Clinical Study Results

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Study Sponsor:	UCB Biopharma SRL
Treatment Studied:	Bimekizumab
Protocol Number:	HS0004
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, 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?

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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 participants who received bimekizumab had their skin lesions reduced, 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 43.9% of participants who had medical problems that the study doctors reported as possibly related to the study treatment. This was 220 out of 501 participants who received at least 1 dose of study treatment.

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 treatment?

Who participated in the study?

There were 509 males and females with HS who participated in this study. They were 18 to 75 years old when they joined.

The study included participants in 14 countries:

Country	Number of participants	Country	Number of participants
Australia	5	Ireland	1
Bulgaria	61	Israel	2
Canada	36	Japan	27
Czech Republic	23	Poland	124
France	52	Spain	17
Germany	36	United Kingdom	5
Hungary	7	United States	113

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 was in the study for up to 73 weeks, but the whole study lasted for a little more than 2.5 years. The study started in March 2020 and ended in September 2022.

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 according to 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
	291 participants	144 participants	74 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. Part 2 lasted for 32 weeks.

The chart below shows the treatments the researchers planned to study in Part 2. Not all of the participants from Part 1 continued into 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)
	131 participants	133 participants	130 participants	69 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.

The study doctors:

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. During **Part 2** of the study, the participants visited the clinic 16 times. The study doctors gave the participants their study treatments and kept track of any medical problems reported by the participants or observed by the doctors or study staff.

At all visits during Part 1 and Part 2, the study doctors also:

Gave the participants their study treatments.

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.

At some visits during Part 1 and Part 2, the study doctors also:

Checked the participants' heart health using an ECG.

Took blood and urine samples.

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

Took photos of the participants' skin lesions, if the participants agreed.

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.

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.

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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 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 in **Part 1**, more participants who received bimekizumab had their skin lesions reduced, 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 compared to before the participants started treatment.

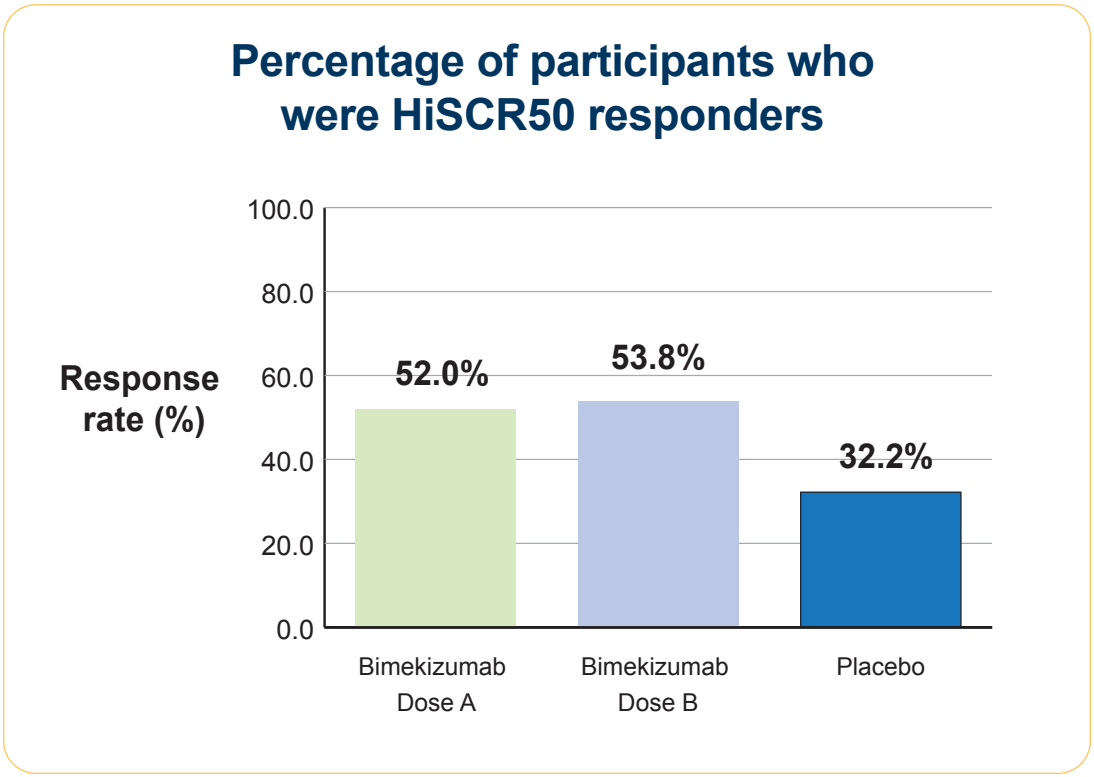
Then, they counted the number of participants who had a reduction of at least 50% in their combined number of abscesses and inflammatory nodules. They also needed to have no increase in the number of abscesses or draining tunnels. This is known as the **Hidradenitis Suppurativa Clinical Response 50**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

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

- The HiSCR50 response rate was **52.0%** for the participants who received **bimekizumab Dose A**.
- The HiSCR50 response rate was **53.8%** for the participants who received **bimekizumab Dose B**.
- The HiSCR50 response rate was **32.2%** for the participants who received the **placebo**.

The graph below shows these results.



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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 501 out of 509 participants. These results are for the full 48 weeks of the study, including Part 1 and Part 2.

Did any adverse reactions happen during this study?

	Bimekizumab Dose A (out of 144 participants)	**Bimekizumab Dose B** (out of 142 participants)	**Bimekizumab Dose A** then **Bimekizumab Dose B** (out of 146 participants)	**Placebo** then **Bimekizumab Dose A** (out of 69 participants)
How many participants had serious adverse reactions?	2.1% (3 participants)	1.4% (2 participants)	none	none
How many participants had adverse reactions?	50.0% (72 participants)	35.2% (50 participants)	52.7% (77 participants)	30.4% (21 participants)
How many participants left the study due to adverse reactions?	4.2% (6 participants)	2.1% (3 participants)	2.1% (3 participants)	none

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

There were 5 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 144 participants)	**Bimekizumab Dose B** (out of 142 participants)	**Bimekizumab Dose A** then **Bimekizumab Dose B** (out of 146 participants)	**Placebo** then **Bimekizumab Dose A** (out of 69 participants)
Inflamed large intestine and rectum (Colitis ulcerative)	0.7% (1 participant)	none	none	none
Rash with pus-filled bumps (Rash pustular)	0.7% (1 participant)	none	none	none
Worsening of HS	0.7% (1 participant)	none	none	none
Inflamed digestive system (Crohn's disease)	none	0.7% (1 participant)	none	none
Gallstones (Cholelithiasis)	none	0.7% (1 participant)	none	none
Sudden inflammation of the gallbladder (Cholecystitis acute)	none	0.7% (1 participant)	none	none

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 5% or more of participants in any treatment group. There were other adverse reactions, but these happened in fewer participants.

	Bimekizumab Dose A (out of 144 participants)	**Bimekizumab Dose B** (out of 142 participants)	**Bimekizumab Dose A** then **Bimekizumab Dose B** (out of 146 participants)	**Placebo** then **Bimekizumab Dose A** (out of 69 participants)
Yeast infection in the mouth (Oral candidiasis)	13.2% (19 participants)	7.7% (11 participants)	14.4% (21 participants)	4.3% (3 participants)
Inflamed hair follicles (Folliculitis)	5.6% (8 participants)	3.5% (5 participants)	3.4% (5 participants)	2.9% (2 participants)
Yeast infection around the vagina and vulva (Vulvovaginal candidiasis)	2.1% (3 participants)	5.6% (8 participants)	2.1% (3 participants)	1.4% (1 participant)
Itchy, swollen skin (Eczema)	1.4% (2 participants)	1.4% (2 participants)	5.5% (8 participants)	4.3% (3 participants)

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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/NCT04242498
- https://www.clinicaltrialsregister.eu/ctr-search/search?query=2019-002551-42

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

Study Information

Protocol Number: HS0004

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 Study Number: NCT04242498

EudraCT Number: 2019-002551-42

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.

This summary was last updated on 07 December 2023.
The final clinical study report is dated 30 August 2023.