NOVARTIS

Clinical Trial Results Summary

A clinical trial to learn more about the long-term safety of erenumab in people with migraines

Thank you!

Thank you to the participants who took part in the clinical trial for migraines. Every participant helped the researchers learn more about the trial drug **AMG334**, also called **erenumab**.

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: CAMG334ADE03

Novartis drug studied: AMG334, also known as erenumab

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 learn more about the long-term safety of the drug **AMG334** in people with episodic or chronic migraines.

Migraines are a type of headache that regularly comes back and often has other symptoms, such as:

- Severe throbbing or pounding pain on one side of the head that can last from 4 hours to 3 days
- Feeling sick to the stomach or throwing up
- Sensitivity to sound or light

People with **episodic** migraines have 4 to 14 migraine days a month. People with **chronic** migraines have 15 or more headache days a month, which includes 8 or more migraine days.

AMG334 is a drug to prevent migraines. Based on results from past trials, it has been approved for use in adults with migraines in Germany and certain other countries.

Trial drug
AMG334 also called **erenumab**
Pronounced as
eh-**ren**-yoo-mab

The trial purpose was to answer these main questions:

- What was the long-term safety of AMG334 in people with migraines?
- What adverse events did the participants have?
  - ↳ An **adverse event** is any sign or symptom that participants have during a trial.

How long was this trial?

The trial began in September 2019 and ended in March 2023. Each participant was in the trial for up to about 2 and a half years.

Who was in this trial?

701 participants with episodic or chronic migraines received treatment in this trial in Germany − 93 men and 608 women.

Participants' ages ranged from 18 to 67 years. Their average age was 42 years.

The number of participants by race is shown below.

Race

1 Asian	4 Other
695 White	1 Unknown

The participants could take part in this trial if they:

- Had taken part in a past trial for **AMG334** called CAMG334ADE01 – they had to start this trial within 3 months after their last visit in the past trial
- Had not recently received certain treatments for migraines or pain
- Did not have other long-term pain conditions, such as fibromyalgia

What treatments did the participants receive?

The treatment in this trial was:

AMG334 given as an injection once every 4 weeks. This trial looked at 2 starting doses of **AMG334**:

- 70 milligrams (mg)
- 140 mg

Participants used a pre-filled pen called an autoinjector to give themselves the injections of **AMG334**.

The dose of **AMG334** each participant started with in this trial was based on what they received every 4 weeks in the past trial. The trial doctor could change the participants' dose or pause treatment.

In this trial, the participants and clinical trial team knew what treatment each participant received. All participants received **AMG334**.

What happened during this trial?

Before treatment Up to 2 weeks

Trial doctors checked the participants' health, migraines, and participation in the past trial, CAMG334ADE01, to make sure they could be in this trial.

During treatment Up to 2 and a half years

701 participants received **AMG334** as injections every 4 weeks. Their starting dose of **AMG334** was either 70 or 140 mg based on what they received every 4 weeks in the past trial.

The trial doctor could switch the participants to the lower or higher dose or pause treatment.

Researchers checked the participants' health and asked about adverse events throughout the trial.

After treatment 2 months

Participants returned to their trial site about 2 months after they received their last dose of trial treatment for researchers to check their health.

What were the main results of this trial?

What was the long-term safety of AMG334 in people with migraines?

The researchers found that, on average, a participant could expect to have about one adverse event per each year of treatment with **AMG334**.

To learn about the long-term safety, researchers counted the total number of adverse events participants had during treatment with **AMG334**. Then, researchers calculated the number of adverse events participants could expect by year of treatment.

A year of treatment of **AMG334** is one dose a month for 12 months.

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 up to 2 months after the last dose of trial 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.

Most of the participants (601 of 701) had adverse events. 86 participants had adverse events that were considered serious. 24 participants left the trial due to an adverse event.

How many participants had adverse events?

Participants who:	AMG334 701 participants
Had at least 1 **serious adverse event**	**86 of 701**
Had at least 1 **other adverse event**	**514 of 701**
Left the trial due to an adverse event	**24 of 701**
Died during the trial	**0 of 701**

What serious adverse events did the participants have?

86 participants had serious adverse events. No participants died.

The table below shows the most common serious adverse events that happened in **4 or more** participants.

	AMG334 701 participants
Herniated, bulging, or slipped disc in the spine Intervertebral disc protrusion	**7 of 701** 1%
Depression	**5 of 701** 1%
Inflammation in the appendix Appendicitis	**4 of 701** 1%
Back pain	**4 of 701** 1%

What other adverse events did the participants have?

514 participants had other adverse events.

The table below shows the other adverse events that happened in **46 or more** participants.

	AMG334 701 participants
COVID-19	**242 of 701** 35%
The common cold Nasopharyngitis	**134 of 701** 19%
Trouble passing stool Constipation	**103 of 701** 15%
Feeling tired or having low energy Fatigue	**61 of 701** 9%
High blood pressure Hypertension	**46 of 701** 7%

What were the other results of this trial?

How many participants stopped treatment with AMG334 during this trial?

Of 701 participants, 155 participants stopped treatment during this trial:

- 29 participants (4%) due to adverse events
- 126 participants (18%) due to other reasons

The researchers concluded these results were similar to the past trial, CAMG334ADE01.

What was learned from this trial?

Researchers learned more about the long-term safety of **AMG334** in people with episodic or chronic migraines in Germany.

The researchers concluded:

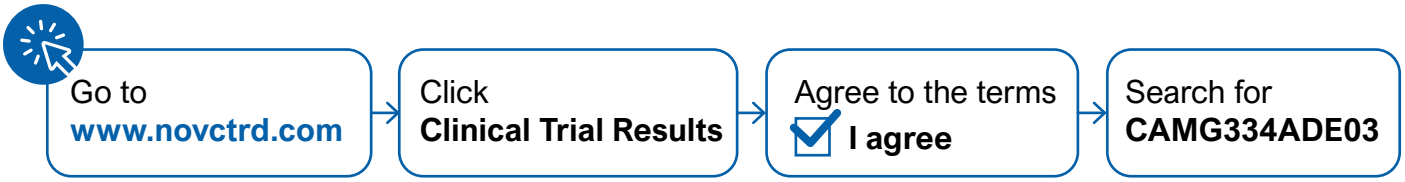
- On average, a participant could expect to have about one adverse event per each year of treatment with **AMG334**
- A similar number of participants stopped treatment during this trial compared to the past trial, CAMG334ADE01
- There were no long-term safety concerns for **AMG334** in this trial

When this summary was written, the sponsor did not have plans for future trials of **AMG334** in people with migraines.

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 **NCT04084314**
- clinicaltrialsregister.eu/ctr-search/search – search using the number **2019-002201-22**

Other trials of **AMG334** may appear on the public websites above. When there, search for **AMG334** or **erenumab.**

Full clinical trial title: Assessment of Prolonged safety and tolerability of erenumab in migraine patients in a Long-term OpeN-label study (APOLLON)

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