Clinical Study Results

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Study Sponsor:	UCB Biopharma SRL
Treatment Studied:	Bimekizumab
Protocol Number:	PA0010
Short Study Title:	A study to learn how well bimekizumab works in people with psoriatic arthritis (PsA)

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 psoriatic arthritis (**PsA**). 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.

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 PsA. 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?

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The participants in this study received either bimekizumab and a placebo, another drug already approved for PsA called adalimumab, or a placebo only. A placebo looks like a drug but does not have any drug in it.

What were the results of this study?

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

- **Did bimekizumab help improve the participants' PsA joint signs and symptoms compared with the placebo?**

  Yes. The researchers found that **43.9%** of participants who received bimekizumab had an improvement in their PsA joint signs and symptoms, compared to **10.0%** of participants who received the placebo only.

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

  There were 2 parts of this study. In Part 1, 23.2% of participants had medical problems that the study doctors reported as possibly being related to bimekizumab. This was 100 out of 431 participants. In Part 2, there were 24.4% of participants who had medical problems that the study doctors reported as possibly being related to bimekizumab. This was 167 out of 685 participants.

  In Part 1, the most common medical problem that the study doctors reported as possibly being related to bimekizumab was **inflammation of the nose and throat (nasopharyngitis)**. There were **9 out of 431** participants who had nasopharyngitis. This was **2.1%** of the participants who received bimekizumab.

  In Part 2, the most common medical problem the study doctors reported as being possibly related to bimekizumab was an **infection of the mouth caused by yeast (oral candidiasis)**. There were **24 out of 685** participants who had oral candidiasis. This was **3.5%** of the participants who received bimekizumab.

  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 websites listed on the last page. If a full report of the study results is available, it can also be found on those 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 psoriatic arthritis (**PsA**). They also wanted to learn if the participants had any medical problems during the study.

Arthritis is a long-term condition that causes pain and inflammation in the joints that can result in irreversible joint damage. PsA is a type of arthritis that can also affect some people who have a skin condition called **psoriasis** or a family history of psoriasis. Symptoms of PsA include joint pain, fatigue, and swelling in the fingers and toes.

PsA happens when the body's immune system mistakenly attacks the tissues in and around the joints. This causes the joints to become stiff, swollen, and painful.

People with PsA often manage their symptoms by taking medicines called disease-modifying antirheumatic drugs (DMARDs). But, some people cannot take DMARDs, or their symptoms do not improve when taking DMARDs. Researchers are looking for other treatments to manage the symptoms of PsA.

The study treatment, bimekizumab, is designed to block proteins called interleukin-17s (**IL-17**) from working. IL-17 proteins help to activate certain parts of the body's immune system that cause inflammation. Researchers hope that blocking IL-17 proteins from working will lower inflammation in the skin and joints of people with PsA. This would help to reduce symptoms like stiffness, swelling, and pain.

In this study, researchers want to find out how well bimekizumab works in people with PsA.

What were the main questions studied?

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

- Did bimekizumab help improve the participants' PsA joint signs and symptoms compared with the placebo?
- What medical problems did the study doctors report as possibly related to the study treatments?

Who participated in the study?

There were 852 males and females with PsA who participated in this study. They were 20 to 84 years old when they joined.

The study included participants in 14 countries:

Country	Number of participants	Country	Number of participants
Australia	65	Italy	5
Belgium	6	Japan	23
Canada	11	Poland	276
Czech Republic	115	Russia	113
France	3	Spain	35
Germany	76	United Kingdom	2
Hungary	30	United States	92

In this study, the researchers planned to include participants living with PsA who:

- had been diagnosed with PsA for at least 6 months before the start of the study
- had not previously been treated with certain DMARDs known as biologics

Each participant was in the study for up to a little more than 18 months, but the whole study lasted for a little more than 3 years. The study started in April 2019 and ended in July 2022. After the study finished, the participants had the option to continue receiving bimekizumab. This is called an open label extension.

What treatments did the participants receive?

There were 2 parts in this study. In Part 1, the participants received either bimekizumab and a placebo, adalimumab, or a placebo only. In Part 2, the participants received either bimekizumab and a placebo or adalimumab. The participants who were in the placebo-only group in Part 1 of the study joined the bimekizumab group in Part 2. All treatments were given through a needle under the skin, known as a subcutaneous injection.

The placebo injection looked like a drug 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 the study drug. Doses of bimekizumab and adalimumab were measured in milligrams (mg).

None of the participants, study doctors, or study staff knew what treatment each participant was taking. UCB staff also did not know. Some studies are done this way because knowing what treatment the participants are taking 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 and a placebo, adalimumab, or a placebo in Part 1. 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 in Part 1:

Part 1

	Bimekizumab	Adalimumab	Placebo
	431 participants	140 participants	281 participants
	160 mg of bimekizumab and the placebo as an injection under the skin	40 mg of adalimumab as an injection under the skin	The placebo as an injection under the skin
	Injections once every 2 weeks, switching between bimekizumab and the placebo for 16 weeks	Once every 2 weeks for 16 weeks	Once every 2 weeks for 16 weeks

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The chart below shows the treatments the researchers planned to study in Part 2:

Part 2

	Bimekizumab	Adalimumab
	685 participants	136 participants
	160 mg of bimekizumab and the placebo as an injection under the skin	40 mg of adalimumab as an injection under the skin
	Injections once every 2 weeks, switching between bimekizumab and the placebo for 36 weeks	Once every 2 weeks for 36 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 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. This part lasted between 2 and 5 weeks.

The study doctors:

Did a physical exam and asked about the participants' medications.

Counted the number of swollen and tender joints that the participants had.

Assessed the severity of the participants' psoriasis.

Checked the participants' heart health using an electrocardiogram (ECG).

Checked the participants' bones and joints using an X-ray.

Took blood and urine samples.

During Part 1 of the study, the participants visited their clinic 9 times. **During Part 2 of the study**, the participants visited their clinic 18 times. The study doctors kept track of any medical problems reported by the participants or observed by the doctors or study staff. The study doctors also:

Gave the participants their study treatments.

Did physical exams and asked about the participants' medications.

Counted the number of swollen and tender joints that the participants had.

Assessed the severity of the participants' psoriasis.

Checked the participants' heart health using an ECG at some visits.

Checked the participants' bones and joints using an X-ray at some visits.

Took blood and urine samples.

Asked the participants to answer some questionnaires about their quality of life and their PsA symptoms.

After the last treatment, the participants visited their clinic once. This visit happened 20 weeks after the participants received their final dose of study treatment. At this visit, the study doctors checked the participants' health and asked about any medical problems. The study doctors also:

Did a physical exam and asked about the participants' medications.

Counted the number of swollen and tender joints that the participants had.

Assessed the severity of the participants' psoriasis.

Checked the participants' heart health using an ECG.

Took blood and urine samples.

Checked the participants' bones and joints using an X-ray.

Asked the participants to answer some questionnaires about their quality of life and their PsA symptoms.

What were the results of this 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 help improve the participants' PsA joint signs and symptoms compared with the placebo?

Yes. Overall, the researchers found that the participants who received bimekizumab had an improvement in their PsA joint signs and symptoms compared to the participants who received the placebo only.

To answer this question, the researchers counted the number of tender and swollen joints that the participants had throughout the study. They also checked for certain other changes in the participants' symptoms or laboratory test results. The researchers also asked the participants to answer questionnaires about their PsA symptoms.

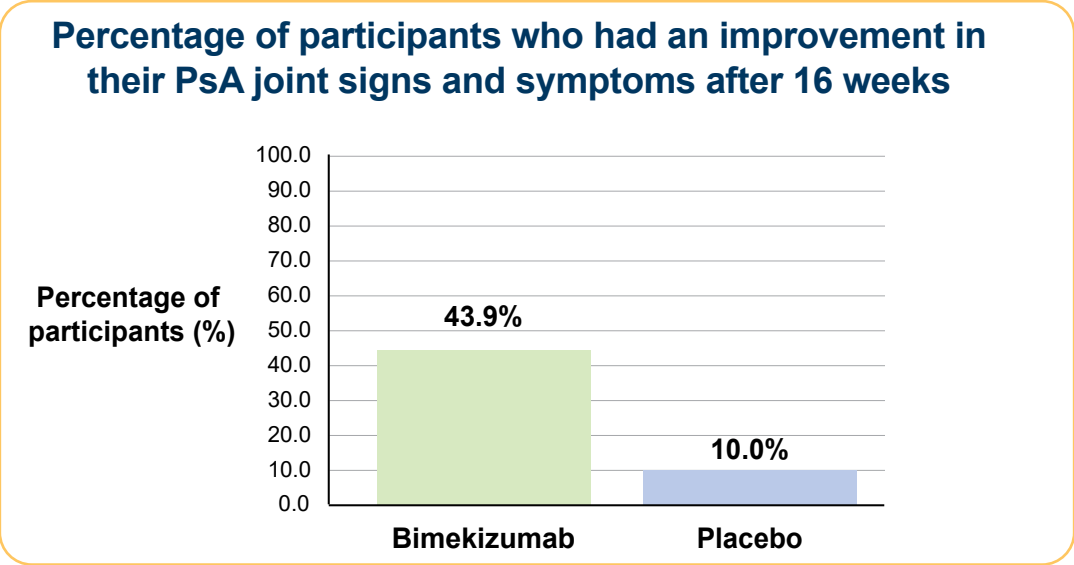
Using this information, the researchers calculated scores for the participants' PsA joint signs and symptoms before and after the participants received the study treatments. Then, they counted the number of participants who had an improvement of over 50% in their PsA signs and symptoms scores. This is known as the **ACR50 response criteria**.

Then, they compared the percentage of participants who had an improvement in their PsA joint signs and symptoms in the bimekizumab group and in the placebo group.

After 16 weeks of treatment:

- **43.9%** of the participants who received **bimekizumab** had an improvement in their PsA joint signs and symptoms. This was **189 out of 431** participants.
- **10.0%** of the participants who received **the placebo** had an improvement in their PsA joint signs and symptoms. This was **28 out of 281** participants.

The graph below shows these results.



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, adalimumab, or the placebo when medical problems happened.

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 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 Part 1 of this study?

Adverse reactions in Part 1 of this study

	Bimekizumab (out of 431 participants)	**Adalimumab** (out of 140 participants)	**Placebo** (out of 281 participants)
How many participants had serious adverse reactions?	0.5% (2 participants)	none	none
How many participants had adverse reactions?	23.2% (100 participants)	24.3% (34 participants)	12.5% (35 participants)
How many participants left the study due to adverse reactions?	0.9% (4 participants)	2.1% (3 participants)	0.4% (1 participant)

What serious adverse reactions did the participants have in Part 1 of this study?

There were 2 participants who experienced serious adverse reactions during Part 1 of this study. The serious adverse reactions in Part 1 of this study were:

- Injury to the liver due to a drug in 0.2% of participants in the bimekizumab group. This was 1 out of 431 participants.
- Lung infection (Pneumonia) in 0.2% of participants in the bimekizumab group. This was 1 out of 431 participants.

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What adverse reactions did the participants have in Part 1 of this study?

The most common adverse reaction was inflammation of the nose and throat area (Nasopharyngitis).

The table below shows the adverse reactions that happened in 3 or more participants in any treatment group. There were other adverse reactions, but these happened in fewer participants.

Adverse reactions in 3 or more of the participants in any treatment group in Part 1

Adverse reaction	Bimekizumab (out of 431 participants)	Adalimumab (out of 140 participants)	Placebo (out of 281 participants)
Inflammation of the nose and throat area (Nasopharyngitis)	2.1% (9 participants)	2.9% (4 participants)	1.4% (4 participants)
Infection of the nose, sinuses, and throat (Upper respiratory tract infection)	2.1% (9 participants)	none	2.5% (7 participants)
Infection of the mouth caused by yeast (Oral candidiasis)	1.9% (8 participants)	none	none
Low number of a type of white blood cell called lymphocytes (Lymphopenia)	0.9% (4 participants)	0.7% (1 participant)	0.7% (2 participants)
Diarrhea	0.7% (3 participants)	0.7% (1 participant)	0.7% (2 participants)
Headache	1.2% (5 participants)	none	0.4% (1 participant)
Increase of a protein called alanine aminotransferase, a possible sign of liver damage	0.5% (2 participants)	2.9% (4 participants)	none
Infection of the throat area called the pharynx (Pharyngitis)	0.7% (3 participants)	1.4% (2 participants)	0.4% (1 participant)
Low number of a type of white blood cell called leukocytes (Leukopenia)	0.9% (4 participants)	0.7% (1 participant)	none
Low number of a type of white blood cell called neutrophils (Neutropenia)	0.9% (4 participants)	0.7% (1 participant)	none

Red skin where the injection was given	0.2% (1 participant)	2.9% (4 participants)	none
Hair loss (Alopecia)	0.7% (3 participants)	0.7% (1 participant)	none
Inflammation inside the nose (Rhinitis)	0.7% (3 participants)	0.7% (1 participant)	none
Nausea	0.7% (3 participants)	none	0.4% (1 participant)
Dry skin	0.7% (3 participants)	none	none
Fungal infection of the tongue	0.7% (3 participants)	none	none

Did any adverse reactions happen during Part 2 of this study?

Adverse reactions in Part 2 of this study

Adverse reaction	**Bimekizumab** (out of 685 participants)	**Adalimumab** (out of 136 participants)
How many participants had serious adverse reactions?	0.4% (3 participants)	1.5% (2 participants)
How many participants had adverse reactions?	24.4% (167 participants)	27.2% (37 participants)
How many participants left the study due to adverse reactions?	1.2% (8 participants)	2.2% (3 participants)

What serious adverse reactions did the participants have in Part 2 of this study?

There were 5 participants who had serious adverse reactions during Part 2 of this study. The serious adverse reactions in Part 2 of this study were:

Serious adverse reactions in Part 2 of this study

Serious adverse reaction	Bimekizumab (out of 685 participants)	Adalimumab (out of 136 participants)
A type of blood cancer called chronic lymphocytic leukemia	0.1% (1 participant)	none
Infection of the nose, sinuses, and throat (Upper respiratory tract infection)	0.1% (1 participant)	none
Stroke	0.1% (1 participant)	none
Fatty liver disease that is not caused by alcohol (Non-alcoholic steatohepatitis)	none	0.7% (1 participant)
Infection of the middle part of the ear (Otitis media)	none	0.7% (1 participant)

What adverse reactions did the participants have in Part 2 of this study?

The most common adverse reaction was infection of the mouth caused by yeast (oral candidiasis).

The table below shows the adverse reactions that happened in 5 or more participants in any treatment group. There were other adverse reactions, but these happened in fewer participants.

Adverse reactions in 5 or more of the participants in either treatment group in Part 2

Adverse reaction	Bimekizumab (out of 685 participants)	Adalimumab (out of 136 participants)
Infection of the mouth caused by yeast (Oral candidiasis)	3.5% (24 participants)	0.7% (1 participant)
Infection of the nose, sinuses, and throat (Upper respiratory tract infection)	2.0% (14 participants)	0.7% (1 participant)
Inflammation of the nose and throat (Nasopharyngitis)	2.0% (14 participants)	0.7% (1 participant)
Infection of the body parts that make and carry urine (Urinary tract infection)	1.6% (11 participants)	0.7% (1 participant)
Red skin where the injection was given	0.7% (5 participants)	4.4% (6 participants)
Infection of the mouth caused by fungus	1.3% (9 participants)	none
Increase of a protein called alanine aminotransferase, a possible sign of liver damage	0.7% (5 participants)	1.5% (2 participants)
Low number of a type of white blood cell called leukocytes (Leukopenia)	0.7% (5 participants)	0.7% (1 participant)
Low number of a type of white blood cell called neutrophils (Neutropenia)	0.7% (5 participants)	0.7% (1 participant)
Change in color of the tongue	0.7% (5 participants)	none
Skin infection caused by fungus	0.7% (5 participants)	none

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 PsA.

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 websites listed below:

- https://clinicaltrials.gov/study/NCT03895203?term=NCT03895203&rank=1
- https://www.clinicaltrialsregister.eu/ctr-search/search?query=2017-002322-20

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

Study Information

Protocol Number: PA0010

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, Active Reference (Adalimumab) Study Evaluating the Efficacy and Safety of Bimekizumab in the Treatment of Subjects With Active Psoriatic Arthritis

National Clinical Trial Number: NCT03895203

EudraCT Number: 2017-002322-20

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 11 December 2023.
The final clinical study report is dated 18 April 2023.