NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about the effects of QGE031 in adolescents and adults with peanut allergy

Thank you!

Thank you to the participants who took part in the clinical trial for peanut 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: CQGE031G12301

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 shows the results of a single clinical trial. Other clinical trials may have different findings.

What was the main purpose of this trial?

The purpose of this trial was to learn more about the effects of **QGE031** in participants with peanut allergy, compared to a **placebo**.

Peanut allergy is a type of food allergy. In people with food allergies, the immune system considers certain food items or their content harmful and produces **antibodies** against them that cause an allergic reaction. Such food items or their content are called food allergens.

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.

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/severe symptoms such as a sudden drop in blood pressure, difficulty breathing, and loss of consciousness (this is known as anaphylaxis).

QGE031 is a type of antibody 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 trial 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 purpose was to answer these main questions:

- How many participants could eat 600 milligrams (mg) or more of peanut protein without any symptoms of an allergic reaction after 3 months of treatment?
- What adverse events did the participants have during this trial?
  - ↳ An **adverse event** is any sign or symptom that participants have during a trial.

How long was this trial?

The trial began in December 2021 and ended in November 2023. It was planned for the participants to be in the trial for about 2 years.

The researchers ended this trial early with fewer participants than planned. The decision to stop enrolling participants and end the trial early was because researchers decided to further study the dose of **QGE031** that was tested for peanut allergy. This decision was not due to any safety concerns.

When the trial ended, the researchers collected information from participants and created a report of the trial results. This summary is based on that report.

Who was in this trial?

211 participants with peanut allergy received treatment in this trial. Participants' ages ranged from 12 to 45 years. Their average age was 19 years.

The number of participants by age group, gender, and race are shown below.

Age group

- 119 **12 to 17 years**
- 92 **18 to 55 years**

Gender

- 113 **Boys / Men**
- 98 **Girls / Women**

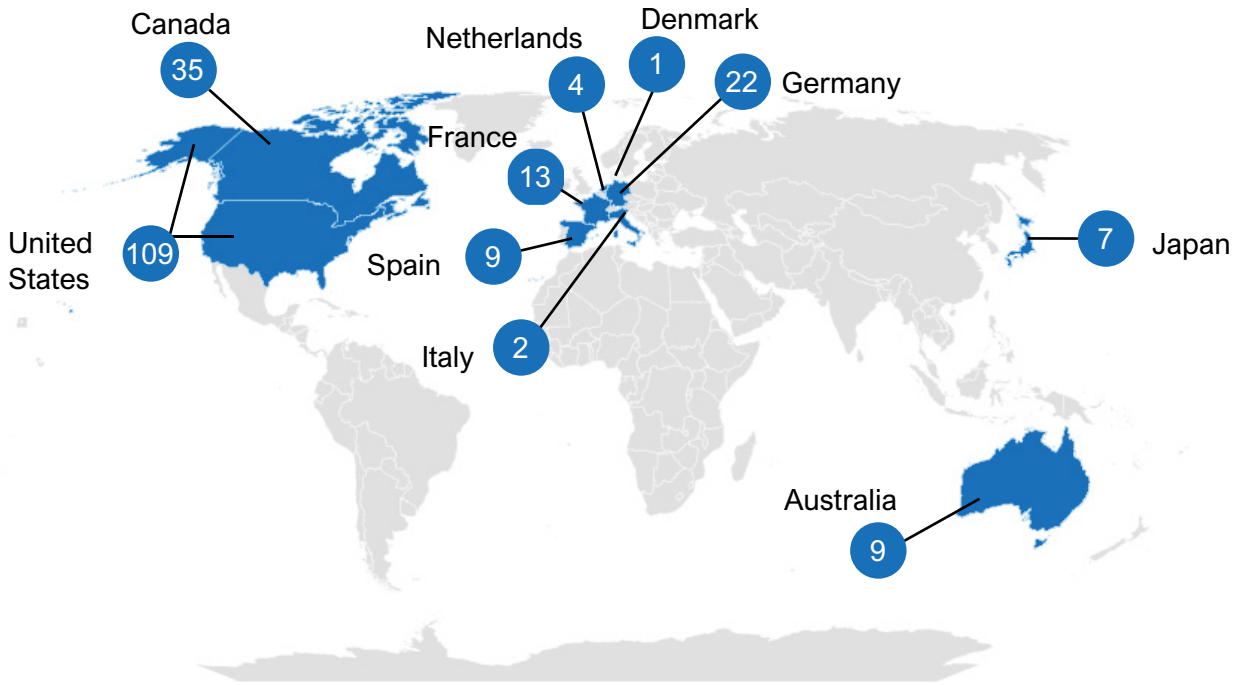
Race

- 165 **White**
- 25 **Asian**
- 12 **Black** or **African American**
- 5 **Multiple**
- 4 **Unknown**

The participants could take part in this trial if they:

- weighed more than 20 kilograms (kg) or 44 pounds
- had an allergy to peanuts or peanut-containing foods
- had a positive skin prick test for peanut allergens at the time of joining the trial
- had peanut-specific antibodies in their blood
- had not had a severe or life-threatening food allergy in the 2 months before joining the trial

211 participants from 10 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, also called ligelizumab, given as an injection under the skin once a month. Participants could receive either of the following two doses of **QGE031** in this trial:

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

Placebo, given as an injection under the skin once a month.

Participants could also take additional medicines like epinephrine, diphenhydramine, and cetirizine if they experienced an allergic reaction during the trial. These medicines together can help quickly manage and resolve the symptoms of an allergic reaction in the body.

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 — Up to 1 month

Trial doctors checked the participants' peanut allergies and overall health to ensure they could take part in this clinical trial.

During treatment — Up to 1 year

Participants were randomly assigned to one of the following five groups:

Group 1	**QGE031 240 mg** (47 participants)
Group 2	**QGE031 120 mg** (51 participants)
Group 3	**Placebo** for 2 months followed by **QGE031 240 mg** (46 participants)
Group 4	**Placebo** for 2 months followed by **QGE031 120 mg** (44 participants)
Group 5*	**Placebo** for 4 months (23 participants) → **QGE031 240 mg** (11 participants); **QGE031 120 mg** (12 participants)

*Participants in **Group 5** were divided equally to receive **QGE031 240 mg** or **QGE031 120 mg** following 4 months of treatment with **placebo**.

Researchers ended the trial when all the eligible participants completed at least 3 months of treatment.

After treatment — Up to 4 months

Participants returned to their trial site up to 4 times after receiving their last dose of trial treatment for follow-up visits.

Trial doctors checked participants for their overall health throughout the trial.

What was the main result of this trial?

How many participants could eat 600 mg* or more of peanut protein without any symptoms of an allergic reaction after 3 months of treatment?

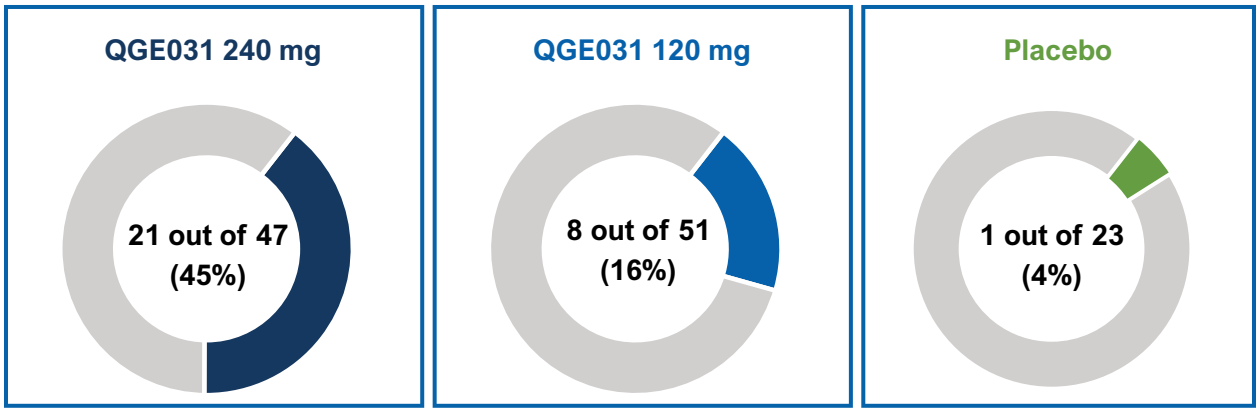
*Eating 600 mg of peanut protein is similar to having 2–3 whole peanuts.

21 out of 47 (45%) participants who received **QGE031 240 mg**, 8 out of 51 (16%) participants who received **QGE031 120 mg**, and 1 out of 23 (4%) participants who received **placebo** could eat 600 mg or more of peanut protein without any severe symptoms of an allergic reaction after 3 months of treatment.

To learn this, researchers assessed changes in participants' peanut allergies during an **oral food challenge** after 3 months of treatment with **QGE031**, compared with **placebo**.

Oral food challenge is a test in which a person eats increasing amounts of the allergen under the supervision of a doctor. The doctor studies the extent of the allergic symptoms that participants experience after eating the allergen.

Number of participants (percentage) who could eat 600 mg or more of peanut protein after 3 months of treatment



What adverse events did the participants have?

Trial doctors keep track of all **adverse events** that happen in trials, 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 treatment until 4 months after the last treatment.

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.

Adverse events are presented separately for participants who received:

- at least one dose of **QGE031 240 mg** or **QGE031 120** mg including those who received **placebo** at the start of the trial. Participants received **QGE031** for up to 1 year in this trial
- **placebo** for up to 2 months of treatment
- **placebo** for up to 4 months of treatment

Most of the participants had adverse events. 1 participant had an adverse event that was considered serious. None of the participants died during the trial. 1 participant left the trial due to an adverse event. The researchers concluded that there were no new safety concerns with the use of **QGE031** in this trial.

How many participants had adverse events?

Number (percentage) of participants who had adverse events

	At least one dose of QGE031		Placebo	
Participants who:	**240 mg** 99 participants	**120 mg** 101 participants	**up to 2 months** 113 participants	**up to 4 months** 23 participants
Had at least 1 serious adverse event	**0**	**1 of 101** 1%	**0**	**0**
Had at least 1 other adverse event	**57 of 99** 58%	**53 of 101** 53%	**27 of 113** 24%	**9 of 23** 39%
Left the trial due to an adverse event	**2 of 99** 2%	**0**	**0**	**0**

What serious adverse events did the participants have?

One participant who received at least one dose of **QGE031 120 mg** during the trial had a serious adverse event of **complication after a procedure** (post-procedural complication) that was not related to the treatment or the trial.

What other adverse events did the participants have?

The following table shows the other adverse events that happened in 10% or more of participants in any group during the trial.

Number (percentage) of participants who had other adverse events

	At least one dose of QGE031		Placebo	
	240 mg 99 participants	**120 mg** 101 participants	**up to 2 months** 113 participants	**up to 4 months** 23 participants
Participants who:				
Redness of the skin at the site of injection Injection site erythema	**15 of 99** 15%	**13 of 101** 13%	**0**	**0**
COVID-19 infection	**7 of 99** 7%	**14 of 101** 14%	**2 of 113** 2%	**0**
Common cold Nasopharyngitis	**19 of 99** 19%	**14 of 101** 14%	**5 of 113** 4%	**3 of 23** 13%
Headache	**10 of 99** 10%	**12 of 101** 12%	**5 of 113** 4%	**1 of 23** 4%
Hives Urticaria	**11 of 99** 11%	**6 of 101** 6%	**1 of 113** Less than 1%	**0**

What was learned from this trial?

Researchers learned about the effects of **QGE031** in adolescents and adults with peanut allergy.

The trial ended earlier with fewer participants than planned because researchers decided to further study the dose of **QGE031** to be tested for peanut allergy.

From this trial, the researchers concluded that:

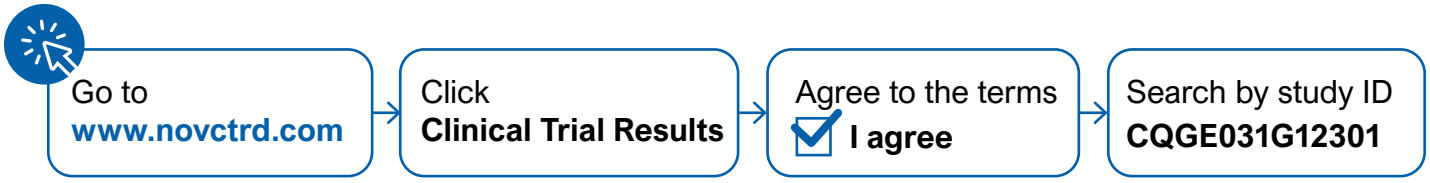
- more participants who received **QGE031 240 mg** could eat 600 mg or more of peanut protein after 3 months of treatment compared to those who received **placebo**.
- there were no new safety concerns with the use of **QGE031** in this trial.

When this summary was written, one trial with **QGE031** (CQGE031G12303B) was ongoing and researchers were considering the next steps for the clinical program.

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 the following websites:

- **www.clinicaltrials.gov** - search using the number **NCT04984876**
- **clinicaltrialsregister.eu/ctr-search/search** - search using the number **2020-005339-56**

If more trials are planned, they will appear on the public websites above.

When there, search for **QGE031** or ligelizumab.

Full clinical trial title: A 52-week, multi-center, randomized, double-blind placebo-controlled study to assess the clinical efficacy and safety of ligelizumab (QGE031) in decreasing the sensitivity to peanuts in patients with peanut allergy

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