Clinical Study Results

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Study Sponsor:	UCB Biopharma SRL
Treatment Studied:	Bimekizumab
Protocol Number:	HS0003
Short Study Title:	A study to learn how well bimekizumab works in people with hidradenitis suppurativa (HS)

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 hidradenitis suppurativa (**HS**). Bimekizumab is also called UCB4940.

This is a summary of the main results of this study. An independent, non-profit organization helped prepare this summary of the study results.

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 HS. 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?

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

What were the results of this study?

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

- **Did more participants show an improvement in their HS skin lesions when treated with bimekizumab compared to the placebo?**
  Yes. Overall, the researchers found that more of the participants who received bimekizumab at a certain dose had an improvement in their HS skin lesions compared to the participants who received the placebo.

- **What medical problems did the study doctors report as possibly related to the study treatment?**
  There were 46.8% of participants who had medical problems that the study doctors reported as possibly being related to the study treatments. This was 231 out of 494 participants.

More details about the results of 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 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 hidradenitis suppurativa (HS). They also wanted to learn if the participants had any medical problems during the study.

HS is a long-term condition that causes inflammation in the skin. This can result in pain and wounds called skin lesions.

Skin lesions include abscesses, inflammatory nodules, and draining tunnels. These skin lesions can fill with pus, leak, and become infected and smell bad. Skin lesions in HS most commonly happen in areas of the body that sweat, such as the armpits and the groin. These skin lesions can lead to more serious medical problems such as reduced mobility. HS can also cause stress and anxiety and have a negative effect on mental health and wellbeing.

The symptoms of HS and their effects can have a significant impact on the quality of life of people living with HS.

Bimekizumab is designed to block proteins called interleukin-17s (IL-17s) from working. IL-17 proteins help to activate certain parts of the body's immune system that cause inflammation. Researchers think that blocking IL-17 proteins from working will lower inflammation in the skin of people with HS. This would help to reduce symptoms like skin lesions, scarring, and pain.

The researchers in this study wanted to find out how well bimekizumab works in participants living with HS. They also wanted to learn if the participants had any medical problems during the study.

What were the main questions studied?

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

- Did more participants show an improvement in their HS skin lesions when treated with bimekizumab compared to the placebo?
- What medical problems did the study doctors report as related to the study treatments?

Who participated in the study?

There were 505 males and females with HS who participated in this study. They were 18 to 78 years old when they joined.

The study included participants in 15 countries:

Country	Number of participants
Australia	22
Belgium	8
Canada	30
Denmark	6
France	38
Germany	52
Greece	45
Israel	3

Country	Number of participants
Italy	24
Netherlands	18
Norway	2
Spain	30
Switzerland	4
Turkey	17
United States	206

In this study, the researchers planned to include participants living with HS who:

- Had been diagnosed with HS at least 6 months before the start of the study.
- Had skin lesions in at least 2 different parts of the body.
- Had 5 or more specific types of HS skin lesions known as abscesses and inflammatory nodules.
- Had previously been on antibiotics for their HS, but it had not helped.

Each participant could be in the study for up to 71 weeks, but the whole study lasted for 3 years. The study started in February 2020 and ended in February 2023.

What treatments did the participants receive?

There were 2 parts in this study. In the first part, the participants received bimekizumab or a placebo. In the second part, all the participants received bimekizumab. The participants received bimekizumab and the placebo as an injection just under the skin.

The placebo injection looked like the bimekizumab injection but did not have any bimekizumab in it. The researchers used the placebo to help make sure the effects they found in the study were actually caused by bimekizumab.

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 a placebo. This helped make sure the treatments were chosen fairly and comparing the results for the treatments was as accurate as possible.

In **Part 1**, the participants received either bimekizumab at 1 of 2 different doses (**Dose A** or **Dose B**) or the placebo. Part 1 lasted for 16 weeks.

The chart below shows the treatments the researchers planned to study in Part 1:

Part 1	Bimekizumab Dose A	Bimekizumab Dose B	Placebo
	289 participants	144 participants	72 participants
	Injections of bimekizumab Dose A	Injections of bimekizumab Dose B	Injections of the placebo
	16 weeks		

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In **Part 2**, some of the participants who received bimekizumab Dose A in Part 1 changed to bimekizumab Dose B. All of the participants who received the placebo in Part 1 changed to bimekizumab Dose A. The rest of the participants stayed on the same treatment they received during Part 1. Not all of the participants from Part 1 continued into Part 2. Part 2 lasted for 32 weeks.

The chart below shows the treatments the researchers planned to study in Part 2.

Part 2	**Continued bimekizumab Dose A**	**Continued bimekizumab Dose B**	**Changed to bimekizumab Dose B** (from bimekizumab Dose A)	**Changed to bimekizumab Dose A** (from the placebo)
	129 participants	125 participants	129 participants	65 participants
	Injections of bimekizumab Dose A	Injections of bimekizumab Dose B	Injections of bimekizumab Dose B	Injections of bimekizumab Dose A
	32 weeks			

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What happened during this study?

This section shows how the study was planned to be done.

Before joining the study, the participants visited their clinic once. 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 2 to 5 weeks.

At this visit, the study doctors also:

Did physical exams, took vital signs, and asked about the participants' medications and any medical problems.

Counted the number of skin lesions that the participants had.

Assessed the severity of the participants' HS.

Checked the participants' heart health using an electrocardiogram (ECG).

Checked the participants' lungs using an X-ray.

Took blood and urine samples.

Asked the participants to answer some questionnaires about their quality of life, their HS symptoms, and their health.

During **Part 1** of the study, the participants visited the clinic 10 times. This part of the study lasted 16 weeks. During **Part 2** of the study, the participants visited the clinic 16 times. This part of the study lasted 32 weeks.

During both parts, the study doctors gave the participants their study treatments at most visits. They also kept track of any medical problems reported by the participants or observed by the doctors or study staff and asked about the participants' medications.

During both parts, the study doctors also:

Did physical exams at some visits, and checked the participants' vital signs.

At most visits, counted the number of skin lesions that the participants had.

At most visits, assessed the severity of the participants' HS.

At most visits, asked the participants to answer some questionnaires about their quality of life, their HS symptoms, and their health.

At some visits, took photos of the participants' skin lesions if the participant agreed.

At some visits, checked the participants' heart health using an ECG.

Took blood and urine samples.

After the last treatment, the participants could choose to continue receiving bimekizumab in another study or stop receiving bimekizumab. The participants who stopped receiving bimekizumab visited their clinic once. This visit happened 20 weeks after the participants received their final dose of study treatment. At this visit, the study doctors checked the participants' health and asked about any medical problems.

At this visit, the study doctors also:

Did a physical exam, took vital signs, and asked about the participants' medications and any medical problems.

Checked the participants' heart health using an ECG.

Took blood and urine samples.

Asked the participants to answer some questionnaires about their health.

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 include only the data from Part 1.

Did more participants show an improvement in their HS skin lesions when treated with bimekizumab compared to the placebo?

Yes. Overall, the researchers found that more of the participants who received **bimekizumab Dose A** during **Part 1** of this study had an improvement in their HS skin lesions compared to the participants who received the placebo.

For the participants who received **bimekizumab Dose B** during **Part 1**, the researchers did not see a significant enough difference in the number of participants who had an improvement in their HS skin lesions compared to the participants who received the placebo.

To answer this question, the researchers counted the number of different types of skin lesions that the participants had throughout Part 1. Using this information, the researchers calculated the reduction in skin lesions after 16 weeks of treatment compared to before the participants started treatment.

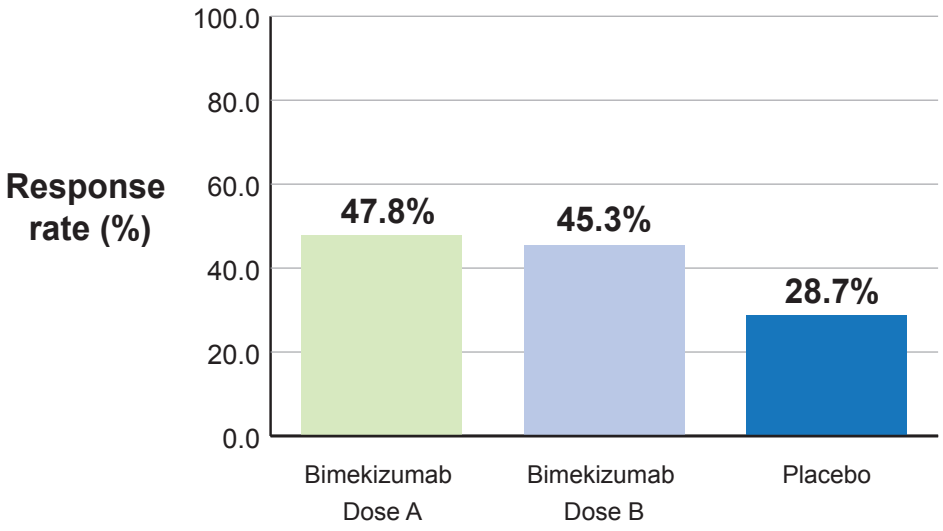
Then, they counted the number of participants who had a reduction of at least 50% in their combined number of abscesses and inflammatory nodules. They also needed to have no increase in the number of abscesses or draining tunnels. This is known as the **Hidradenitis Suppurativa Clinical Response 50** (**HiSCR50**) **criteria**. Participants who meet these criteria are known as **HiSCR50 responders**.

Then, the researchers calculated the percentage of HiSCR50 responders for each group and compared the results from the bimekizumab groups to the placebo group.

After 16 weeks of treatment at the end of Part 1:

- The HiSCR50 response rate was **47.8%** for the participants who received **bimekizumab Dose A**.
- The HiSCR50 response rate was **45.3%** for the participants who received **bimekizumab Dose B**.
- The HiSCR50 response rate was **28.7%** for the participants who received the **placebo**.

Percentage of participants who were HiSCR50 responders



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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**.

In this study, the doctors did not know whether the participants were receiving bimekizumab or the placebo when medical problems happened.

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 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.

The results below include the participants who received at least 1 dose of bimekizumab. This was 494 out of 505 participants. These results are for the full study, including Part 1 and Part 2.

Did any adverse reactions happen during this study?

	Bimekizumab Dose A (out of 141 participants)	**Bimekizumab Dose B** (out of 143 participants)	**Bimekizumab Dose A** then **Bimekizumab Dose B** (out of 145 participants)	**Placebo** then **Bimekizumab Dose A** (out of 65 participants)
How many participants had serious adverse reactions?	1.4% (2 participants)	2.8% (4 participants)	1.4% (2 participants)	none
How many participants had adverse reactions?	46.8% (66 participants)	45.5% (65 participants)	49.7% (72 participants)	43.1% (28 participants)
How many participants left the study due to adverse reactions?	2.8% (4 participants)	4.9% (7 participants)	4.8% (7 participants)	6.2% (4 participants)

What serious adverse reactions did the participants have during this study?

There were 8 participants who had serious adverse reactions during this study. Some participants may have had more than 1 serious adverse reaction.

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

	Bimekizumab Dose A (out of 141 participants)	**Bimekizumab Dose B** (out of 143 participants)	**Bimekizumab Dose A** then **Bimekizumab Dose B** (out of 145 participants)	**Placebo** then **Bimekizumab Dose A** (out of 65 participants)
Inflammation of the front of the eye (Keratitis)	none	0.7% (1 participant)	none	none
Inflammation of the large intestine and rectum (Ulcerative colitis)	none	none	0.7% (1 participant)	none
Injury to the liver caused by a drug	0.7% (1 participant)	none	none	none
Kidney stones	none	none	0.7% (1 participant)	none
Thinking about suicide (Suicidal ideation)	none	0.7% (1 participant)	none	none
Worsening of HS	0.7% (1 participant)	none	none	none
Yeast infection around the genitals (Genital candidiasis)	none	0.7% (1 participant)	none	none
Yeast infection in the mouth and throat (Oropharyngeal candidiasis)	none	0.7% (1 participant)	none	none

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What adverse reactions did the participants have during this study?

The most common adverse reaction was a yeast infection in the mouth (Oral candidiasis).

The table below shows the adverse reactions that happened in 2% or more participants in total. There were other adverse reactions, but these happened in fewer participants.

	Bimekizumab Dose A (out of 141 participants)	**Bimekizumab Dose B** (out of 143 participants)	**Bimekizumab Dose A** then **Bimekizumab Dose B** (out of 145 participants)	**Placebo** then **Bimekizumab Dose A** (out of 65 participants)
Yeast infection in the mouth, also known as oral thrush (Oral candidiasis)	8.5% (12 participants)	7.7% (11 participants)	10.3% (15 participants)	1.5% (1 participant)
Diarrhea	2.8% (4 participants)	4.2% (6 participants)	2.8% (4 participants)	3.1% (2 participants)
Headache	2.1% (3 participants)	3.5% (5 participants)	2.8% (4 participants)	3.1% (2 participants)
Worsening of HS	3.5% (5 participants)	2.8% (4 participants)	1.4% (2 participants)	3.1% (2 participants)
Infection of the urinary tract, which may include the kidneys and bladder	2.1% (3 participants)	2.8% (4 participants)	2.1% (3 participants)	none
Reaction where the injection was given, such as bruising, pain, or itching	3.5% (5 participants)	0.7% (1 participant)	2.1% (3 participants)	1.5% (1 participant)
Skin infection caused by a fungus	2.1% (3 participants)	0.7% (1 participant)	2.8% (4 participants)	3.1% (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 HS.

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 HS 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:

- https://clinicaltrials.gov/study/NCT04242446
- https://www.clinicaltrialsregister.eu/ctr-search/search?query=2019-002550-23

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

Study Information

Protocol Number: HS0003

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

Full Study Title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study Evaluating the Efficacy and Safety of Bimekizumab in Study Participants With Moderate to Severe Hidradenitis Suppurativa

National Clinical Trial Number: NCT04242446

EudraCT Number: 2019-002550-23

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.

This summary was last updated on 31 January 2024.
The final clinical study report is dated 05 September 2023.