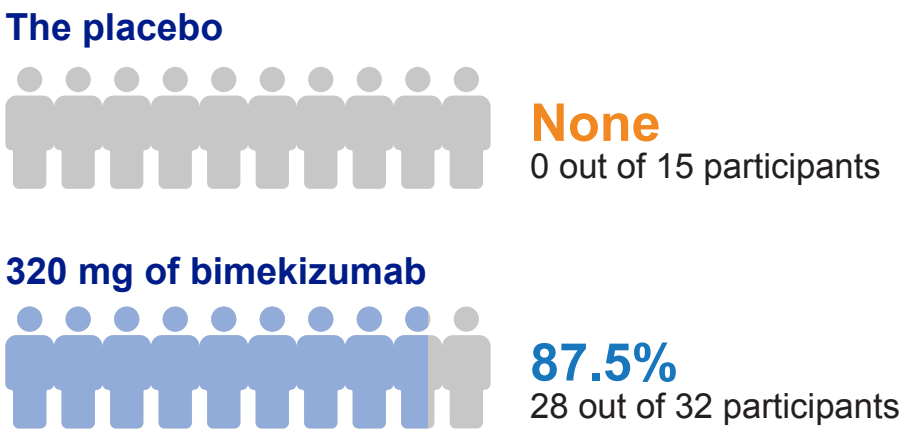
Protocol number: PS0032

Results using the IGA scale:

- None of the participants (0 out of 15) who received the placebo had an IGA score that improved by at least 2 points and had no or very mild psoriasis symptoms after finishing study treatment.
- 87.5% of the participants (28 out of 32) who received 320 mg of bimekizumab had an IGA score that improved by at least 2 points and had no or very mild psoriasis symptoms after finishing study treatment.

The image below shows these results.

Percentage of participants whose IGA score improved by at least 2 points and had no or very mild psoriasis symptoms after finishing treatment



Protocol number: PS0032

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”.

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?

Adverse reactions in this study

	Group 1 **The placebo** (out of 15 participants)	**Group 2** **320 mg of bimekizumab** (out of 32 participants)
How many participants had serious adverse reactions?	none	none
How many participants had adverse reactions?	none	none
How many participants left the study due to adverse reactions?	none	none

What serious adverse reactions did the participants have?

None of the participants had any serious adverse reactions.

What adverse reactions did the participants have?

None of the participants had any adverse reactions.

What did the researchers learn from this study?

The results of this study have helped researchers learn more about using bimekizumab in Korean 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.

When 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 website listed below:

- www.clinicaltrials.gov/ct2/show/study/NCT05020249

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

Study Information

Protocol Number: PS0032

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, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Bimekizumab in Adult Korean Study Participants With Moderate to Severe Plaque Psoriasis

National Clinical Trial Number: NCT05020249

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 19 April 2024.
The final clinical study report is dated 14 March 2023.