

Clinical Trial Results Summary

A clinical trial to collect long-term information on the safety of QGE031 in adolescents and adults with food allergies

Thank you!

Thank you to the participants who took part in the clinical trial for **food allergy**. Every participant helped the researchers learn more about the trial drug **QGE031**, also called **ligelizumab**.

Novartis sponsored this trial and believes it is important to share what was learned from the results of this trial with the participants and the public. We hope this helps the participants understand their important role in medical research.

Trial information

Trial number: CQGE031G12303B

Novartis drug studied: **QGE031**,
also known as **ligelizumab**

Sponsor: Novartis

If you were a participant and have any questions about the results, please talk to the doctor or staff at the trial site.

This summary only shows the results of a single clinical trial. Other clinical trials may have different results.

What was the main purpose of this trial?

The purpose of this trial was to collect long-term information on the safety of **QGE031** in participants with **food allergies** who had previously participated in other **QGE031** clinical trials. However, only participants from 1 trial, **CQGE031G12301**, who had peanut allergy joined this trial.



In people with **food allergies**, including peanut allergy, the immune system considers certain food items, or their content harmful, and produces **antibodies** against them; these antibodies cause an allergic reaction. Such food items or their contents are called food allergens.

Typical peanut allergy symptoms include skin rashes, itching or pain in the throat, diarrhea, vomiting, and shortness of breath. Sometimes, people also experience life-threatening or severe symptoms such as a sudden drop in blood pressure, difficulty breathing, and loss of consciousness (this is known as anaphylaxis).

Antibodies are made by our immune system (the body's natural defense system) to fight off infections or anything that is harmful to our body.



QGE031 is the trial drug that binds to the antibody produced in response to the food allergen and prevents it from causing allergic reactions. In this trial, it is being studied for its effects on peanut allergy.



A **placebo** looks like the trial drug but does not have any drug in it. Using a placebo helps researchers better understand the effect of a trial drug.



Trial drug

QGE031, also called ligelizumab

Pronounced as
ligee-liz-ue-mab



The trial's purpose was to answer this main question:

- How many participants had medical problems, also called adverse events, during this trial?
 - ↳ An **adverse event** is any sign or symptom that participants have during a trial. Adverse events **may** or **may** not be caused by treatments in the trial.

How long was this trial?



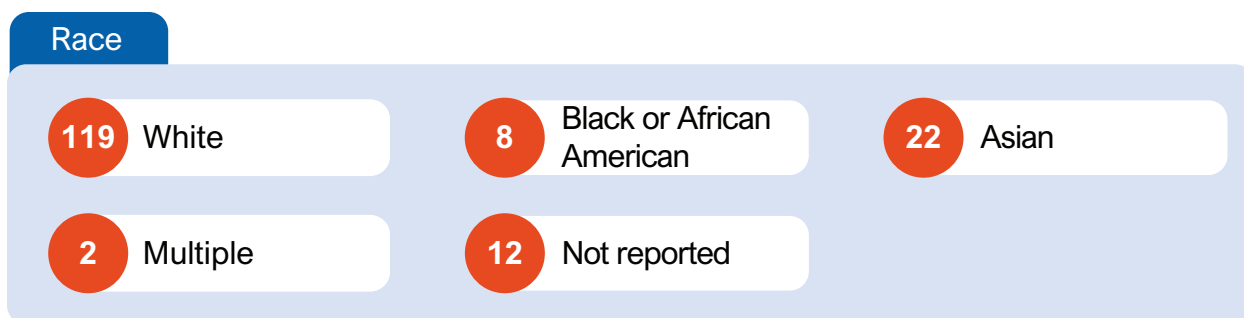
This trial began in April 2023. It was planned for participants to be in the trial for about 3 years. However, the trial ended early in March 2025. The researchers stopped the trial earlier than planned, but not because of any medical problems.

When the trial stopped, a report was created of the trial results. This summary is based on that report.

Who was in this trial?



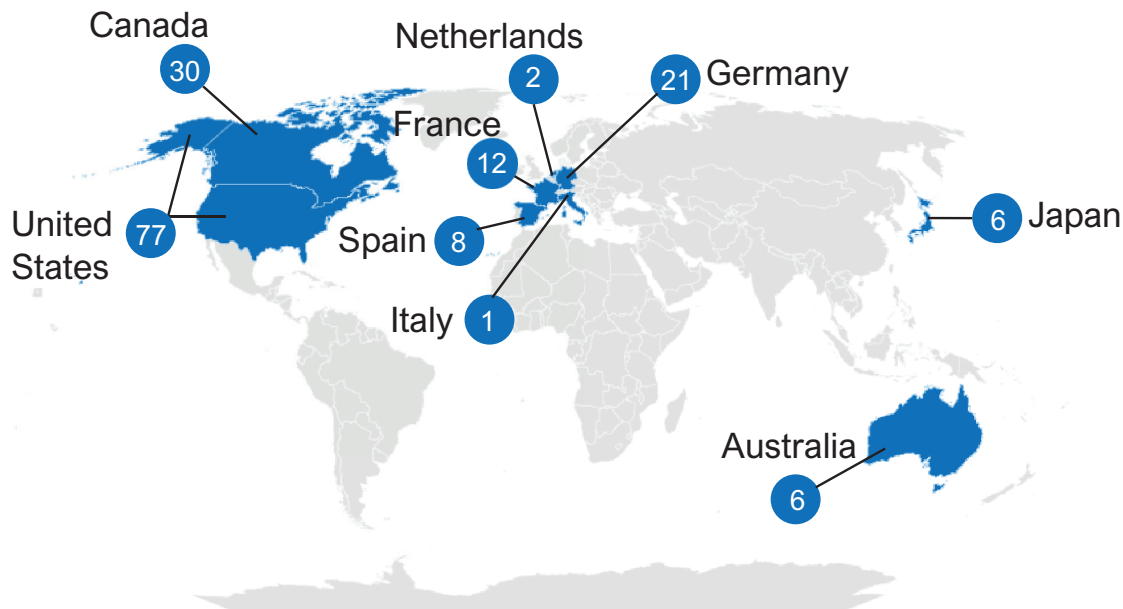
163 participants with **food allergy** received treatment in this trial – 90 men and 73 women. Participants' ages ranged from 12 to 47 years. Their average age was 19 years. The number of participants by race is shown below.



The participants could take part in this trial if:

- they had completed treatment in a previous **QGE031** trial for food allergy
- they agreed to continue avoiding peanuts or any food they had an allergy to for the entire trial
- their trial doctor confirmed that it was safe for them to continue **QGE031** treatment

163 participants from 9 countries received treatment. The map below shows the number of participants who took part in each country.



What treatments did the participants receive?

The treatments in this trial were:



QGE031: All participants received **QGE031** as an injection under the skin once a month. They received either of the following doses of **QGE031**, as per their treatment in the previous trial:

- **QGE031 120 milligrams (mg)**
- **QGE031 240 mg**



Placebo: Participants in the **QGE031 120 mg** group also received **placebo** as an injection under the skin once a month.

In this trial, **placebo** was used to make sure that everyone got the same number of injections.

None of the participants, trial staff, or researchers knew what treatment each participant received during the trial. Some trials are done this way because knowing what treatment the participants receive can affect the results of the trial. Doing a trial this way helps to make sure that the results are looked at with fairness across all treatments.

What happened during this trial?

Before treatment

Day 1



The trial staff checked to make sure the participants could be in this trial. All participants had previously taken part in another trial (**CQGE031G12301**) and continued their treatment in this trial.

During treatment

About 1 year and 3 months

Participants continued receiving the treatment they received in the previous trial, in either of the following groups:

Group 1

QGE031 120 mg (81 participants): Participants received 1 injection of 120 mg of **QGE031** and 1 injection of **placebo** once a month

Group 2

QGE031 240 mg (82 participants): Participants received 2 injections of 120 mg of **QGE031** once a month

During the trial, participants underwent allergy tests which included receiving small amounts of peanut protein at different times to check if their treatment was working.

Most participants continued the trial treatment until they could tolerate the highest amount of peanut protein without allergy symptoms. Some participants then stopped **QGE031** treatment and remained off treatment until their symptoms returned. They were allowed to resume treatment during the trial.

After treatment

Up to 4 months



Trial staff checked participants' general health and for any medical problems for up to 4 months after participants' last dose of trial treatment.

What were the main results of this trial?

How many participants had medical problems, also called adverse events, during this trial?

Trial doctors keep track of all medical problems, also called **adverse events**, that happen in trials. They track adverse events even if they think the adverse events are not related to the trial treatments. Many trials are needed to know if a drug or treatment causes an adverse event.

This section is a summary of the adverse events that happened from the start of the treatment until 4 months after receiving the last dose of **QGE031**.

An **adverse event** is:

- Any **sign or symptom** that the participants have during a trial
- Considered **serious** when it is life-threatening, causes lasting problems, the participant needs hospital care, or results in death

Adverse events **may** or **may not** be caused by treatments in the trial.



125 out of 163 participants had adverse events.

- 5 participants had adverse events that were considered serious.
- 2 participants left the trial due to an adverse event.
- None of the participants died during the trial.

The researchers concluded there were no new safety concerns with the use of **QGE031** in this trial.

How many participants had adverse events?

	Group 1 QGE031 120 mg 81 participants	Group 2 QGE031 240 mg 82 participants
Had at least 1 adverse event (include serious and other)	68 of 81	57 of 82
Had at least 1 serious adverse event	3 of 81	2 of 82
Left the trial due to an adverse event	1 of 81	1 of 82

None of the participants died during the trial.

What serious adverse events did the participants have?

5 participants had **serious adverse events**.

The table below shows the serious adverse events:

	Group 1 QGE031 120 mg 81 participants	Group 2 QGE031 240 mg 82 participants
Damage to the heart muscle Cardiomyopathy	0	1 of 82
Diabetes Type 1 diabetes mellitus	1 of 81	0
Difficulty breathing Dyspnea	1 of 81	0
Feeling sick Nausea	1 of 81	0
Inflamed colon Colitis	1 of 81	0
Itching due to allergy Pruritus allergic	1 of 81	0
Lip swelling	1 of 81	0
Sudden, severe allergic reaction Anaphylactic reaction	0	1 of 82
Swollen tongue	1 of 81	0
Swollen face Swelling face	1 of 81	0

	Group 1 QGE031 120 mg 81 participants	Group 2 QGE031 240 mg 82 participants
Throat irritation	1 of 81	0
Throat swelling Pharyngeal swelling	1 of 81	0

What other (not including serious) adverse events did the participants have?

The table below shows the most common other (not including serious) adverse events:

	Group 1 QGE031 120 mg 81 participants	Group 2 QGE031 240 mg 82 participants
Common cold Nasopharyngitis	19 of 81	17 of 82
Cough	6 of 81	3 of 82
COVID-19 Infection	6 of 81	7 of 82
Flu Influenza	9 of 81	4 of 82
Hardness or thickening at the injection site Injection site induration	1 of 81	6 of 82
Headache	13 of 81	5 of 82
Infection in the nose and throat Upper respiratory tract infection	12 of 81	10 of 82
Inflamed stomach and intestine Gastroenteritis	2 of 81	6 of 82
Injection site swelling due to fluid build-up Injection site oedema	4 of 81	11 of 82
Redness at the injection site Injection site erythema	7 of 81	14 of 82
Swelling at the injection site Injection site swelling	2 of 81	7 of 82

What was learned from this trial?



Researchers learned more about the long-term effects of **QGE031** in participants with a **food allergy**. They stopped the trial earlier than planned, but not because of any medical problems.

- Researchers concluded that there were no new safety concerns with the use of **QGE031** in this trial.

When this summary was written, the sponsor had no plans for future trials for **QGE031** in people with **food allergy**.

Where can I learn more about this trial?

More information about the results and adverse events in this trial can be found in the scientific summary of the results available on the Novartis Clinical Trial Results website, www.novctrd.com.

Follow these steps to find the scientific summary:



For more information about this trial, go to any of these websites:

- clinicaltrials.gov – search using the number **NCT05678959**
- euclinicaltrials.eu – search using the number **2022-502366-25-00**

Other trials of **QGE031** may appear on the public websites above. When there, search for **QGE031** or **ligelizumab**.

Full clinical trial title: A three-year, multi-center, double-blind, extension study to evaluate the long-term safety and efficacy of ligelizumab in patients who completed ligelizumab's Phase III studies in food allergy



Novartis is a global healthcare company based in Switzerland that provides solutions to address the evolving needs of patients worldwide.

1-888-669-6682 (US) | +41-61-324 1111 (EU)

www.novartis.com/clinicaltrials