Clinical Study Results

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Study Sponsor:	UCB Biopharma SRL
Treatment Studied:	Bimekizumab
Protocol Number:	PA0011
Short Study Title:	A study to learn how well bimekizumab works in people with psoriatic arthritis

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, also called “PsA”. Bimekizumab is also called UCB4940.

This is a summary of the main results of this study. This study is sometimes called the “BE COMPLETE” 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 well the treatment works and how safe it is.

What treatments did the participants receive?

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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?

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

- **How many participants showed an improvement in their PsA symptoms when treated with bimekizumab?**
  The researchers found that **43.4%** of participants who received bimekizumab had an improvement in their PsA symptoms, compared to **6.8%** of participants who received the placebo.

- **What medical problems did the study doctors report as related to the study treatments?**
  The most common medical problem that the study doctors reported as possibly being related to bimekizumab was **oral thrush**. There were **6 out of 267** participants who had oral thrush. This was **2.2%** of participants who received bimekizumab.

More details about 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 the study results are available, they 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, also called “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”. Symptoms of psoriasis include red, scaly patches on the skin.

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, or “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, also known as “IL-17s”, 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. It is hoped that this could help to reduce symptoms like stiffness, swelling, and pain.

What were the main questions studied?

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

- How many participants showed an improvement in their PsA symptoms when treated with bimekizumab?
- What medical problems did the study doctors report as related to the study treatments?

Who participated in the study?

There were 400 males and females with PsA who participated in this study. They were 20 to 85 years old when they joined.

The study included participants in 11 countries.

Countries	Participants	Countries	Participants
Australia	1	Japan	12
Canada	9	Poland	113
Czech Republic	27	Russia	102
Germany	22	United Kingdom	2
Hungary	8	United States of America	100
Italy	4		

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 previously been treated with a PsA DMARD known as a “TNF-α inhibitor”, but their symptoms did not improve, or they had too many side effects.

Each participant was in the study for up to around 9 months. The study started in March 2019 and ended in February 2022.

What treatments did the participants receive?

The participants in this study received bimekizumab or a placebo through a needle under their skin. The placebo injections looked like the bimekizumab injections, but did not have any bimekizumab in them. The researchers used the placebo injections to help make sure the effects they found in the study were actually caused by bimekizumab. Doses of bimekizumab were measured in milligrams, also called “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:

	Bimekizumab	Placebo
	267 participants	133 participants
	160 mg of bimekizumab as an injection under the skin	The placebo as an injection under the skin
	Once every 4 weeks for 16 weeks	Once every 4 weeks for 16 weeks

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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 between 14 and 35 days. 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 electrocardiogram, also known as an “ECG”.

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

Took blood and urine samples.

During the study, the participants visited the clinic 5 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.

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, some participants entered another study. The participants who did not enter the other study visited their study site 1 more time. This visit happened 20 weeks after the participants received their final dose of study treatment. At the 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.

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

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.

How many participants showed an improvement in their PsA symptoms when treated with bimekizumab?

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

To answer this question, the researchers counted the number of tender and swollen joints that the participants had throughout the study. They also assessed the participants' skin and 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 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 symptom scores. This is known as the "ACR50 response criteria".

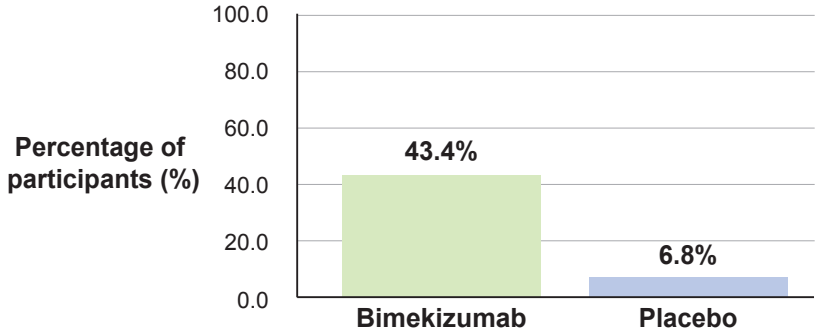
Then, they compared the percentage of participants who had an improvement in their PsA symptoms in the bimekizumab group and in the placebo group.

After 16 weeks of treatment:

- **43.4%** of the participants who received **bimekizumab** had an improvement in their PsA symptoms. This was **116 out of 267** participants.
- **6.8%** of the participants who received **the placebo** had an improvement in their PsA symptoms. This was **9 out of 133** participants.

The graph below shows these results.

Percentage of participants who had an improvement in their PsA symptoms after 16 weeks



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What medical problems did the study doctors report as 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 the placebo when 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 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.

The results below include 399 out of 400 participants. This is because 1 participant left the study before receiving any treatment.

Did any adverse reactions happen during this study?

Adverse reactions in this study

	Bimekizumab 160 mg once every 4 weeks (267 participants)	**Placebo Once every 4 weeks** (132 participants)
How many participants had serious adverse reactions?	None	None
How many participants had adverse reactions?	13.1% (35 participants)	3.0% (4 participants)
How many participants left the study due to adverse reactions?	0.4% (1 participant)	None

What serious adverse reactions did the participants have?

There were no serious adverse reactions in this study. None of the participants died due to serious adverse reactions.

What adverse reactions did the participants have?

The most common adverse reaction was **oral thrush** (also known as “oral candidiasis”), which is a fungal infection in the mouth.

There were 0.4% of participants in the bimekizumab group who had to leave the study due to adverse reactions. This was 1 out of 267 participants. This adverse reaction was oral thrush.

There were no participants in the placebo group who had to leave the study due to adverse reactions.

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

Adverse reactions in 2 or more participants in the study

Adverse reaction	Bimekizumab 160 mg once every 4 weeks (267 participants)	Placebo Once every 4 weeks (132 participants)
Oral thrush (also known as “oral candidiasis”)	2.2% (6 participants)	None
Infection of the lungs (also known as “bronchitis”)	0.7% (2 participants)	None
Infection of the upper respiratory tract	0.7% (2 participants)	None
Oral inflammation (also known as “stomatitis”)	0.7% (2 participants)	None
Oral pain	0.7% (2 participants)	None
Nausea	0.7% (2 participants)	None
Reaction at the injection site	0.7% (2 participants)	None
Throat pain (also known as “oropharyngeal pain”)	0.7% (2 participants)	None
Inflammation of the bladder (also known as “cystitis”)	0.4% (1 participant)	0.8% (1 participant)
Infection of the urinary tract (also known as a “UTI”)	None	1.5% (2 participants)

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.

At the time this document was approved, further clinical studies in PsA 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/NCT03896581
- www.clinicaltrialsregister.eu/ctr-search/search?query=2017-002804-29

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

Study Information

Protocol Number: PA0011

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

Full Study Title: A Multicenter, Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of Bimekizumab in the Treatment of Subjects With Active Psoriatic Arthritis.

National Clinical Study Number: NCT03896581

EudraCT Number: 2017-002804-29

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 16 August 2022.
The final clinical study report is dated 01 June 2022, with an approved addendum dated 25 July 2022.