Clinical Study Results

Inspired by patients. Driven by science.

Study Sponsor: UCB Biopharma SRL

Drug Studied: Bimekizumab

Protocol Number: PS0020

Short Study Title: A study to learn how bimekizumab moves throughout the body over time and about its safety in adolescents with plaque psoriasis

Thank you

UCB thanks all the participants of this study and their caregivers. All the participants and caregivers helped the researchers learn more about how bimekizumab acts in the blood of adolescent patients with 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, their caregivers, 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.

This summary was approved by UCB Biopharma SRL on 03 September 2025. The information in this summary is current as of this date.

Overview of this study

Why was the research needed?

Researchers are looking for a different way to treat plaque psoriasis in children and adolescents. 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 treatment did the participants receive?

The participants in this study received bimekizumab.

What were the results of this study?

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

- **How did bimekizumab move throughout the body over time?**
  Overall, the researchers found that the levels of bimekizumab in the participants' blood increased until becoming stable 16 to 20 weeks after their first dose. The participants who received the higher dose of bimekizumab (Dose A) had higher levels in their blood compared to the participants who received the lower dose (Dose B).

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

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

36.6% of participants (15 out of 41) had medical problems that the study doctors reported as **possibly related** to study treatment.

The most common possibly related medical problems were common cold (Nasopharyngitis) and urinary tract infection.

Where can I learn more about this study?

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?

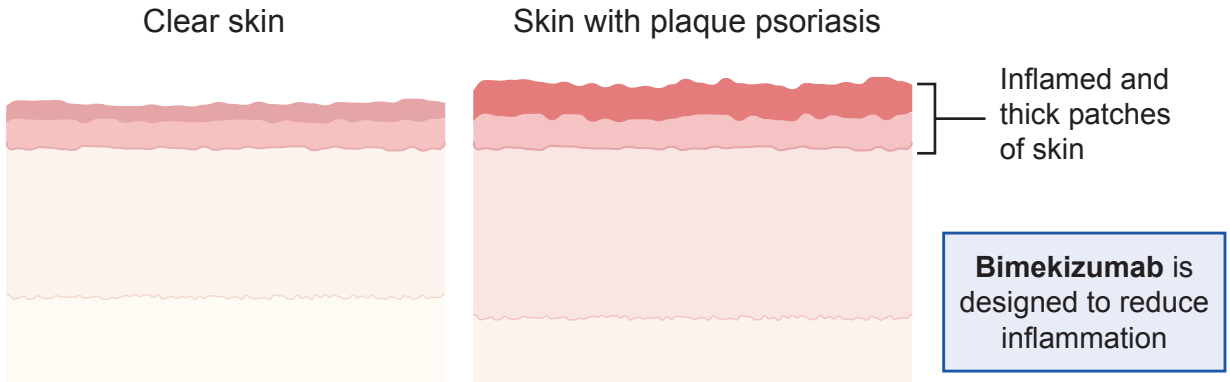
Before a treatment is available for children or adolescents to receive, researchers do clinical studies to get information about how well the treatment works and about how safe it is.

The researchers in this study wanted to learn how bimekizumab moves throughout the body in adolescents living with plaque psoriasis. They also wanted to learn if the participants had any medical problems during the study.

Plaque psoriasis is an inflammatory condition that causes dry, scaly patches of skin. These patches are called plaques. In people with light skin, plaques are usually pink or red. In people with darker skin, plaques can be light brown, dark brown, purple, gray, or the same color as the skin around it. Plaques can form on any part of the body but most often on the elbows, knees, scalp, and lower back. They can also be itchy and painful and can sometimes crack and bleed, especially around the joints.

The study drug **bimekizumab** is designed to work by stopping certain proteins in the body that cause inflammation. Bimekizumab is already approved for adults 18 years of age and older with plaque psoriasis in certain countries, but not for children and adolescents.

In this study, the researchers wanted to learn how bimekizumab moves throughout the body over time in adolescents with plaque psoriasis. This information is important to know before bimekizumab can be approved for adolescents to receive.



What was the main question studied?

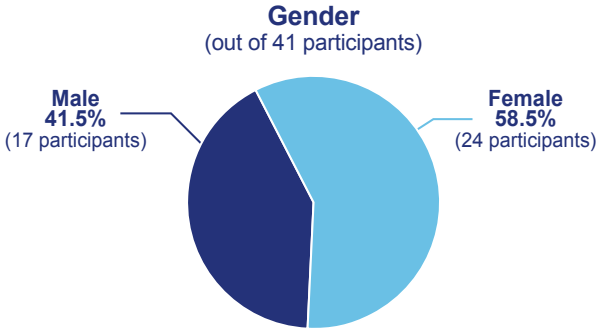
The main question the researchers wanted to answer in this study was:

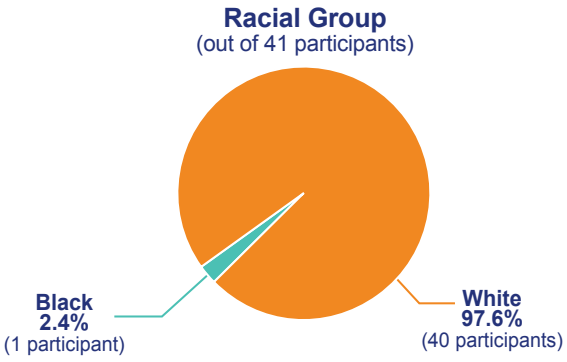
- How did bimekizumab move throughout the body over time?

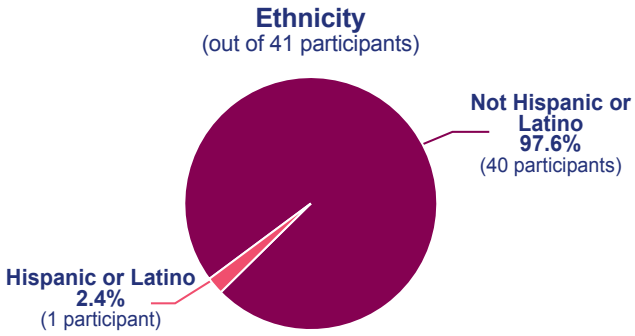
The researchers also wanted to know what medical problems happened that were possibly related to study treatment.

Who participated in the study?

There were 41 participants with plaque psoriasis who participated in this study. They were 12 to 17 years old when they joined.







Clinical Study Results

The study included participants in 4 countries.

In this study, the researchers included adolescents living with plaque psoriasis who:

- Had plaque psoriasis for at least 3 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
- Had plaque psoriasis that might have benefited from “systemic” treatments, which are treatments that enter the bloodstream and affect the whole body

Each participant who completed the study was in the study for up to a little less than 3 years. The whole study lasted a little less than 4 years. The study started in April 2021 and ended in March 2025.

What treatment did the participants receive?

The participants in this study received bimekizumab. Doses of bimekizumab were measured in milligrams, also called mg.

The participants were assigned to receive bimekizumab in either **Dose Group A** or **Dose Group B**. Dose Group A was a higher dose and researchers expected that it would lead to the same levels of bimekizumab in the blood as measured in adults. Dose Group B was a lower dose and researchers expected that it would lead to lower levels of bimekizumab in the blood.

For each dose group, participants were further divided into 1 of 2 weight categories based on their body weight. This determined the actual dose of bimekizumab that each participant received. The participants' body weight was measured in kilograms, also called kg.

The researchers used a computer program to randomly choose the assigned dose group of bimekizumab for each participant. This helped make sure the dose groups were chosen fairly and comparing the results for the doses was as accurate as possible.

The participants, study doctors, study staff, and UCB staff knew what dose the participants were receiving.

The participants received treatment in 2 different parts of this study. The first part was called the Initial Treatment Period, and the second part was called the Open-Label Extension Period.

The participants were in the **Initial Treatment Period** for 20 weeks and received bimekizumab at their study site.

The participants who completed the Initial Treatment Period could join the **Open-Label Extension Period** if:

- They did not have too many medical problems while receiving bimekizumab.
- Their plaque psoriasis symptoms improved by a certain amount.

The participants were in the Open-Label Extension Period for 2 years and received bimekizumab either at home or at the study site. The participants remained in the same dose group that they were in during the Initial Treatment period.

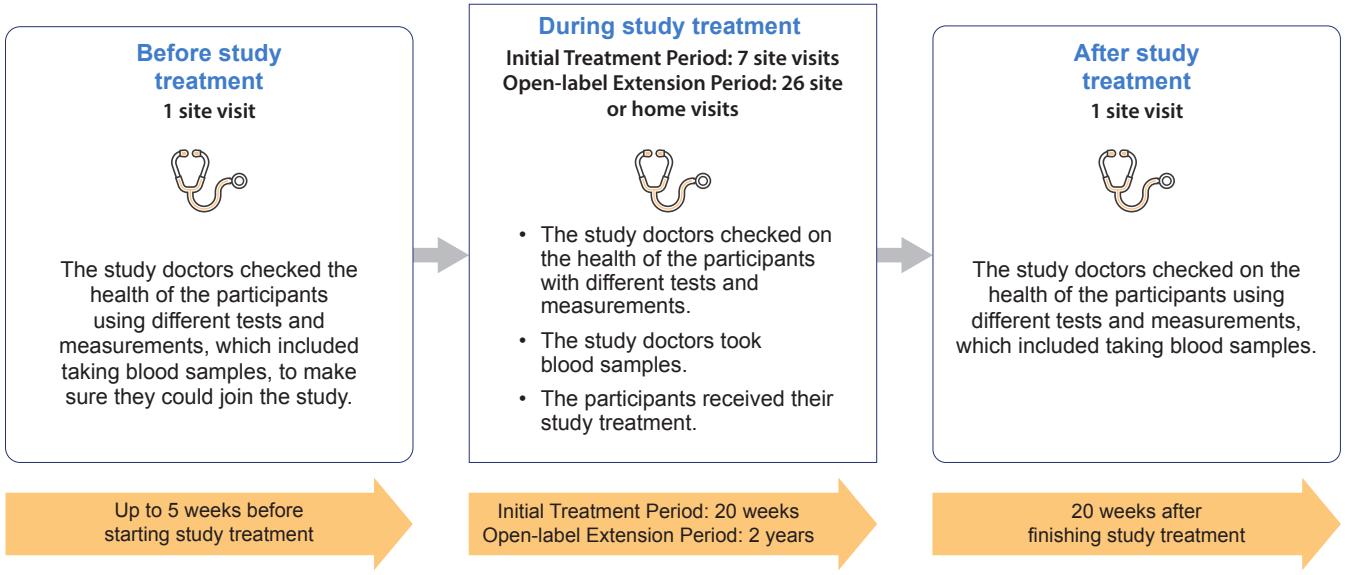
The chart below shows the treatments the researchers planned to study:

	Dose Group A of bimekizumab	Dose Group B of bimekizumab
	20 participants	21 participants
	Dose Group A: High dose of bimekizumab	**Dose Group B:** Low dose of bimekizumab
	Bimekizumab was given as injections just under the skin	
	Initial Treatment Period: 20 weeks **Open-Label Extension Period:** 2 years	

What happened during this study?

Each participant's parent or caregiver learned about the study and decided to let the participant join the study in a process called "informed consent".

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



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 participants were assigned to bimekizumab in either Dose Group A or Dose Group B. For each dose group, the actual dose that the participants received was based on their body weight. **Dose Group A** was a **higher** dose, and **Dose Group B** was a **lower** dose.

How did bimekizumab move throughout the body over time?

Overall, the researchers found that the levels of bimekizumab in the participants' blood increased until becoming stable 16 to 20 weeks after their first dose. The participants who received the higher dose of bimekizumab (Dose Group A) had higher levels in their blood compared to the participants who received the lower dose (Dose Group B).

To answer this question, the researchers took blood samples from the participants before they received study treatment and at different times after they started receiving study treatment. Then, they measured the levels of bimekizumab in the participants' blood samples.

The researchers found that:

- The levels of bimekizumab increased in the participants' blood until the levels became stable between Week 16 and Week 20.
- The participants who received Dose A had higher levels of bimekizumab in their blood than the participants who received Dose B.

The levels of bimekizumab in the blood were similar to what the researchers expected. The participants who received Dose A had levels of bimekizumab in their blood that were similar to the levels of bimekizumab in the blood of adults who took bimekizumab in other studies.

What medical problems did the study doctors report as possibly related to 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 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.

Did any adverse reactions happen during this study?

There were 36.6% of participants (15 out of 41) who had an adverse reaction in this study.

Adverse reactions in this study

	Dose Group A of bimekizumab (out of 20 participants)	**Dose Group B of bimekizumab** (out of 21 participants)
How many participants had **serious** adverse reactions?	none	none
How many participants had adverse reactions?	40.0% (8 participants)	33.3% (7 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 a serious adverse reaction.

What adverse reactions did the participants have?

The most common adverse reactions were common cold (Nasopharyngitis) and urinary tract infection.

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

Adverse reaction	**Dose Group A of bimekizumab** (out of 20 participants)	**Dose Group B of bimekizumab** (out of 21 participants)
Common cold (Nasopharyngitis)	5.0% (1)	9.5% (2)
Urinary tract infection	5.0% (1)	9.5% (2)
Skin redness where the injection was given	10.0% (2)	none
Eye irritation (Conjunctivitis)	5.0% (1)	4.8% (1)
Nose and throat infection (Upper respiratory tract infection)	none	9.5% (2)

What did the researchers learn from this study?

The results of this study have helped researchers learn more about using bimekizumab in adolescents living with plaque psoriasis.

In this study, the researchers found that:

- The levels of bimekizumab increased in the participants' blood until the levels became stable 16 to 20 weeks after their first dose.
- The participants who received Dose A had higher levels of bimekizumab in their blood than the participants who received Dose B.
- There were 36.6% of participants (15 out of 41) who had an adverse reaction during this study.
- The most common adverse reactions were common cold (Nasopharyngitis) and urinary tract infection.

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 or your child's health or situation, please contact your doctor.

When this document was approved, further clinical studies with bimekizumab in children and adolescents were ongoing.

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/NCT04718896
- euclinicaltrials.eu/search-for-clinical-trials/?lang=en&EUCT=2023-509832-24-00

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

Study Information

Protocol Number: PS0020

National Clinical Trial Number: NCT04718896

EU CT Number: 2023-509832-24-00

EudraCT Number: 2020-001724-34

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

Full Study Title: A Multicenter, Open-Label, Randomized Study to Assess the Pharmacokinetics, Safety, and Efficacy of Two Doses of Bimekizumab in Adolescent Study Participants With Moderate to Severe Plaque Psoriasis

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 03 September 2025.
The final clinical study report is dated 25 July 2025.