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Study Sponsor:	UCB Biopharma SRL
Treatment Studied:	Bimekizumab
Protocol Number:	UP0119
Short Study Title:	A study to learn how bimekizumab works in the bodies of healthy participants

Thank you

UCB thanks all the participants of this study. All the participants helped the researchers learn more about how bimekizumab acts in the blood of healthy participants.

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?

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Researchers are looking for a different way to treat moderate to severe **plaque psoriasis** (**PSO**) and other diseases. Before a drug is available for all patients, researchers do clinical studies to learn more about the drug and how safe it is.

What treatment did the participants receive?

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The participants in this study received bimekizumab either as a single injection or as 2 separate smaller injections.

What were the results of the study?

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

- **Did similar amounts of bimekizumab get into the participants' blood when given as a single injection compared to 2 separate injections?**
  Yes. Overall, the researchers found that similar amounts of bimekizumab got into the participants' blood when given as a single injection compared to 2 separate injections.

- **What medical problems did the study doctors report as possibly related to the study treatment?**
  There were **22.3%** of participants who had medical problems that the study doctors reported as possibly being related to the study treatment. This was **27** out of **121** participants.

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

Where can I learn more about this study?

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

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 about how much bimekizumab gets into the bodies of healthy participants and if the participants had any medical problems during the study. A “healthy participant” is someone who does not have the condition the treatment is trying to treat or other serious health conditions.

Plaque psoriasis (**PSO**) is a disease that happens when a person’s immune system does not work as well as it should. In healthy people, the immune system fights infections or anything it does not recognize by creating certain proteins. These include proteins called **interleukin-17s** (**IL-17**). In people who have psoriasis, the body creates too many of these proteins. This can result in several medical problems. These include red, itchy, scaly patches called “plaques” that form on the skin. There are also other diseases that are caused by too many IL-17 proteins.

The study drug **bimekizumab** is designed to block IL-17 from working. Researchers hope that blocking IL-17 proteins from working will lower inflammation in the skin of people with PSO. This would help to reduce plaques from forming on the skin. Bimekizumab is also being developed for the treatment of other diseases linked to IL-17.

Bimekizumab given as 2 separate injections is already approved in some countries for people with PSO. But, researchers want to find out if the same amount of bimekizumab can be given in a single injection. This information is important to help researchers to understand if there are different dosing options for people with PSO to receive bimekizumab.

In this study, the researchers wanted to find out if similar amounts of bimekizumab got into the participants’ blood when they received the same amount of bimekizumab using 1 of 2 methods. **Method 1** used a **single** injection, and **Method 2** used **2 separate** smaller injections.

What were the main questions studied?

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

- Did similar amounts of bimekizumab get into the participants' blood when given as a single injection compared to 2 separate injections?
- What medical problems did the study doctors report as possibly related to the study treatment?

Who participated in the study?

There were 121 healthy participants in this study. This included 73 males and 48 females. They were 21 to 65 years old when they joined.

The study included 67 participants in Germany and 54 participants in the United States of America.

Each participant could have been in the study for just over 5 and a half months, but the whole study lasted for a little less than 10 months. The study started in March 2022 and ended in January 2023.

What treatment did the participants receive?

The participants in this study received bimekizumab as an injection just under the skin. Doses of bimekizumab were measured in milligrams (mg). The amount of liquid used in the injections was measured in milliliters (ml).

The participants, study doctors, study staff, and UCB staff knew that all the participants in this study were receiving bimekizumab.

In this study, the participants received bimekizumab using 1 of 2 methods:

- **Method 1**, which means the participants received a **single 2 ml injection** of bimekizumab
- **Method 2**, which means the participants received **2 separate 1 ml injections** of bimekizumab

The total amount of bimekizumab the participants received was the same. But, researchers wanted to find out more about giving participants bimekizumab as a single injection or 2 separate smaller injections.

The researchers used a computer program to randomly choose if the participants received bimekizumab by **Method 1** or **Method 2**. 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.

	Method 1	Method 2
	60 participants	61 participants
	320 mg of bimekizumab as a **single 2 ml injection** just under the skin	320 mg of bimekizumab as **2 separate 1 ml injections** just under the skin
	1 injection	2 injections

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 once. 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. Only eligible participants continued the study visits, others left the study. This part lasted up to 4 weeks.

At this visit, the study doctors also:

- Did physical exams, checked the participants' vital signs, and asked about the participants' medications and any medical problems.
- Checked the participants' heart health using an electrocardiogram (ECG).
- Took blood and urine samples.
- Gave the participants some health-related questionnaires to complete.

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While receiving study treatment, the participants stayed at their clinic for 4 days. The study doctors gave the participants their single dose of study treatment on Day 2. They also kept track of any medical problems reported by the participants or observed by the doctors or study staff and asked about the participants' medications.

On different days during this visit, the study doctors:

- Did physical exams, checked the participants' vital signs, and asked about the participants' medications and any medical problems.
- Checked the participants' heart health using an ECG.
- Took blood and urine samples.
- Tested the participants for COVID-19.

After completing study treatment, the participants visited their clinic up to 17 more times. At these visits, the study doctors checked the participants' health. They also kept track of any medical problems reported by the participants or observed by the doctors or study staff and asked about the participants' medications. This part lasted up to 4.5 months.

At these visits, the study doctors:

- Did physical exams, checked the participants' vital signs, and asked about the participants' medications and any medical problems.
- At some visits, checked the participants' heart health using an ECG.
- Took blood and urine samples.

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.

The results below include 119 out of 121 participants for the first 2 measurements. There are 120 out of 121 participants included for the third measurement. This is because 2 participants left the study before completing all of the study assessments, meaning the researchers had not collected enough data from these 2 participants.

Did similar amounts of bimekizumab get into the participants' blood when given as a single injection compared to 2 separate injections?

Yes. Overall, the researchers found that a similar amount of bimekizumab got into the participants' blood with Method 1 (single injection) compared to Method 2 (2 separate injections).

To answer this question, the doctors took blood samples from the participants before and after they received bimekizumab.

Using the blood samples, the researchers measured:

- On average, the **total** concentrations of bimekizumab in the participants' blood **over time**. This is called the **AUCinf**.
- On average, the **total** concentrations of bimekizumab in the participants' blood **up until the last blood sample**. This is called the **AUClast**.
- On average, the **highest** concentrations of bimekizumab in the participants' blood. This is called the **Cmax**.

The researchers compared these 3 measurements from the participants who received bimekizumab using Method 1 to the participants who received bimekizumab using Method 2.

To do this, the researchers calculated how similar the measurements for the 2 methods were using percentages. The closer the results were to 100.0%, the more similar a measurement was for the 2 methods.

The table below shows the results.

	AUCinf	AUClast	Cmax
Similarity between the 2 methods	97.5%	97.1%	96.2%

Overall, the researchers found that all 3 measurements were similar for the participants who received bimekizumab with Method 1 and the participants who received bimekizumab with Method 2.

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**.

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?

Adverse reactions in this study

	Method 1 **1 bimekizumab injection** (out of 60 participants)	**Method 2** **2 bimekizumab injections** (out of 61 participants)
How many participants had serious adverse reactions?	none	none
How many participants had adverse reactions?	20.0% (12 participants)	24.6% (15 participants)
How many participants left the study due to adverse reactions?	none	none

What serious adverse reactions did the participants have?

There were no participants who had serious adverse reactions during this study.

What adverse reactions did the participants have?

The most common adverse reaction was headache.

The table below shows the adverse reactions that happened in 2 or more participants in total. There were other adverse reactions, but those happened in only 1 participant each.

Adverse reactions in 2 or more participants in total

Adverse reaction	Method 1 1 bimekizumab injection (out of 60 participants)	Method 2 2 bimekizumab injections (out of 61 participants)
Headache	6.7% (4)	9.8% (6)
Feeling tired (Fatigue)	1.7% (1)	4.9% (3)
Pain where the injection was given	1.7% (1)	4.9% (3)
Dizziness	none	3.3% (2)
Swelling where the injection was given	3.3% (2)	none

What did the researchers learn from this study?

The results of this study have helped researchers learn more about giving bimekizumab to healthy people in 2 different ways. This should help researchers understand more about the different ways they can give bimekizumab to people with PSO.

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 website listed below:

- https://clinicaltrials.gov/search?term=UP0119

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

Study Information

Protocol Number: UP0119

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

Full Study Title: An Open-Label, Randomized, Parallel-Group, Single-Dose Bioequivalence Study of Bimekizumab Given as 1x2mL or 2x1mL Subcutaneous Injection Using an Autoinjector in Healthy Study Participants

National Clinical Trial Number: NCT05292131

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.

This summary was last updated on 25 April 2024.
The final clinical study report is dated 09 May 2023.