Clinical Study Results

Inspired by patients. Driven by science.

Study Sponsor: UCB Biopharma SRL

Drug Studied: Galvokimig

Protocol Number: UP0089

Short Study Title: A study to learn more about the safety of galvokimig and how well it works to treat eczema

Thank you

UCB thanks all the participants of this study. All the participants helped the researchers learn more about using galvokimig for people living with atopic dermatitis, also called eczema. Galvokimig is also called UCB9741.

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.

This summary was approved by UCB Biopharma SRL on 03 June 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 way to treat eczema. 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 either galvokimig or a placebo. A placebo looks like a drug but does not have any medicine in it.

What were the results of this study?

This study had 2 parts. **Part A** had **healthy participants**, and **Part B** had **participants with eczema**. The main questions the researchers wanted to answer in this study were:

- **Part B only —** Did galvokimig help improve the participants' eczema?
  - Overall, the researchers found that most participants who received galvokimig had an improvement in their eczema compared with the participants who received the placebo.
- **Parts A and B —** What medical problems did the participants have during this study?
  - The most common medical problem during both parts of the study was headache.
  - In Part A, 67.8% of participants (40 of 59) had medical problems. In Part B, 66.0% of participants (31 of 47) had medical problems.

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

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

- **Part A**
  - The most common possibly related medical problem was skin redness where the injection of study treatment was given.
  - 11.9% of participants (7 out of 59) had medical problems that the study doctors reported as **possibly related** to study treatment.
- **Part B**
  - The most common possibly related medical problems were headache and nose and throat infection (Upper respiratory tract infection).
  - 17.0% of participants (8 out of 47) had medical problems that the study doctors reported as **possibly related** to study treatment.

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.

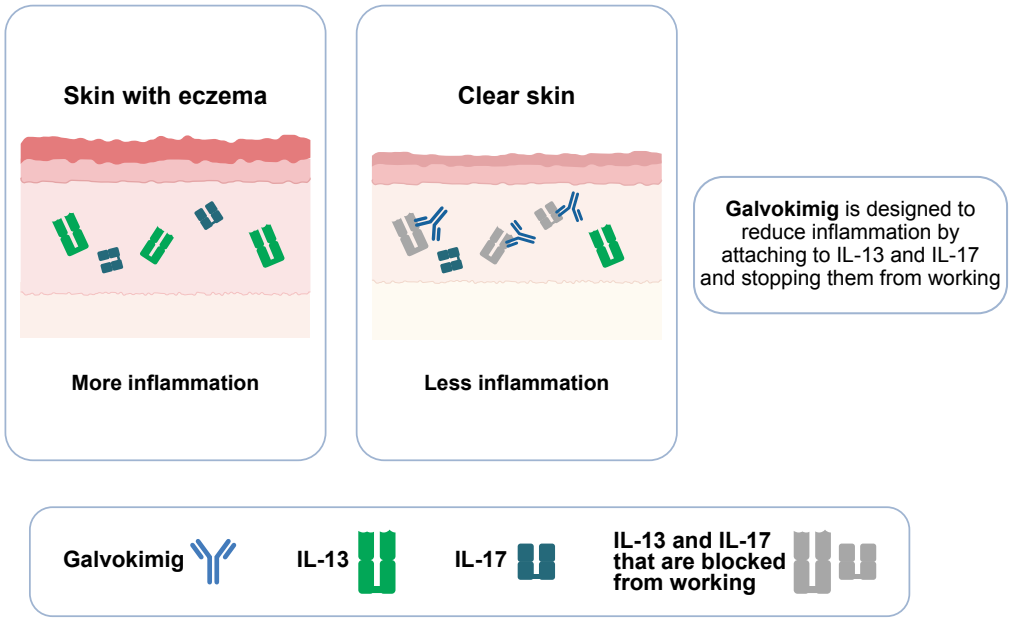
Why was the research needed?

Before a treatment is available to the public, 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 galvokimig works in healthy participants and participants with eczema. A “healthy participant” is someone who does not have the condition the treatment is trying to treat or other serious health conditions. The researchers also wanted to find out if the participants had any medical problems during the study. This information is important to know before additional studies can be done that help find out if galvokimig can improve the health of people living with eczema.

Atopic dermatitis, also called **eczema**, is a long-term condition that causes the skin to become dry, itchy, and cracked. On paler colored skin, atopic dermatitis can look red. On darker colored skin, atopic dermatitis can look grey or purple. It can affect any area of the skin, but it is more common in areas such as the inside of the elbows, behind the knees, and on the face and neck. The exact cause of eczema is unknown, but it tends to run in families. It can be triggered by allergies, stress, dry skin, and infection.

The study drug **galvokimig** is designed to work by stopping certain proteins of the immune system from working. The immune system is the body’s natural defense system. These proteins are called interleukin-13 (IL-13) and interleukin-17 (IL-17), and they are known to cause inflammation or swelling that can lead to eczema. Researchers think that by stopping IL-13 and IL-17 from working, people could have less inflammation and an improvement in their eczema.



What were the main questions studied?

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

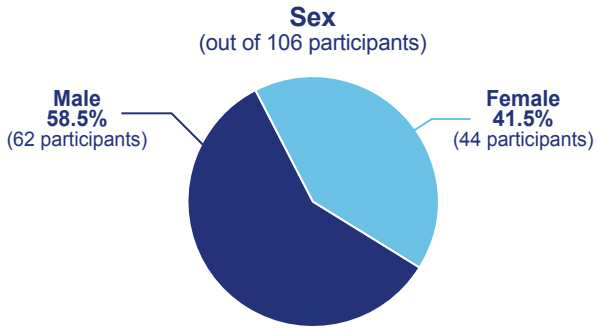
- **Part B only** — Did galvokimig help improve the participants' eczema?
- **Parts A and B** — What medical problems did the participants have during this study?

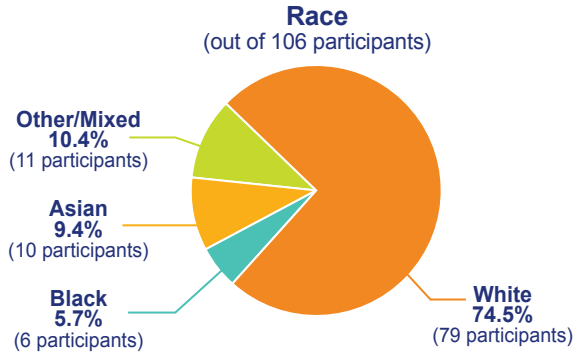
The researchers also wanted to know what medical problems happened that were possibly related to study treatment.

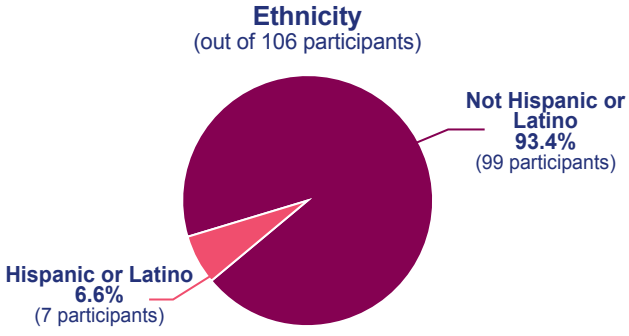
Who participated in the study?

There were 106 participants in this study:

- In **Part A**, there were 59 **healthy participants**. They were 18 to 55 years old when they joined.
- In **Part B**, there were 47 **participants with eczema**. They were 19 to 64 years old when they joined.

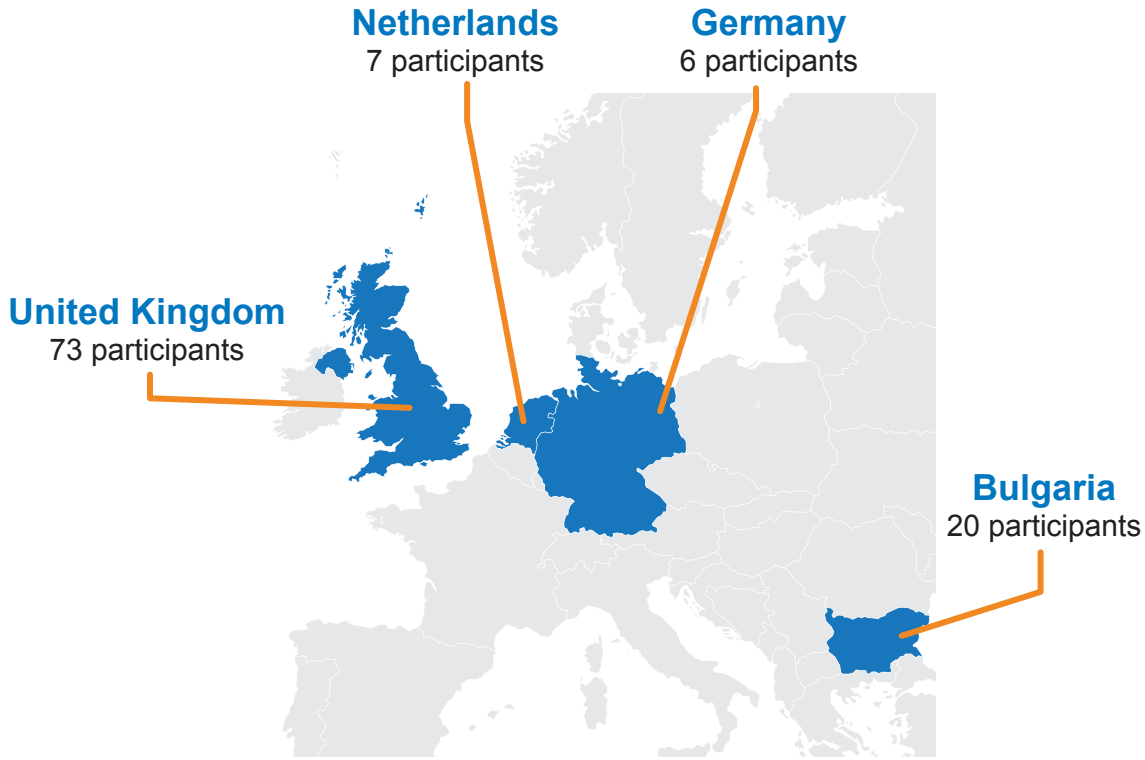






Clinical Study Results

The study included participants in 4 countries.



In this study, the researchers included participants who:

- Did not have eczema (Part A)
- Had moderate to severe eczema for at least 1 year (Part B)
- Did not have other major health issues (Parts A and B)

Each participant who completed **Part A** of the study was in the study for up to about 16 weeks. Each participant who completed **Part B** of the study was in the study for up to about 22 weeks. The whole study lasted 3 years and 8 months. The study started in November 2020 and ended in June 2024.

What treatments did the participants receive?

The participants in this study received galvokimig or a placebo either through a needle directly into a vein over a period of time (IV infusion) or as an injection just under the skin (subcutaneous, also called an SC injection). The placebo looked like galvokimig but did not have any galvokimig in it. The researchers used the placebo to better understand what effects may have been related to galvokimig.

In this summary, “study treatment” means anything the participants took as a part of the study. This includes galvokimig and the placebo. **Galvokimig** is the drug that the researchers wanted to learn more about.

In both parts of the study, none of the participants, study doctors, or study staff knew what treatment the participants were receiving. Some studies are done this way because knowing what treatment the participants are receiving can affect the results of the study. To help run the study, a small number of UCB staff may have known what treatment the participants were receiving during one or both parts. After the study was completed, UCB learned what treatment each participant received so they could create a report of the results.

Part A was a **single ascending dose** part. This means that a group of healthy participants started out receiving a single low dose of galvokimig. The doctors looked at the results for these participants. Then, the researchers decided whether to increase the dose in the next group of healthy participants. Researchers use single ascending dose parts of studies to learn about the safety of a specific dose before participants are given a higher dose or multiple doses.

Part B was a **repeated dose** part. This means that participants with eczema received a dose of galvokimig based on what was learned about its safety in Part A. Each participant in Part B received the same dose of galvokimig at repeated intervals of time for 10 weeks. Repeated dose studies help researchers learn more about how well a specific dose works in people with eczema and how safe it is.

In both parts of the study, the researchers used a computer program to randomly choose if the participants received galvokimig or the placebo. This helped make sure the treatments were chosen fairly and comparing the results for the treatments was as accurate as possible.

Participants were able to participate in Part A if they were healthy volunteers **or** Part B if they had eczema.

Clinical Study Results

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

Part A

	Group 1	Group 2	Group 3	Group 4	Group 5
	11 participants	5 participants	6 participants	6 participants	6 participants
	Placebo	Placebo	Dose A of galvokimig	Dose B of galvokimig	Dose C of galvokimig
	Single dose given once				

Part A (cont.)

	Group 6	Group 7	Group 8	Group 9
	6 participants	7 participants	6 participants	6 participants
	Dose D of galvokimig	Dose E of galvokimig	Dose F of galvokimig	Dose G of galvokimig
	Single dose given once			

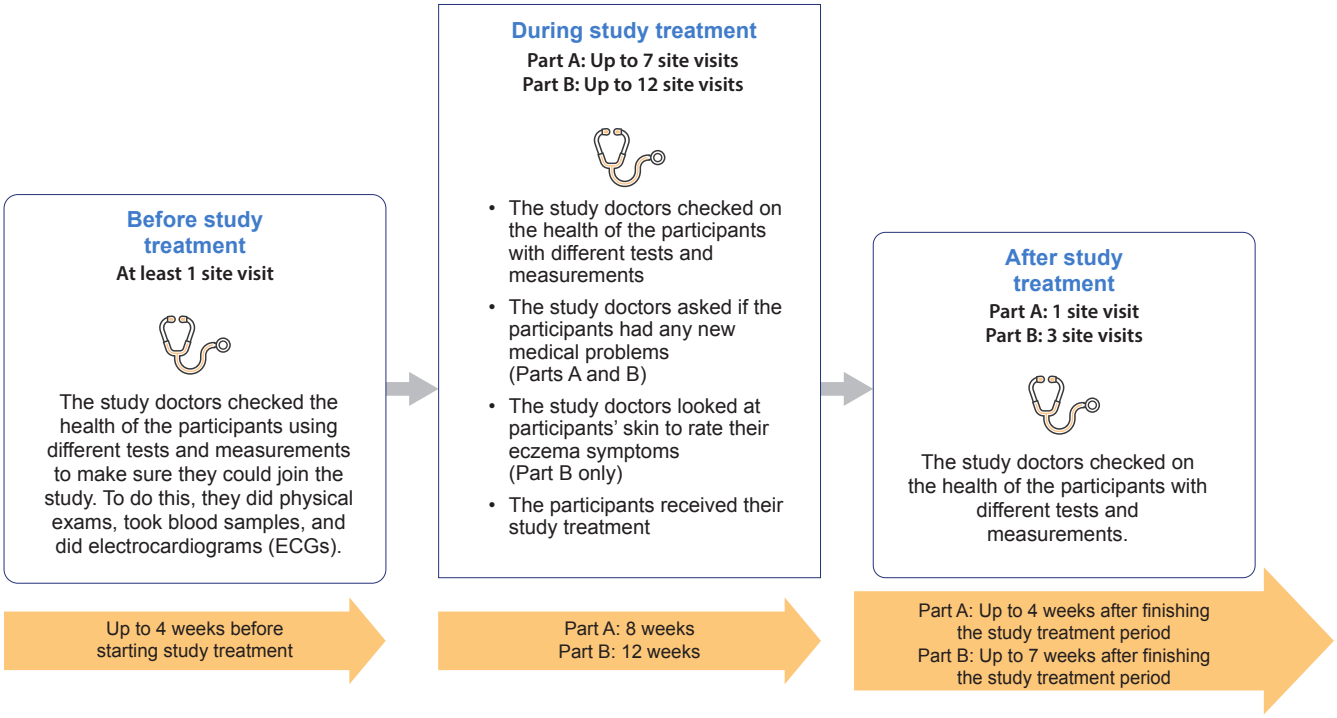
Based on the single ascending dose part (Part A), the researchers investigated **Dose F** of galvokimig in the repeated dose part (Part B).

	Part B	
	14 participants	33 participants
	Placebo	**Dose F** of galvokimig
	Received at repeated intervals of time for 10 weeks	

What happened during this study?

All the participants first learned about the study and then decided to join. This is 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.

Details about the treatment groups are in the “What treatments did the participants receive?” section.

Did galvokimig help improve the participants’ eczema?

Overall, the researchers found that most participants who received galvokimig had an improvement in their eczema compared with the participants who received the placebo.

To answer this question, the researchers looked at the results from **Part B only**. The researchers used the **Eczema Area and Severity Index** (**EASI**). The EASI is used to measure how severe a person’s eczema symptoms are. The doctor looks at 4 different body areas:

- Head and neck
- Arms
- Torso
- Legs and buttocks

The study doctors looked at 4 different types of eczema signs in each of the 4 body areas. These were:

- Redness
- Scratching and picking
- Swelling
- Thickened and leathery skin

The study doctors checked how severe the participants' symptoms were and how much of their skin was affected by eczema in each body area. They used this information to give each participant an EASI score. Higher scores meant that a participant's symptoms were more severe or covered more body areas.

Then, the researchers calculated how many of the participants had their EASI scores improve by at least 75.0% after receiving study treatment for 12 weeks. This is called an **EASI 75** response. Researchers used a mathematical model to calculate the percentage of participants who had an EASI 75 response at 12 weeks. These results are shown below:

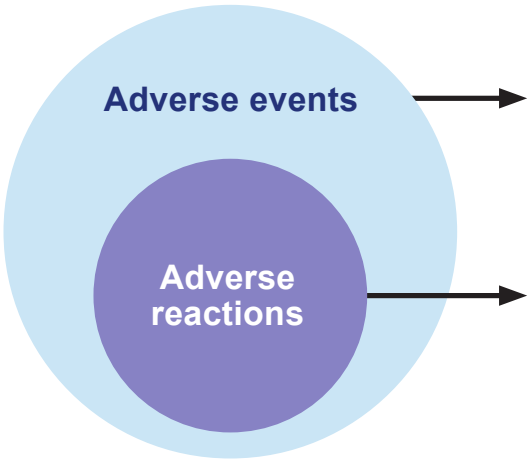
- **12.3%** of participants who received the **placebo** had an EASI 75 response at Week 12
- **64.9%** of participants who received **galvokimig** had an EASI 75 response at Week 12

What medical problems did the participants have during this study?

To answer this question, the doctors kept track of the "adverse events" that the participants had in both Part A and Part B. **Part A** had **healthy participants**, and **Part B** had **participants with eczema**.

In this summary, there is information about 2 different types of medical problems that the participants had during the study. An **adverse event** is **any** medical problem that a participant has during a study. Doctors keep track of all adverse events that happen in studies, whether or not these may be related to study treatment. An **adverse reaction** is different from an adverse event because it is reported by the doctor as **possibly related** to study treatment. An adverse event or adverse reaction is considered "serious" when it is life-threatening, causes lasting problems, or requires hospital care.

Adverse reactions are adverse events that the study doctors reported as possibly related to study treatment



Adverse events are all of the medical problems the participants had during this study.

Adverse reactions are medical problems the participants had during this study that the study doctors reported as possibly related to study treatment.

The information below is a summary of the **adverse events** that happened in this study.

There were 67.8% of participants (40 of 59) who had an adverse event in **Part A** of this study.

There were 66.0% of participants (31 of 47) who had an adverse event in **Part B** of this study.

Details about the treatment groups are in the “What treatments did the participants receive?” section.

Adverse events in Part A

	Group 1 (out of 11 participants)	Group 2 (out of 5 participants)	Group 3 (out of 6 participants)	Group 4 (out of 6 participants)	Group 5 (out of 6 participants)
How many participants had **serious** adverse events?	none	none	none	none	none
How many participants had adverse events?	54.5% (6 participants)	80.0% (4 participants)	66.7% (4 participants)	50.0% (3 participants)	66.7% (4 participants)
How many participants left the study due to adverse events?	none	none	none	none	none

Adverse events in Part A (cont.)

	Group 6 (out of 6 participants)	Group 7 (out of 7 participants)	Group 8 (out of 6 participants)	Group 9 (out of 6 participants)
How many participants had **serious** adverse events?	none	14.3% (1 participant)	none	none
How many participants had adverse events?	66.7% (4 participants)	85.7% (6 participants)	83.3% (5 participants)	66.7% (4 participants)
How many participants left the study due to adverse events?	none	none	none	none

The **serious** adverse event that happened during Part A was a suicide attempt.

The most common adverse events during Part A were:

- Headache
- Skin redness where the injection of study treatment was given
- COVID-19
- Mouth and throat pain (Oropharyngeal pain)

Adverse events in Part B

	Placebo (out of 14 participants)	**Dose F of galvokimig** (out of 33 participants)
How many participants had **serious** adverse events?	none	3.0% (1 participant)
How many participants had adverse events?	50.0% (7 participants)	72.7% (24 participants)
How many participants left the study due to adverse events?	7.1% (1 participant)	6.1% (2 participants)

The **serious** adverse event that happened during Part B was diarrhea with blood in it (Hemorrhagic diarrhea).

The most common adverse events were:

- Stuffy nose
- Common cold (Nasopharyngitis)
- Headache
- Dizziness
- Mouth and throat pain (Oropharyngeal pain)

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**".

In this study, the doctors did not know what the participants were receiving when the medical problems happened. The study doctors reported the medical problems they thought were caused by their study drug, even though the participants could have received the placebo. So, some adverse reactions may be reported in participants who received the placebo, even though the placebo does not directly cause medical problems.

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.

Some of the adverse reactions listed below may also be listed in the adverse events section earlier in this summary.

Did any adverse reactions happen during this study?

Details about the treatment groups are in the “What treatments did the participants receive?” section.

There were 11.9% of participants (7 out of 59) who had an adverse reaction during Part A of this study and 17.0% of participants (8 out of 47) who had an adverse reaction during Part B of this study.

Adverse reactions in Part A

	Group 1 (out of 11 participants)	**Group 2** (out of 5 participants)	**Group 3** (out of 6 participants)	**Group 4** (out of 6 participants)	**Group 5** (out of 6 participants)
How many participants had **serious** adverse reactions?	none	none	none	none	none
How many participants had adverse reactions?	none	none	none	none	none
How many participants left the study due to adverse reactions?	none	none	none	none	none

Adverse reactions in Part A (cont.)

	Group 6 (out of 6 participants)	**Group 7** (out of 7 participants)	**Group 8** (out of 6 participants)	**Group 9** (out of 6 participants)
How many participants had **serious** adverse reactions?	none	none	none	none
How many participants had adverse reactions?	none	28.6% (2 participants)	66.7% (4 participants)	16.7% (1 participant)
How many participants left the study due to adverse reactions?	none	none	none	none

Adverse reactions in Part B

	Placebo (out of 14 participants)	**Dose F of galvokimig** (out of 33 participants)
How many participants had **serious** adverse reactions?	none	3.0% (1 participant)
How many participants had adverse reactions?	14.3% (2 participants)	18.2% (6 participants)
How many participants left the study due to adverse reactions?	none	none

What serious adverse reactions did the participants have?

There was 1 participant who had a **serious** adverse reaction during this study. This participant was in the galvokimig (Dose F) group in Part B. The serious adverse reaction was diarrhea with blood in it (Hemorrhagic diarrhea).

None of the participants died during this study.

What adverse reactions did the participants have?

The most common adverse reaction in Part A was skin redness where the injection of study treatment was given.

The table below shows all the adverse reactions that happened in Part A of this study.

Adverse reactions in Part A

Adverse reaction	Group 1 (out of 11 participants)	Group 2 (out of 5 participants)	Group 3 (out of 6 participants)	Group 4 (out of 6 participants)	Group 5 (out of 6 participants)
Skin redness where the injection of study treatment was given	none	none	none	none	none
Pain where the injection of study treatment was given	none	none	none	none	none
Fungal infection that causes rashes around facial hair (Tinea barbae)	none	none	none	none	none
Eczema	none	none	none	none	none
Inflammation of the mouth caused by herpes	none	none	none	none	none

Adverse reactions in Part A (cont.)

Adverse reaction	Group 6 (out of 6 participants)	Group 7 (out of 7 participants)	Group 8 (out of 6 participants)	Group 9 (out of 6 participants)
Skin redness where the injection of study treatment was given	none	28.6% (2 participants)	33.3% (2 participants)	none
Pain where the injection of study treatment was given	none	14.3% (1 participant)	none	none
Fungal infection that causes rashes around facial hair (Tinea barbae)	none	none	16.7% (1 participant)	none
Eczema	none	none	16.7% (1 participant)	none
Inflammation of the mouth caused by herpes	none	none	none	16.7% (1 participant)

The most common adverse reactions in Part B were headache and nose and throat infection (Upper respiratory tract infection).

The table below shows the adverse reactions that happened in 2 or more participants in any treatment group. There were other adverse reactions, but those happened in only 1 participant each.

Adverse reactions in 2 or more participants in Part B

Adverse reaction	Placebo (out of 14 participants)	Dose F of galvokimig (out of 33 participants)
Headache	none	6.1% (2 participants)
Nose and throat infection (Upper respiratory tract infection)	none	6.1% (2 participants)

What did the researchers learn from this study?

The results of this study have helped researchers learn more about using galvokimig in people living with eczema. In this study, the researchers found that:

- 67.0% of participants (71 out of 106) had medical problems during this study.
- 14.2% of participants (15 out of 106) had medical problems during this study that were possibly related to study treatment.
- In Part B, the participants who received galvokimig had an improvement in their eczema compared with the participants who received the placebo.

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 new 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.

When this document was approved, further clinical studies with galvokimig 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/NCT04643457
- www.clinicaltrialsregister.eu/ctr-search/search?query=2020-003639-41

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

Study Information

Protocol Number: UP0089

National Clinical Trial Number: NCT04643457

EudraCT Number: 2020-003639-41

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

Full Study Title: A Phase I/IIA, Randomized, Placebo-Controlled, Single-Ascending Dose (Part A, Participant- And Investigator-Blind) And Repeated-Dose (Part B, Participant-, Investigator-, And Sponsor-Blind) Study To Investigate The Safety, Pharmacokinetics, And Efficacy Of UCB9741 In Healthy Study Participants (Part A) And In Study Participants With Moderate-To-Severe Atopic Dermatitis (Part B)

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 June 2025.
The final clinical study report is dated 25 November 2024.