# Clinical Study Results

Inspired by patients. Driven by science.

**Study Sponsor:** UCB Biopharma SRL

**Treatment Studied:** Bimekizumab

**Protocol Number:** PS0015

**Study Purpose:** A study to learn how well bimekizumab works in adults with moderate to severe plaque psoriasis

## 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 plaque psoriasis.

This is a summary of the main results of this study. This study is sometimes called the BE RADIANT 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?

Researchers are looking for a different way to treat plaque psoriasis. 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 treatments did the participants get?

The participants in this study received bimekizumab or secukinumab for 1 year. Some participants also received a placebo in addition to bimekizumab. This was to keep the number of injections the same between all treatment groups. This helped make sure the participants did not accidentally learn which treatment group they were assigned to. A placebo looks like a drug but does not have any drug in it.

After 1 year, participants could receive bimekizumab for up to 3 years.

## What were the results of the study?

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

- **Did bimekizumab help more participants have their skin completely cleared of psoriasis plaques than secukinumab?**

  **Yes**. Overall, the researchers found that more of the participants who received bimekizumab had their skin completely cleared after 16 weeks compared to the participants who received secukinumab. The results were maintained throughout the first year of the trial.

- **What medical problems did the study doctors report as possibly related to the study treatments during the first year of the trial?**

  There were 37.3% of participants who had medical problems that the study doctors reported as possibly being related to either study treatment. This was 277 out of 743 participants.

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

## 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 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 better than secukinumab in a large number of participants living with moderate to severe 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, 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. These plaques can also be itchy and painful, and can sometimes crack and bleed, especially around the joints.

**Secukinumab** is a drug approved and used in many countries to treat moderate to severe plaque psoriasis. Secukinumab works by reducing both the inflammation and the growth of skin plaques.

The drug that researchers are studying, **bimekizumab**, is designed to work by stopping certain proteins in the body that cause inflammation. In this study, researchers wanted to learn if bimekizumab works better than secukinumab and how safe it is in adults with moderate to severe plaque psoriasis.

# What were the main questions studied?

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

- Did bimekizumab help more participants have their skin completely cleared than secukinumab?
- What medical problems did the study doctors report as possibly related to the study treatments during the first year of the trial?

# Who participated in the study?

There were 743 participants, which included 486 males and 257 females, with moderate to severe plaque psoriasis who participated in this study. They were 18 to 85 years old when they joined.

The study included participants in 11 countries:

| Country | Number of Participants |
|---|---|
| Australia | 27 |
| Belgium | 6 |
| Canada | 88 |
| France | 11 |
| Germany | 99 |
| Netherlands | 5 |

| Country | Number of Participants |
|---|---|
| Poland | 255 |
| Spain | 23 |
| Turkey | 18 |
| United Kingdom | 8 |
| United States | 203 |

In this study, the researchers planned to include participants living with moderate to severe plaque psoriasis who:

- Had plaque psoriasis for at least 6 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.
- Might have benefitted from systemic treatments for their plaque psoriasis. Systemic treatments are treatments that enter the bloodstream and affect the whole body.

Participants could stay in the study for up to 3 years and 3 months. Participants in the United States and Canada could stay in the study for up to about 4 years and 7 months.

The whole study lasted for a little more than 5 years. This is because the participants did not all join the study at the same time. The study started in June 2018 and ended in August 2023.

# What treatments did the participants receive?

The participants in this study received bimekizumab and the placebo, or secukinumab. All of these were received as injections just under the skin (subcutaneous injections). The placebo injections looked like a study drug but did not have any medicine in it. The placebo injections helped make sure that all the participants were receiving an injection at the same time so that they were not able to accidently learn which treatment group they were assigned to. Doses of bimekizumab and secukinumab were measured in milligrams (mg).

None of the participants, study doctors, or study staff knew what treatment each participant was receiving during the first 48 weeks (about 1 year). 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 48 weeks, 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 secukinumab. This helped make sure the treatments were chosen fairly and comparing the results for the treatments was as accurate as possible.

This study had 2 main parts: Part 1 and Part 2. The chart below shows the treatments during Part 1:

**Part 1**

| | Group 1 | Group 2 |
|---|---|---|
| | 373 participants | 370 participants |
| | 320 mg of **bimekizumab and the placebo** | 300 mg of **secukinumab** |
| | Bimekizumab one time, then:<br>**Weeks 1 to 3**: the placebo once a week<br>**Weeks 4 to 16**: bimekizumab once every 4 weeks | Secukinumab one time, then:<br>**Weeks 1 to 3**: secukinumab once a week<br>**Weeks 4 to 16**: secukinumab once every 4 weeks |
| | For 16 weeks | |

After Part 1, all the participants could continue into Part 2. All the participants who were in Group 1 during Part 1 continued to receive bimekizumab in Part 2. These participants received bimekizumab either as often (once every 4 weeks) as in Part 1, or less often (once every 8 weeks). The researchers used a computer program to randomly choose if the participants received bimekizumab once every 4 weeks or once every 8 weeks.

All the participants who were in Group 2 during Part 1 continued receiving secukinumab once every 4 weeks during Part 2.

There were 27 participants who left the study before entering Part 2, so Part 2 only included 716 participants.

The chart below shows the treatments during Part 2:

| Part 2 | | | |
|---|---|---|---|
| | **Group 1A** | **Group 1B** | **Group 2** |
| | 147 participants | 215 Participants | 354 participants |
| | 320 mg of **bimekizumab** | 320 mg of **bimekizumab and the placebo** | 300 mg of **secukinumab** |
| | Once every 4 weeks | Bimekizumab or the placebo, alternating, once every 4 weeks | Once every 4 weeks |
| | For 32 weeks | | |

Parts 1 and 2 together lasted for 48 weeks (about 1 year).

After Parts 1 and 2 were over, all the participants could receive bimekizumab for up to a little less than 2 years. During this period, the participants:

- Started by receiving 320 mg of bimekizumab once every 8 weeks **or** once every 4 weeks, depending on how they had responded to their previous treatment.
- Then, received 320 mg of bimekizumab once every 8 weeks.

The participants in the United States and Canada were also given the choice to continue receiving bimekizumab after that period for about another year.

# What happened during the study?

The chart below shows how the study was planned to be done:

## Before starting study treatment

**1 visit**

**The study doctors:**

- Looked at the participants' skin and asked them about their psoriasis symptoms
- Took blood and urine samples
- Checked the participants' vital signs and did a physical exam
- Checked the participants' heart health using an electrocardiogram (ECG)
- Did a chest X-ray
- Asked the participants about how they were feeling, their medical history, and their past and current medication
- Kept track of any medical problems reported by the participants or observed by the study doctors or staff

**Up to 5 weeks before starting study treatment**

## While the participants received study treatment

**1 visit per week during the first 4 weeks, then 1 visit per month until week 64, then 1 visit every 3 months**

**The study doctors:**

- Looked at the participants' skin
- Took blood and urine samples
- Checked the participants' vital signs and did a physical exam
- Checked the participants' heart health using an ECG during the first year
- Asked the participants about their psoriasis symptoms, their feelings and quality of life, and their current medications
- Kept track of any medical problems reported by the participants or observed by the study doctors or staff

**The participants:**

- Received their study treatment

**Up to 3 years and 9 months**

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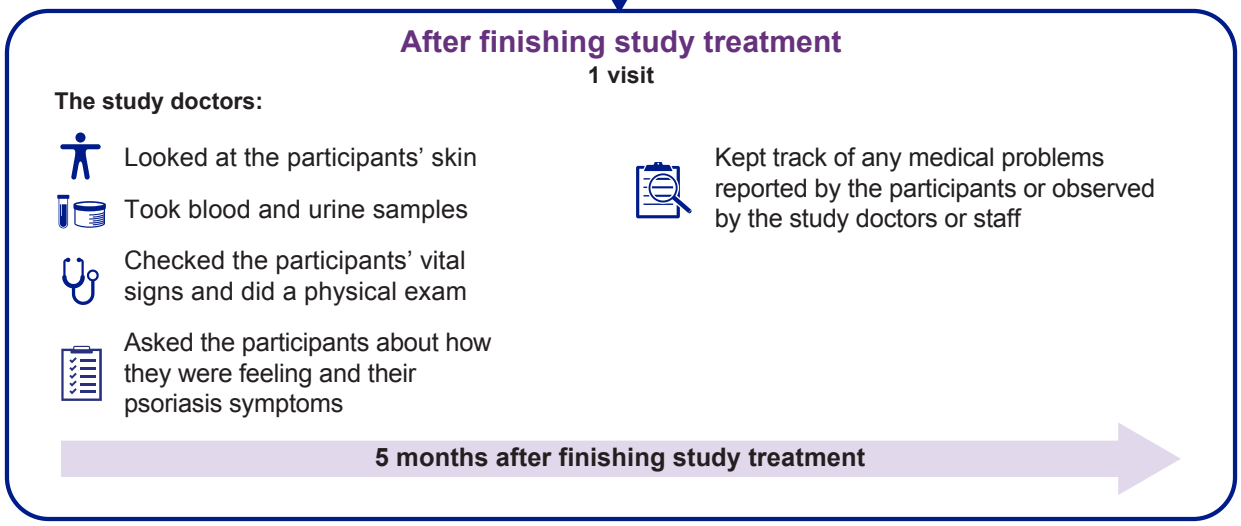



# What were the results of the study?

This is a summary of the main results from this study. These are the results from all the participants. 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 more participants have their skin completely cleared than secukinumab?

**Yes**. In this study, more of the participants who received bimekizumab had their skin completely cleared after 16 weeks (Part 1) compared to the participants who received secukinumab.

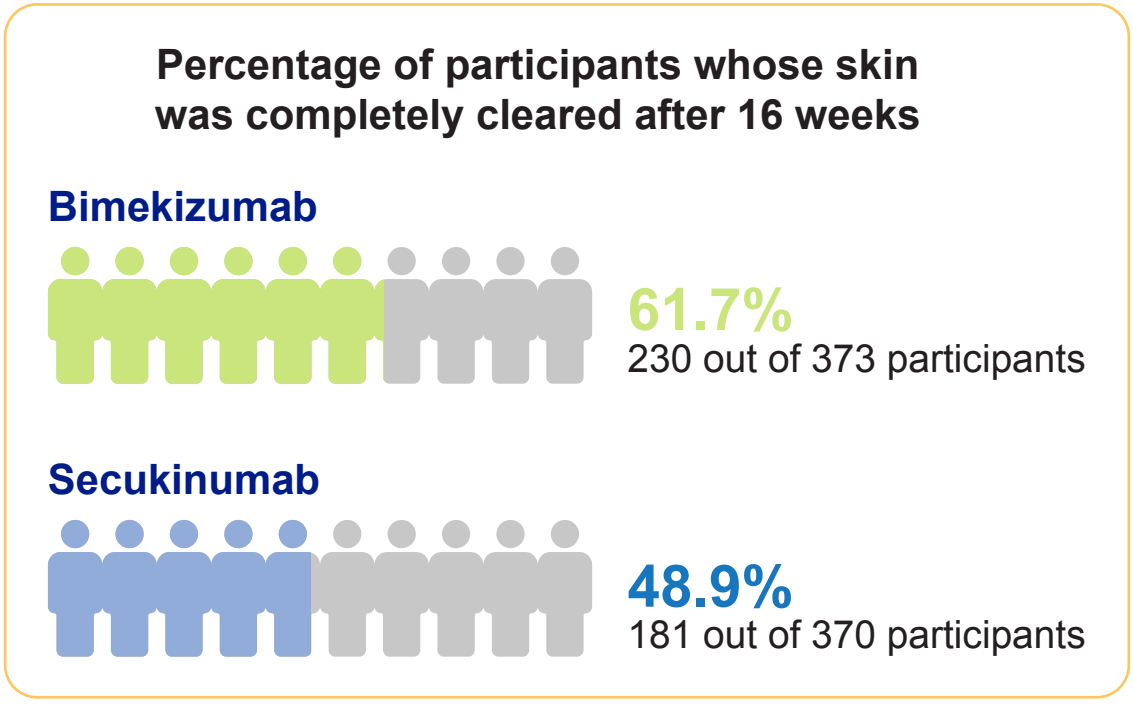
The researchers answered this question by looking at the participants' skin at every visit during Part 1 and assessing how clear it was of psoriasis plaques. They measured this by using a scale called the Psoriasis Area and Severity Index (PASI). The PASI is a scale from 0 to 72, where a lower score means less severe psoriasis.

## Clinical Study Results

In this study, the researchers looked at how many participants had their **skin completely cleared** of psoriasis plaques after finishing 16 weeks of study treatment. These are the results from **Part 1**:

- **61.7%** of the participants (230 out of 373) who received **bimekizumab** had their skin completely cleared after finishing 16 weeks of study treatment.
- **48.9%** of the participants (181 out of 370) who received **secukinumab** had their skin completely cleared after finishing 16 weeks of study treatment.

The image below shows these results.




The number of participants who had their skin completely cleared of psoriasis plaques was maintained during **Part 2** of the trial.

# What medical problems did the study doctors report as possibly related to the study treatments during the first year of the trial?

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 secukinumab when the 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.

These are the results from **Part 1 and Part 2** combined.

## Did any adverse reactions happen during this study?

**Adverse reactions during this study**

| | **Bimekizumab** (out of 373 participants) | **Secukinumab** (out of 370 participants) |
|---|---|---|
| How many participants had serious adverse reactions? | 0.5% (2 participants) | 1.1% (4 participants) |
| How many participants had adverse reactions? | 43.2% (161 participants) | 31.4% (116 participants) |
| How many participants left the study due to adverse reactions? | 2.1% (8 participants) | 1.1% (4 participants) |

## What serious adverse reactions did the participants have?

The table below shows the serious adverse reactions that happened during the study.

**Serious adverse reactions during this study**

| Serious adverse reaction | Bimekizumab (out of 373 participants) | Secukinumab (out of 370 participants) |
|---|---|---|
| Inflammatory bowel disease (Ulcerative colitis) | 0.3% (1) | none |
| Inflammation of the membrane that covers the lungs (Pleurisy) | 0.3% (1) | none |
| A type of lung infection called atypical pneumonia | none | 0.3% (1) |
| A type of lung infection called pneumonia | none | 0.3% (1) |
| A type of skin cancer called basal cell carcinoma | none | 0.3% (1) |
| Pregnancy while taking birth control pills | none | 0.3% (1) |

None of the participants died due to serious adverse reactions during Parts 1 and 2 of this trial.

### What adverse reactions did the participants have?

The most common adverse reaction in the bimekizumab treatment group was yeast infection in the mouth, also known as oral thrush (Oral candidiasis).

The table below shows the adverse reactions that happened in 2.0% or more participants in either treatment group. There were other adverse reactions, but these happened in fewer participants.

**Adverse reactions in 2.0% or more of the participants in either treatment group**

| Adverse reaction | Bimekizumab (out of 373 participants) | Secukinumab (out of 370 participants) |
|---|---|---|
| Yeast infection in the mouth, also known as oral thrush (Oral candidiasis) | 16.1% (60) | 3.0% (11) |
| Nose and throat infection (Upper respiratory tract infection) | 4.8% (18) | 4.3% (16) |
| Common cold | 3.8% (14) | 6.8% (25) |

## 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 moderate to severe plaque psoriasis.

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. So far, the results from this study are consistent with previous studies about bimekizumab in adults with plaque psoriasis.

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 of moderate to severe plaque psoriasis with bimekizumab were ongoing. Bimekizumab is now approved in many countries for adults with plaque psoriasis.

## Where can I learn more about this study?

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

- https://www.clinicaltrials.gov/study/NCT03536884
- https://www.clinicaltrialsregister.eu/ctr-search/search?query=2017-003784-35

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

## Study Information

**Protocol Number:** PS0015

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

**Full Study Title:** A Multicenter, Randomized, Double-Blind, Secukinumab-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Bimekizumab in Adult Subjects With Moderate to Severe Chronic Plaque Psoriasis

**National Clinical Trial Number:** NCT03536884

**EudraCT Number:** 2017-003784-35

## *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 08 August 2024.
The final clinical study report is dated 25 July 2004.