Clinical Study Results

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Study Sponsor:	UCB Biopharma SRL
Treatment Studied:	Bimekizumab
Protocol Number:	PS0009
Short Study Title:	A study to learn how well bimekizumab works and how safe it is 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 moderate to severe plaque psoriasis.

This is a summary of the main results of this study. This study is sometimes called the Be VIVID 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 moderate to severe 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 receive?

The participants in this study received bimekizumab, ustekinumab, or a placebo. A placebo looks like a drug but does not have any drug in it.

What were the results of this study?

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

- **Did bimekizumab improve the participants' psoriasis symptoms after 16 weeks?**

  Yes. Overall, the researchers found that the participants who received bimekizumab had a significant improvement in their psoriasis symptoms after 16 weeks compared to the participants who received the placebo.

  The researchers also wanted to know how well bimekizumab worked compared to a commonly used psoriasis drug called ustekinumab. But, that was not one of the main questions they wanted to answer during this study, so those results are not included in this summary.

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

  There were 2 parts in this study. The doctors kept track of the medical problems that happened in **Part 1** (**16 weeks**) and in **Part 1 and Part 2 combined** (**52 weeks**).

  - In **Part 1** of this study, there were 18.7% of participants who had medical problems that the study doctors reported as possibly being related to the study treatments. This was 106 out of 567 participants.
  - In **Part 1 and Part 2** of this study, there were 32.3% of participants who had medical problems that the study doctors reported as possibly being related to the study treatments. This was 180 out of 558 participants. These numbers only include participants who received bimekizumab or ustekinumab during either part of the study.

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 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 a disease of the immune system where inflammation 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.

Treatments exist for plaque psoriasis, including a commonly used drug called ustekinumab. Ustekinumab is designed to work by stopping certain proteins in the body that cause inflammation. But, currently available treatments do not work well enough for everyone.

The drug that researchers are studying, **bimekizumab**, is also designed to work by stopping different proteins in the body that cause inflammation. In this study, researchers wanted to learn how well bimekizumab works 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 improve the participants' psoriasis symptoms after 16 weeks?
- What medical problems did the study doctors report as possibly related to the study treatments?

Who participated in the study?

There were 567 participants, which included 406 males and 161 females with moderate to severe plaque psoriasis, who participated in this study. They were 18 to 81 years old when they joined.

The study included participants in 11 countries:

Country	Number of Participants
Australia	14
Belgium	6
Canada	61
Germany	62
Hungary	27
Italy	4

Country	Number of Participants
Japan	108
Poland	143
Russian Federation	19
United Kingdom	7
United States	116

In this study, the researchers planned to include participants living with 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 benefited from systemic treatments for their plaque psoriasis. **Systemic treatments** are treatments that enter the bloodstream and affect the whole body. Systemic treatments can be taken by mouth, given as an injection just under the skin, or given through a needle directly into a vein over a period of time (IV infusion). In this study, bimekizumab was given as an injection just under the skin.

Each participant was in the study for up to about 1 and a half years, but the whole study lasted for about 2 years. This is because the participants did not all join the study at the same time.

The study started in December 2017 and ended in December 2019.

What treatments did the participants receive?

The participants in this study received bimekizumab, ustekinumab, or a placebo as injections just under the skin (subcutaneous injections). The placebo injection looked like bimekizumab but did not have any medicine in it. The researchers used the placebo to help make sure the effects they found in the study were actually caused by bimekizumab. Doses of bimekizumab and ustekinumab were measured in milligrams (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, ustekinumab, or the placebo. This helped make sure the treatments were chosen fairly and comparing the results for the treatments was as accurate as possible.

Typically, ustekinumab is given every 12 weeks. So, the participants who received ustekinumab also received placebo injections so that their treatment schedule matched that of all other participants. This was done so that none of the participants or study staff would know what treatment each participant was receiving.

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

Part 1 – Initial Treatment Period (16 Weeks)

	Bimekizumab Group	Ustekinumab Group	Placebo Group
	321 participants	163 participants	83 participants
	320 mg of bimekizumab	45 mg or 90 mg of ustekinumab depending on their weight	Placebo
	Once every 4 weeks for up to 16 weeks	1 time at their first visit and in Week 4, then a placebo injection in Weeks 8 and 12	Once every 4 weeks for up to 16 weeks

After Part 1, all participants could continue into Part 2. All participants in Part 1 who were in either the **bimekizumab group** or the **placebo group** received bimekizumab in Part 2. All the participants in the **ustekinumab group** continued with their same treatment.

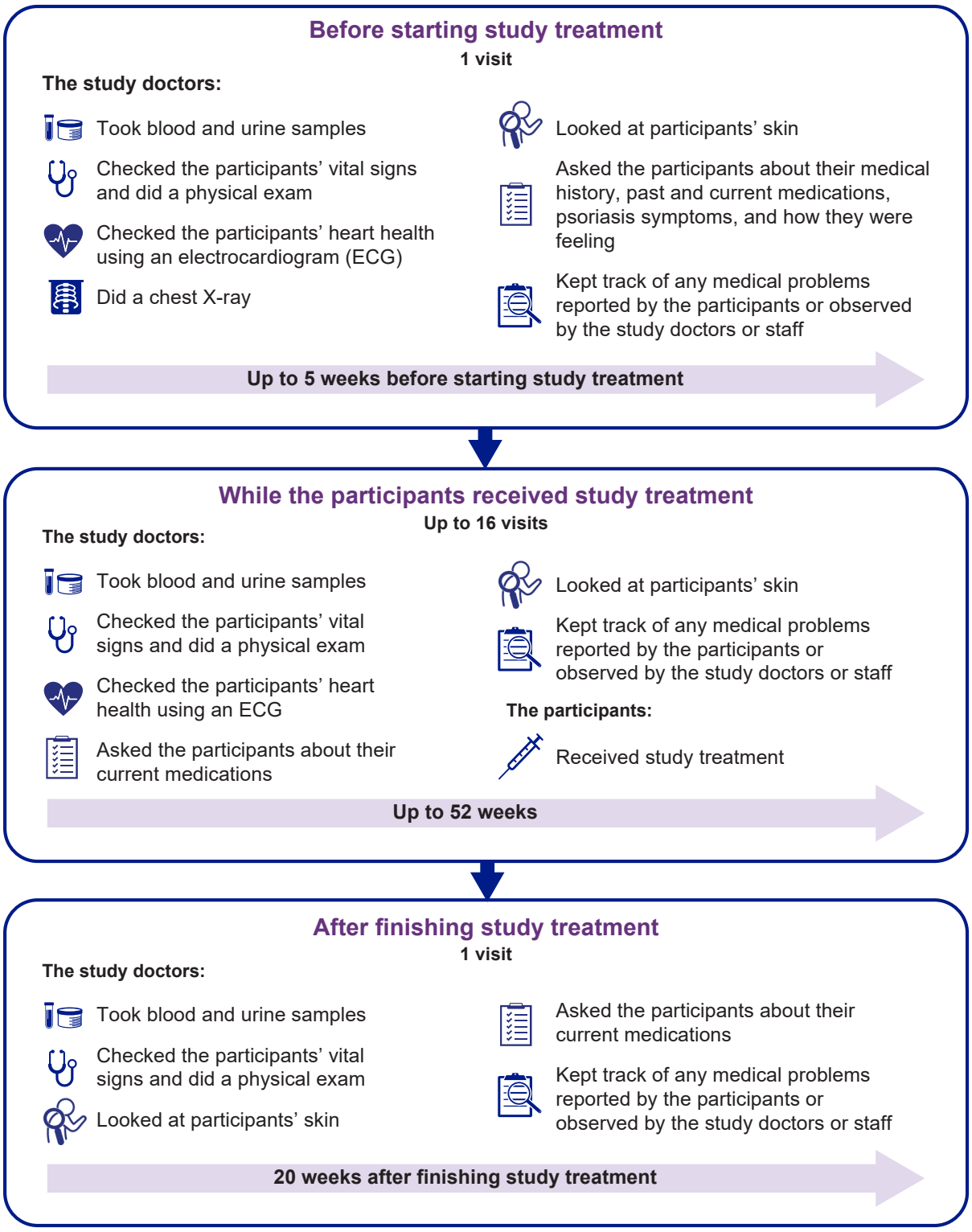
There were 30 participants who stopped participating in the study before entering Part 2 due to medical problems, the treatment not working well for them, or for other reasons.

Part 2 – Maintenance Treatment Period (36 Weeks)

	Bimekizumab Group	Ustekinumab Group
	380 participants	157 participants
	320 mg of bimekizumab	45 mg or 90 mg of ustekinumab depending on their weight
	Once every 4 weeks from Week 16 up to Week 48	1 time in Weeks 16, 28, and 40, and a placebo injection in Weeks 20, 24, 32, 36, 44, and 48

What happened during the study?

The graphic below shows how the study was planned to be done.



After finishing the 52-week treatment period, participants were able to join a separate study to receive bimekizumab. The participants who joined this separate study did not attend the final visit shown in the bottom panel of the chart above.

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 results below are from **Part 1** of the study. The researchers also wanted to know how well bimekizumab worked compared to a commonly used psoriasis drug called ustekinumab. But, that was not one of the main questions they wanted to answer during this study, so those results are not included in this summary.

Did bimekizumab improve the participants' psoriasis symptoms after 16 weeks?

Yes. In this study, the participants who received bimekizumab had a significant improvement in their psoriasis symptoms compared to the participants who received the placebo.

The researchers answered this question by looking at the participants' skin at every visit and assessing the severity of their psoriasis by using 2 different scales: PASI and IGA.

The Psoriasis Area and Severity Index (**PASI**) is a scale from 0 to 72, where a lower score means less severe psoriasis symptoms. In this study, researchers looked at how many participants had at least a 90% improvement in their PASI score from before starting the study to after receiving study treatment (Week 16).

The Investigator's Global Assessment (**IGA**) is a scale from 0 to 4, where:

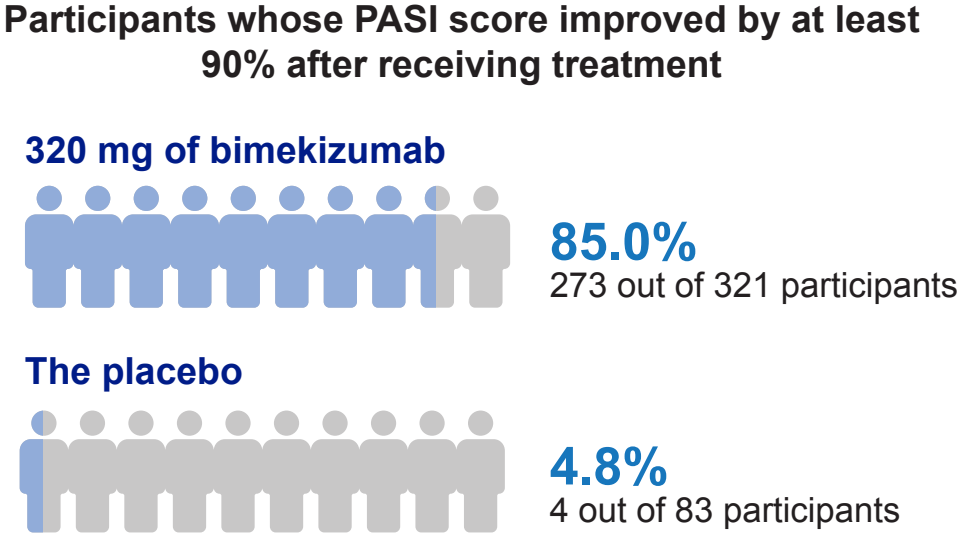
- **0** means **clear skin** or **no signs** of psoriasis
- **1** means **very mild** signs of psoriasis on the skin
- **2** means **mild** signs of psoriasis on the skin
- **3** means **moderate** signs of psoriasis on the skin
- **4** means **severe** signs of psoriasis on the skin

In this study, researchers looked at how many participants had an IGA score that improved by at least 2 points from before starting the study to after receiving study treatment and had no signs or very mild signs of psoriasis after receiving study treatment (Week 16).

Results using the PASI scale at Week 16:

- **85.0%** of the participants (273 out of 321) who received **320 mg of bimekizumab** had at least a 90% improvement in their PASI score after receiving study treatment.
- **4.8%** of the participants (4 out of 83) who received the **placebo** had at least a 90% improvement in their PASI score after receiving study treatment.

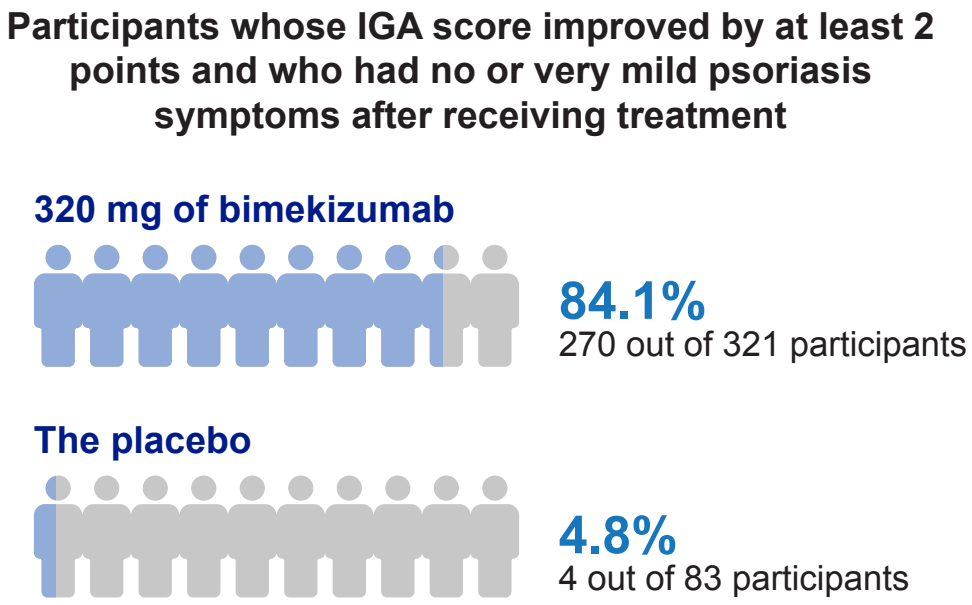
The image below shows these results.



Results using the IGA scale at Week 16:

- **84.1%** of the participants (270 out of 321) who received **320 mg of bimekizumab** had an IGA score that improved by at least 2 points and had no signs or very mild signs of psoriasis after receiving study treatment.
- **4.8%** of the participants (4 out of 83) who received the **placebo** had an IGA score that improved by at least 2 points and had no signs or very mild signs of psoriasis after receiving study treatment.

The image 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, ustekinumab, or the placebo 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.

The results in this section are shown separately for **Part 1 only** and for **Part 1 and Part 2 combined**. The results for **Part 1 and Part 2 combined** only include participants who received bimekizumab or ustekinumab during both parts of the study.

Adverse reactions in Part 1 of this study

	Bimekizumab Group (out of 321 participants)	**Ustekinumab Group** (out of 163 participants)	**Placebo Group** (out of 83 participants)
How many participants had serious adverse reactions?	0.3% (1 participant)	none	none
How many participants had adverse reactions?	24.6% (79 participants)	11.7% (19 participants)	9.6% (8 participants)
How many participants stopped receiving study treatment due to adverse reactions?	1.2% (4 participants)	0.6% (1 participant)	2.4% (2 participants)

Adverse reactions in Part 1 and Part 2 of this study combined

	Bimekizumab Group (out of 395 participants)	**Ustekinumab Group** (out of 163 participants)
How many participants had serious adverse reactions?	0.8% (3 participants)	1.2% (2 participants)
How many participants had adverse reactions?	37.2% (147 participants)	20.2% (33 participants)
How many participants stopped receiving study treatment due to adverse reactions?	4.1% (16 participants)	1.8% (3 participants)

What serious adverse reactions did the participants have?

In the results in this section, it is important to understand that some participants had more than 1 serious adverse reaction.

Serious adverse reactions in Part 1

	Bimekizumab Group (out of 321 participants)	**Ustekinumab Group** (out of 163 participants)	**Placebo Group** (out of 83 participants)
Inflammation in the large intestine and rectum (Ulcerative colitis)	0.3% (1 participant)	none	none

Serious adverse reactions in Part 1 and Part 2 combined		
	Bimekizumab Group (out of 395 participants)	**Ustekinumab Group** (out of 163 participants)
Inflammation in the large intestine and rectum (Ulcerative colitis)	0.3% (1 participant)	none
Yeast infection in the food pipe (Esophageal candidiasis)	0.3% (1 participant)	none
Inflammation of the upper airways caused by an infection (Subglottic laryngitis)	0.3% (1 participant)	none
Vocal cord weakness, which can make it hard to speak or breathe properly (Vocal cord paresis)	0.3% (1 participant)	none
Infection of the bone behind the ear (Mastoiditis)	none	0.6% (1 participant)
Ear infection (Otitis externa)	none	0.6% (1 participant)
Ear infection (Acute otitis media)	none	0.6% (1 participant)
High blood sugar due to the body not creating enough insulin (Diabetes mellitus)	none	0.6% (1 participant)

None of the participants died due to serious adverse reactions.

What adverse reactions did the participants have?

The most common adverse reaction in **Part 1** and in **Part 1 and Part 2 combined** was a yeast infection in the mouth, also known as oral thrush (Oral candidiasis). This adverse reaction only happened to participants in the **bimekizumab group**.

The tables below show the adverse reactions that happened in 2.0% or more of the participants in **any treatment group**. There were other adverse reactions, but these happened in fewer participants.

Adverse reactions in 2.0% or more of participants in any group in Part 1

	Bimekizumab Group (out of 321 participants)	**Ustekinumab Group** (out of 163 participants)	**Placebo Group** (out of 83 participants)
Yeast infection in the mouth, also known as oral thrush (Oral candidiasis)	6.9% (22 participants)	none	none
Common cold	2.8% (9 participants)	3.7% (6 participants)	1.2% (1 participant)
Diarrhea	1.9% (6 participants)	none	2.4% (2 participants)

Adverse reactions in 2.0% or more of participants in any group in Part 1 and Part 2 combined

	Bimekizumab Group (out of 395 participants)	**Ustekinumab Group** (out of 163 participants)
Yeast infection in the mouth, also known as oral thrush (Oral candidiasis)	12.4% (49 participants)	none
Common cold	6.3% (25 participants)	7.4% (12 participants)
Inflammation of hair follicles (Folliculitis)	2.8% (11 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 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.

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:

- www.clinicaltrials.gov/ct2/show/study/NCT03370133
- www.clinicaltrialsregister.eu/ctr-search/search?query=2016-003425-42

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

Study Information

Protocol Number: PS0009

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- and Active Comparator-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: NCT03370133

EudraCT Number: 2016-003425-42

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 06 August 2024.
The final clinical study report is dated 27 August 2020.