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**Study Sponsor:** UCB Biopharma SRL

**Treatment Studied:** Bimekizumab

**Protocol Number:** PS0014

**Short Study Title:** A study to learn about the long-term safety of bimekizumab in adults with psoriasis

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## Thank you

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UCB thanks all the participants of this study. All the participants helped the researchers learn more about the safety of receiving bimekizumab for a long time.

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

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### Why was the research needed?



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

In this study, the researchers wanted to find out how safe a treatment called bimekizumab was and how well it worked when used for a long time in adults with psoriasis.

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### What treatments did the participants receive?

The participants in this study received bimekizumab.

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### What were the results of this study?

This study had 2 main groups of participants called **Group A** and **Group B**:

- **Group A** included participants from around the world with plaque psoriasis who had completed a clinical study for plaque psoriasis.
- **Group B** included participants from Japan with different types of psoriasis: plaque psoriasis (**PSO**), generalized pustular psoriasis (**GPP**), or erythrodermic psoriasis (**EP**).

The main question the researchers wanted to answer in this study was:

- **What medical problems did the participants in Group A have during this study?**

There were **89.4%** of participants in **Group A** who had medical problems during this study. This was 1,150 out of 1,287 participants.

The researchers also kept track of the adverse events that happened in **Group B**, but that was not one of the main questions that the researchers wanted to answer, so those results are not included in this summary.

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The researchers also wanted to know:

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

In **Group A**, there were **36.4%** of participants who had medical problems that the study doctors reported as possibly being related to the study treatment. This was 469 out of 1,287 participants.

In **Group B**, there were:

- 66.7% of participants with **PSO** who had medical problems that the study doctors reported as possibly being related to the study treatment. This was 30 out of 45 participants.
  - 60.0% of participants with **GPP** who had medical problems that the study doctors reported as possibly being related to the study treatment. This was 6 out of 10 participants.
  - 63.6% of participants with **EP** who had medical problems that the study doctors reported as possibly being related to the study treatment. This was 7 out of 11 participants.
- **Did bimekizumab help the participants in Group A keep their psoriasis symptoms well-managed throughout the study?**

**Yes.** The participants in **Group A** joined this study after finishing 1 of 3 other clinical studies on plaque psoriasis. Receiving long-term treatment with bimekizumab during this study helped them keep their psoriasis symptoms well-managed.

The researchers also kept track of the psoriasis symptoms for participants in **Group B**, but that was not one of the main questions that the researchers wanted to answer, so those results are not included in this summary.

This summary only includes the main questions that the researchers wanted to answer during the study. The researchers answered other questions during the study, but those results are not included in this summary.

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

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### 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 can also be found on these websites.

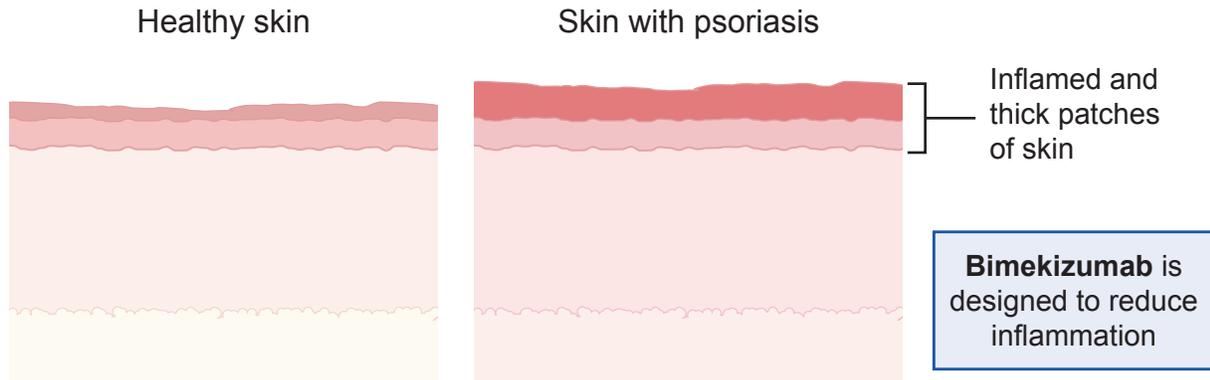


## Why was the research needed?

The researchers in this study wanted to learn how safe bimekizumab was when used for a long period of time in adults with psoriasis.

**Psoriasis** is an inflammatory condition that causes dry, red, and scaly patches on the skin. It is a chronic disease, which means it lasts for a long time and can come and go. Psoriasis happens when the immune system, which usually helps protect the body, starts attacking the skin by mistake. This causes inflammation and makes skin cells grow too quickly, leading to thick, red, and scaly patches that can be itchy and painful.

The study drug **bimekizumab** is designed to help manage psoriasis by stopping certain proteins in the body that cause inflammation.



In this study, the researchers wanted to find out how safe bimekizumab was and how well it worked when used for a long time in adults with psoriasis. The researchers also wanted to learn how safe bimekizumab was and how well it worked in patients with different types of psoriasis:

- **Plaque psoriasis (PSO)** is the most common type of psoriasis. It 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. This was the type of psoriasis that the researchers wanted to focus on in this study.
- **Generalized pustular psoriasis (GPP)** is a rare and severe form of psoriasis that causes large areas of the body to become red and swollen. It also causes pus-filled blisters on the skin.
- **Erythrodermic psoriasis (EP)** is a rare and severe form of psoriasis that causes a painful rash with peeling skin that covers most of the body and can itch or burn intensely.



## What was the main question studied?

The main question the researchers wanted to answer in this long-term study was:

- What medical problems did the participants in **Group A** have during this study?

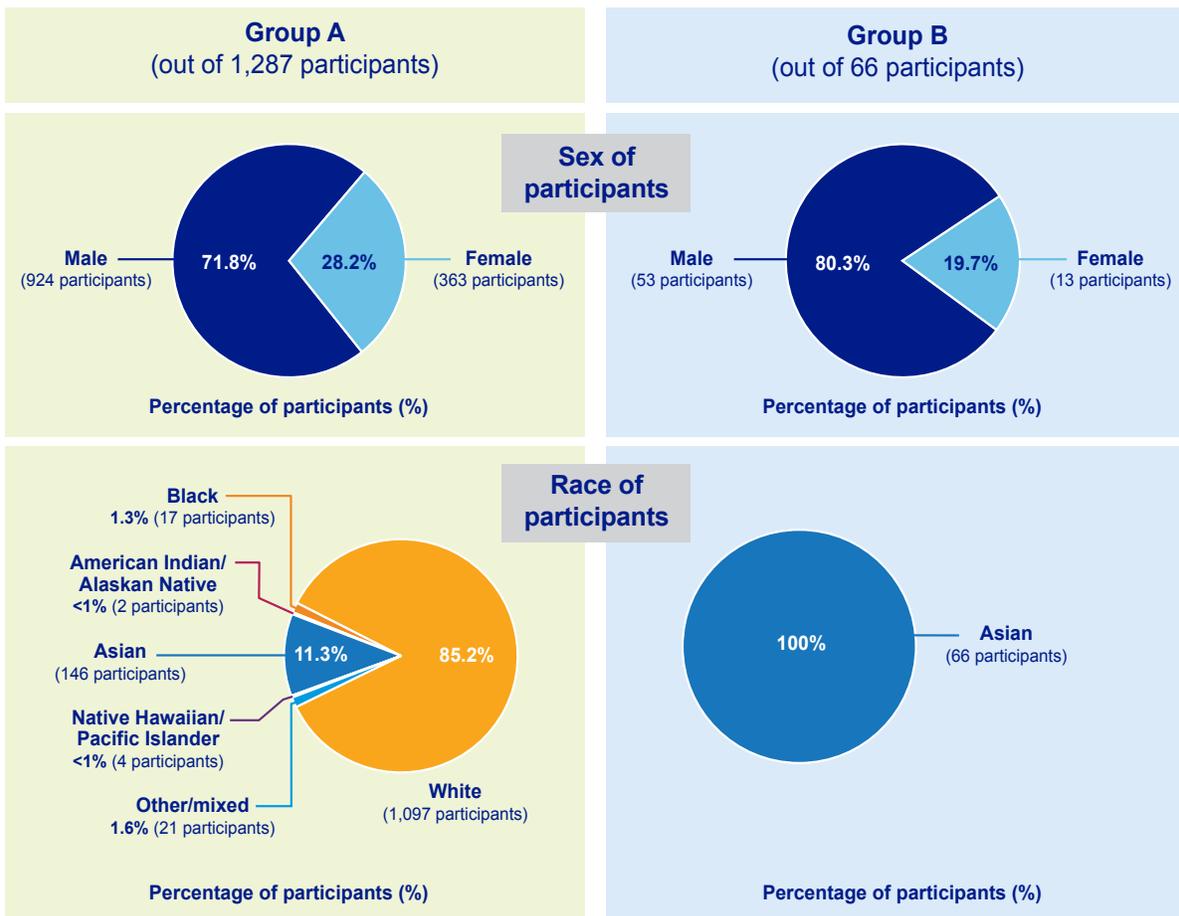
The researchers also wanted to know:

- What medical problems did the study doctors report as possibly related to the study treatment?
- Did bimekizumab help the participants in **Group A** keep their psoriasis symptoms well-managed throughout the study?



## Who participated in the study?

There were 1,353 participants with psoriasis who participated in this study. They were 18 to 83 years old when they joined.



## Clinical Study Results

The study included participants in 13 countries.



**Group A** included participants living with moderate to severe plaque psoriasis who:

- Had completed 1 of the following clinical studies for plaque psoriasis: PS0008, PS0009, or PS0013.

**Group B** included only participants in Japan who had **not** participated in any bimekizumab clinical studies before and had 1 of the following conditions:

- Moderate to severe plaque psoriasis (**PSO**) that had been diagnosed at least 6 months before joining the study and affected at least 10% of their body.
- Generalized pustular psoriasis (**GPP**) based on criteria from the Japanese Dermatological Association.
- Erythrodermic psoriasis (**EP**) that affected at least 80% of their body.

Group B was included to help get approval for the use of bimekizumab in Japan.

Participants who completed this study were in the study for up to 4 years. The study started in September 2018 and ended in November 2023. So, the whole study lasted for about 5 years.



## What treatments did the participants receive?

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The participants in this study received bimekizumab as an injection under their skin. The participants, study doctors, study staff, and UCB staff knew what the participants were receiving.

Participants received bimekizumab either every 4 weeks or every 8 weeks.

### Group A:

How often the participants in Group A received bimekizumab depended on what they had received during their previous study, how well they had responded to bimekizumab during their previous study, and what the study doctors thought was best for them.

All the participants in Group A who were receiving bimekizumab every 4 weeks changed to every 8 weeks during the course of the study as part of a treatment plan update. The researchers made this change because they learned that, for the majority of participants, both dosing schedules worked equally well starting from Week 16.

### Group B:

The participants in Group B received bimekizumab every 4 weeks for 16 weeks (about 4 months). After that, they received bimekizumab either every 4 weeks or every 8 weeks, depending on how well the treatment was working for them. This could also change during the study.

## Clinical Study Results

The chart below shows the treatment the researchers planned to study. The doses of bimekizumab were measured in milligrams, also called mg.

	Group A	Group B
	1,287 participants	66 participants
	320 mg of bimekizumab as an injection	
	Every 4 weeks or every 8 weeks, then every 8 weeks	Every 4 weeks for 16 weeks, then every 4 weeks or every 8 weeks
	For a little less than 3 years	

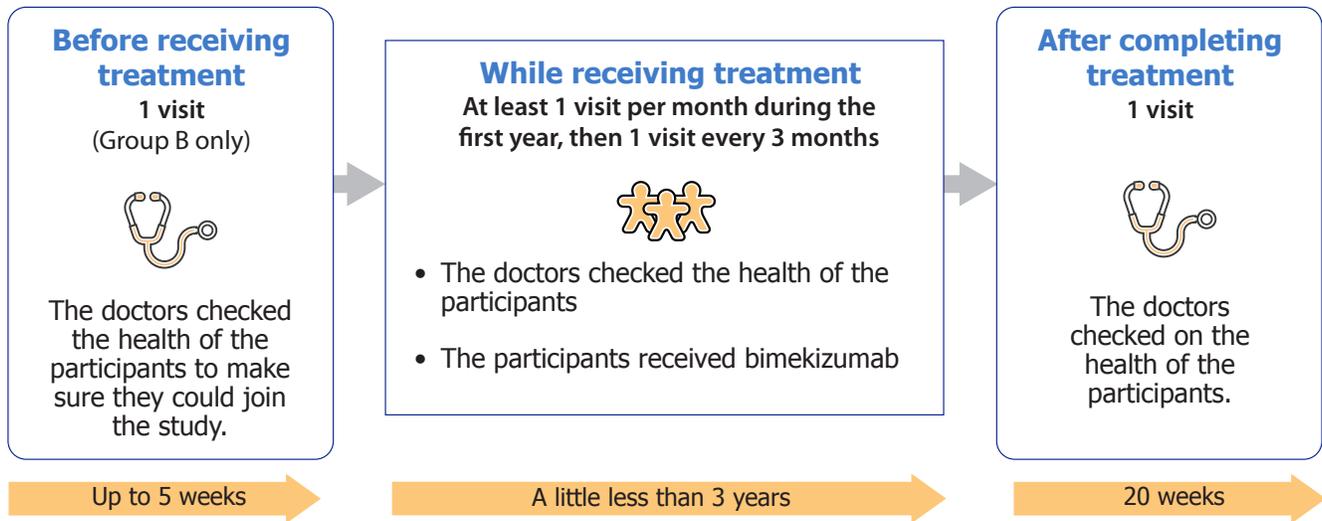
After that, the participants from Group A in the United States and Canada could choose to keep receiving bimekizumab for about another year. This means that some participants in Group A received bimekizumab in this study for a total of about 4 years. The results from this part helped answer other questions that were not the main questions in this study, and they are not included in this summary.

## What happened during this study?

All the participants first learned about the study and then decided to join. This is called “informed consent”. The participants in Group A joined directly from previous studies.

The chart below shows what happened in this study for each participant:

## Clinical Study Results



Some participants in Group A received bimekizumab in this study for a total of about 4 years because they had the option to continue receiving bimekizumab for about another year.

## 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.

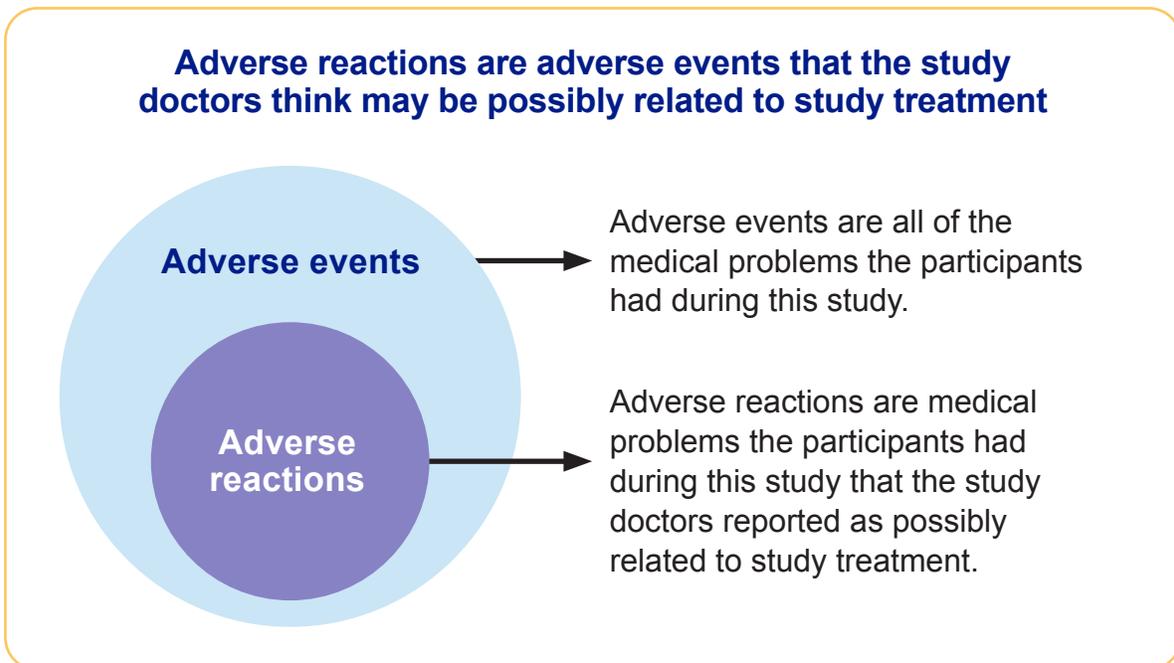
This summary only includes the main questions that the researchers wanted to answer during the study. The researchers answered other questions during the study, but those results are not included in this summary.

## What medical problems did the participants have during this study?

In this summary, there is information about 2 different types of medical problems that the participants had during the study.

- An **adverse event** is **any** medical problem that a participant has during a study. Doctors keep track of all adverse events that happen in studies, whether or not these may be related to the study treatments.
- An **adverse reaction** is different from an adverse event because it is reported by the doctor as **possibly related** to the study treatments.

An adverse event or adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.



## What medical problems did the participants in **Group A** have during this study?

There were 89.4% of participants (1,150 out of 1,287) in Group A who had an adverse event during the 3 years of treatment with bimekizumab in this study.

All the participants in Group A who were receiving bimekizumab every 4 weeks changed to every 8 weeks during the course of the study as part of a treatment plan update. Overall, the participants spent more time receiving bimekizumab every 8 weeks than they did receiving bimekizumab every 4 weeks. The researchers made this change because they learned that, for the majority of participants, both dosing schedules worked equally well starting from Week 16.

The information below is a summary of the **adverse events** that happened in Group A during this study. It includes all the adverse events that happened for all the participants in Group A together, regardless of how often they were receiving bimekizumab at the time of the adverse events.

### Adverse events in Group A

	<b>Bimekizumab (all participants)</b> (out of 1,287 participants)
How many participants had <b>serious</b> adverse events?	14.1% (181 participants) 
How many participants had adverse events?	89.4% (1,150 participants) 
How many participants left the study due to adverse events?	6.1% (78 participants) 

The most common **serious** adverse event was COVID-19 infection. This was because the COVID-19 pandemic started while this study was ongoing.

The most common adverse events were:

- Common cold (Nasopharyngitis)
- Yeast infection in the mouth, also known as oral thrush (Oral candidiasis)
- COVID-19 infection

## Clinical Study Results

The researchers also kept track of the adverse events that happened in **Group B**, but that was not one of the main questions that the researchers wanted to answer, so those results are not included in this summary.

### **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 possibly related to 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.

Some of the adverse reactions listed below may also appear in the adverse events section earlier in this summary.

## Did any adverse reactions happen in **Group A** during this study?

There were 36.4% of participants (469 of 1,287) in Group A who had an adverse reaction in this study.

### Adverse reactions in Group A

	<b>Bimekizumab (all participants)</b> (out of 1,287 participants)
How many participants had <b>serious</b> adverse reactions?	1.2% (16 participants) 
How many participants had adverse reactions?	36.4% (469 participants) 
How many participants left the study due to adverse reactions?	2.0% (26 participants) 

## What serious adverse reactions did the participants in **Group A** have?

The table below shows the only serious adverse reaction that happened in more than 1 participant in Group A. There were other serious adverse reactions, but those happened in only 1 participant each.

### Serious adverse reactions in more than 1 participant in Group A

	<b>Bimekizumab (all participants)</b> (out of 1,287 participants)
An inflammatory disease that affects the lining of the digestive tract (Crohn's disease)	0.2% (2)

None of the participants died due to serious adverse reactions.

## What adverse reactions did the participants in Group A have?

The table below shows the adverse reaction that happened in 5.0% or more of the participants in Group A. There were other adverse reactions, but those happened in fewer participants.

### Adverse reactions in 5.0% or more of participants in Group A

	Bimekizumab (all participants) (out of 1,287 participants)
Yeast infection in the mouth, also known as oral thrush (Oral candidiasis)	15.4% (198)

## Did any adverse reactions happen in Group B during this study?

There were 65.2% of participants (43 of 66) in Group B who had an adverse reaction in this study.

### Adverse reactions in Group B

	PSO sub-group (out of 45 participants)	GPP sub-group (out of 10 participants)	EP sub-group (out of 11 participants)
How many participants had <b>serious</b> adverse reactions?	4.4% (2 participants) ★☆☆☆☆☆☆☆☆	10.0% (1 participant) ★☆☆☆☆☆☆☆☆	18.2% (2 participants) ★★☆☆☆☆☆☆☆☆
How many participants had adverse reactions?	66.7% (30 participants) ★★★★★☆☆☆☆	60.0% (6 participants) ★★★★★☆☆☆☆	63.6% (7 participants) ★★★★★☆☆☆☆
How many participants left the study due to adverse reactions?	4.4% (2 participants) ★☆☆☆☆☆☆☆☆	20.0% (2 participants) ★★☆☆☆☆☆☆☆☆	9.1% (1 participant) ★☆☆☆☆☆☆☆☆

## What serious adverse reactions did the participants in Group B have?

The table below shows the serious adverse reactions that happened in Group B. Some of the participants had more than 1 serious adverse reaction. For example, 1 participant could have had both muscle weakness and swelling.

### Serious adverse reactions in Group B

Serious adverse reaction	PSO sub-group (out of 45 participants)	GPP sub-group (out of 10 participants)	EP sub-group (out of 11 participants)
Infection of the upper layers of the skin (Erysipelas)	2.2% (1)	none	none
Injury to the liver caused by a drug	2.2% (1)	10.0% (1)	none
Liver damage due to the immune system not working as well as it should (Autoimmune hepatitis)	none	10.0% (1)	none
Infection of the lungs caused by bacteria (Pneumonia bacterial)	none	none	9.1% (1)
Inflammation of the tissue that covers the lungs (Pleurisy)	none	none	9.1% (1)
Swelling in the hands, lower legs, or feet	none	none	9.1% (1)
Muscle weakness	none	none	9.1% (1)

None of the participants died due to serious adverse reactions.

## What adverse reactions did the participants in Group B have?

The table below shows the adverse reactions that happened in 5.0% or more of the participants in the PSO sub-group **or** in at least 2 participants in either of the other 2 sub-groups. There were other adverse reactions, but those happened in fewer participants.

### Adverse reactions in at least 5.0% of participants in the PSO sub-group or in at least 2 participants in the GPP and EP sub-groups

Serious adverse reaction	PSO sub-group (out of 45 participants)	GPP sub-group (out of 10 participants)	EP sub-group (out of 11 participants)
Yeast infection in the mouth, also known as oral thrush (Oral candidiasis)	22.2% (10)	10.0% (1)	36.4% (4)
A condition that causes itchy, swollen skin (Eczema)	13.3% (6)	none	none
Common cold (Nasopharyngitis)	11.1% (5)	none	9.1% (1)

## Did bimekizumab help the participants in Group A keep their psoriasis symptoms well-managed throughout the study?

**Yes.** Receiving long-term treatment with bimekizumab during this study helped the participants in Group A keep their psoriasis symptoms well-managed.

To answer this question, the study doctors looked at the participants' skin at every visit and assessed their psoriasis symptoms. They used 2 different scales called the Psoriasis Area and Severity Index (**PASI**) and the Investigator's Global Assessment (**IGA**) to give each participant a score based on:

- The redness of their skin plaques.
- The thickness of their skin plaques.
- The amount of skin peeling around their skin plaques.
- The area of skin affected by psoriasis.

The participants in Group A joined this study after completing 1 of 3 clinical studies on plaque psoriasis. So, overall, their psoriasis symptoms were well-managed at the beginning of this study. In this study, the researchers wanted to know if receiving bimekizumab for a long time helped keep their psoriasis symptoms well-managed.

## Clinical Study Results

The overall results for Group A are in the table below.

<b>Percentage of participants in Group A who had their symptoms well-managed</b>		
	<b>Bimekizumab (all participants)</b>	
	<b>At the beginning of this study</b>	<b>After 3 years of treatment</b>
According to the PASI scale	90.0% (1,157 out of 1,286 participants)	92.2% (965 out of 1,047 participants)
According to the IGA scale	90.3% (1,161 out of 1286 participants)	91.1% (952 out of 1,045 participants)

The number of participants was higher at the beginning of this study than after 3 years of treatment because some participants did not complete all the visits and assessments.

Based on these scales, the researchers saw that, overall, the participants in Group A still had their psoriasis symptoms well-managed after 3 years of treatment with bimekizumab.

The researchers also kept track of the psoriasis symptoms for participants in **Group B**, but that was not one of the main questions that the researchers wanted to answer, so those results are not included in this summary.

## What did the researchers learn from this study?

The results of this study have helped researchers learn more about using bimekizumab for a long time in people living with plaque psoriasis. In this study, the researchers found that the medical problems that the participants had over 3 years were generally manageable and did not severely affect their daily lives. They also found that, overall, the participants' psoriasis symptoms were well-managed throughout this study.

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 ongoing.



## Where can I learn more about this study?

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You can find more information about this study at the websites listed below:

- [www.clinicaltrials.gov/study/NCT03598790](http://www.clinicaltrials.gov/study/NCT03598790)
- [www.clinicaltrialsregister.eu/ctr-search/search?query=2016-003427-30](http://www.clinicaltrialsregister.eu/ctr-search/search?query=2016-003427-30)

If you have questions about this study UCB contact information is available at [www.ucb.com/UCBcares](http://www.ucb.com/UCBcares)

### Study Information

**Protocol Number:** PS0014

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

**Full Study Title:** A Multicenter, Open-Label Study to Assess the Long-Term Safety, Tolerability, and Efficacy of Bimekizumab in Adult Subjects With Moderate to Severe Chronic Plaque Psoriasis

**National Clinical Study Number:** NCT03598790

**EudraCT Number:** 2016-003427-30

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## *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.

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This summary was last updated on October 31 2024.  
The final clinical study report is dated May 13 2024.