

Plain Language Clinical Study Summary

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study medicine works, how it works, and if it is safe to prescribe to patients. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: Pfizer Inc.

Medicine Studied: Nurtec® ODT (also called rimegepant)

Protocol Number: C4951012 (BHV3000-407)

Dates of Study: 07 November 2022 to 08 July 2025

Title of this Study: Efficacy and Tolerability of Rimegepant for the Prevention of Migraine in Adults With History of Inadequate Response to Oral Preventive Medications

[A Phase 4, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Tolerability of Rimegepant for the Prevention of Migraine in Adults With a History of Inadequate Response to Oral Preventative Medications]

Date of this Report: 05 May 2026



– Thank You –

If you participated in this study, Pfizer, the Sponsor, would like to thank you for your participation.

This summary will describe the study results. Do you have any questions about the study or the results? If so, please contact the doctor or staff at your study site.

Why was this study done?

What is migraine?

Migraine is a type of headache disorder. It is a condition affecting the brain with recurrent attacks that are characterized by multiple symptoms, including headache of moderate-to-severe intensity, sensitivity to noise or light, as well as nausea and vomiting.

What is rimegepant?

Rimegepant (ri-ME'-je-pant) is a medicine approved for the treatment and prevention of migraine attacks in a number of countries around the world. It is also known as Nurtec[®] ODT, which is rimegepant in the form of an **orally disintegrating tablet (ODT)**.

Medicines in **ODT** form are placed on or under the tongue and dissolve quickly in the mouth even without water.



“Calcitonin gene-related peptide”, also called **CGRP**, is a protein released in the brain and the nervous system. CGRP is involved in the development of migraine attacks through the transmission of pain signals and swelling of blood vessels. Rimegepant is designed to block CGRP’s effects, thereby relieving symptoms and/or reducing how often people have migraine attacks.

What was the purpose of this study?

The main goal of this study was to find out whether rimegepant, given to adult participants, could prevent migraine headaches that were not prevented by previous medicines.

Researchers wanted to know:

Can rimegepant prevent migraine headaches that were not prevented by previous medicines?

What happened during the study?

How was the study done?

Researchers tested rimegepant 75 milligrams (mg) ODT to find out whether it could prevent migraine headaches that were not prevented by previous medicines.

One (1) month before the treatment began, researchers checked the number of days participants had migraine headaches per month.

Eligible participants were assigned by chance to take either rimegepant or placebo. A placebo does not have any medicine in it, but it looks and feels like rimegepant.

For 3 months, participants took the study treatment (rimegepant or placebo) every other day regardless of whether they had a migraine headache. During this period, neither the participants nor the researchers knew which treatment participants took. This is called a “**double-blind (DB)**” treatment.

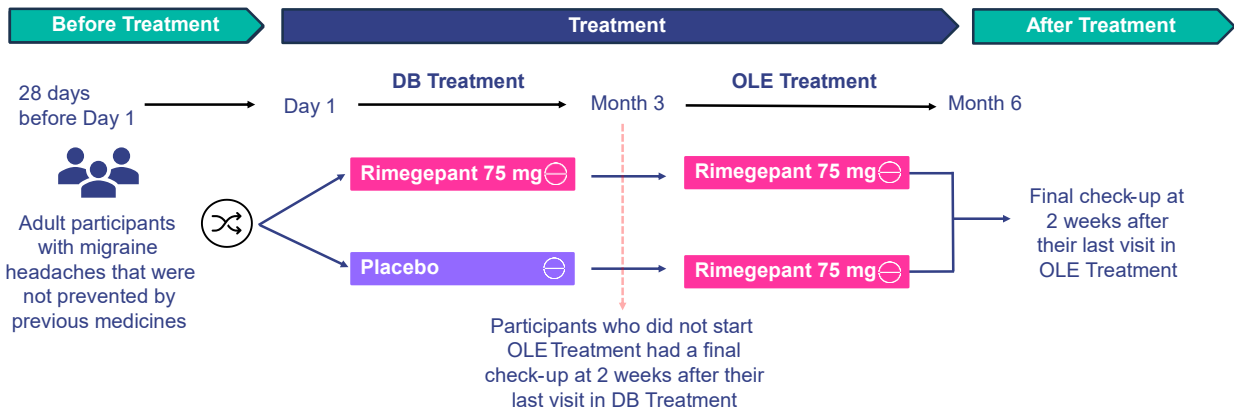
Participants who completed DB Treatment had the option to be in the **open-label extension (OLE)** treatment period where they could take rimegepant every other day, regardless of whether they had a migraine headache, for another 3 months. Open-label treatment period means both participants and researchers knew that participants were taking rimegepant.

- Participants who took rimegepant during DB Treatment continued to take rimegepant during OLE Treatment.
- Participants who took placebo during DB Treatment were asked to take rimegepant during OLE Treatment.

Throughout the study, researchers checked the days in a month participants had migraine headaches and asked participants how they were feeling and what medicines they were taking. Participants had 1 final check-up 2 weeks after their last study visit in either DB or OLE Treatment, whichever visit came later.

Figure 1 below shows how the study was done.

Figure 1. How was the study done?



Where did this study take place?

The Sponsor ran this study at 111 locations in Australia, Europe, and North America.

When did this study take place?

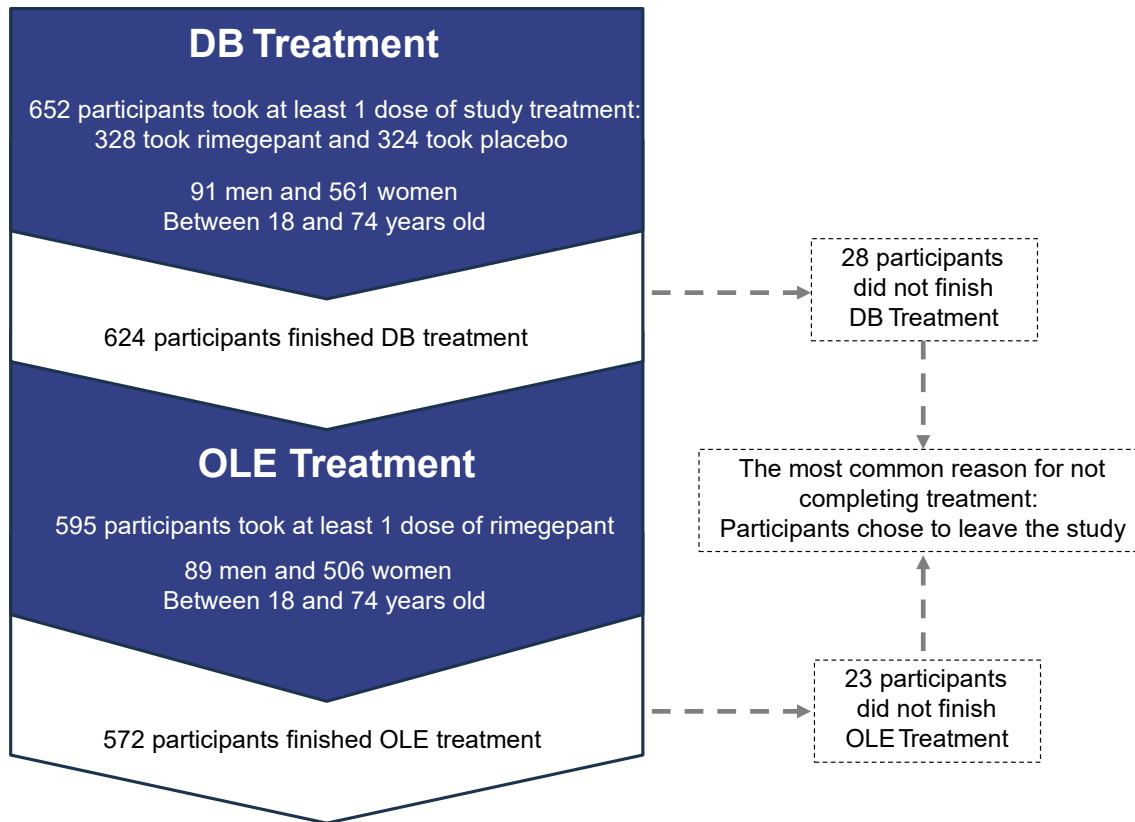
It began on 07 November 2022 and ended on 08 July 2025.

Who participated in this study?

The study included participants who were at least 18 years old and had 4 to 14 migraine days (days participants had migraine headaches) a month that lasted 4 to 72 hours per episode if untreated. Their migraine headaches were not prevented by previous medicines.

Figure 2 below shows the number of participants in the study.

Figure 2. How many participants were in the study?



How long did the study last?

Study participants were in the study for about 7 months. The entire study took about 3 years to complete. The study was completed as planned.

When the study ended in July 2025, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

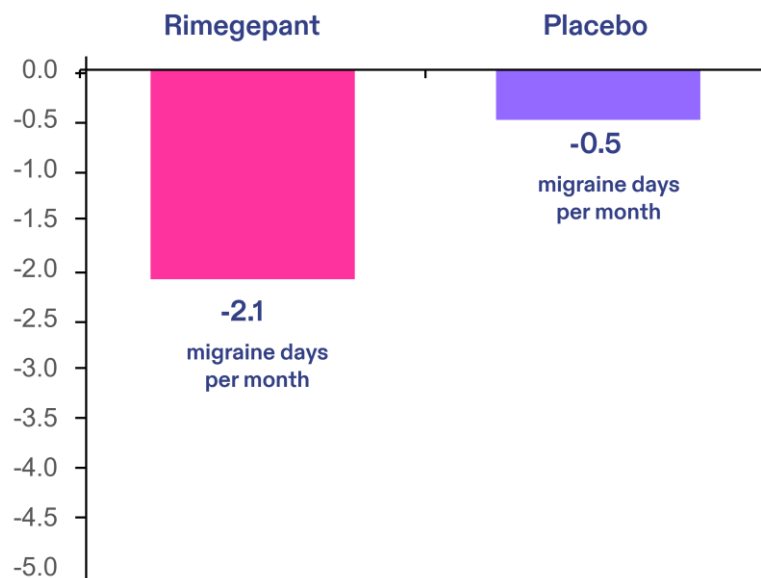
What were the results of the study?

Can rimegepant prevent migraine headaches that were not prevented by previous medicines?

To answer this question, researchers looked at how many days per month participants had migraine headaches at 1 month before DB Treatment and after 3 months of DB Treatment. Researchers then compared the results between the rimegepant and placebo groups.

Figure 3 below shows that, compared to 1 month before DB Treatment, participants who took rimegepant had fewer migraine days per month compared to the placebo group after 3 months of DB Treatment.

Figure 3. Change in the number of migraine days per month after 3 months of DB Treatment compared to 1 month before DB Treatment



A negative number means participants had fewer migraine days per month after 3 months of DB Treatment, as compared to 1 month before DB Treatment.

Based on these results, researchers found that rimegepant may help adults prevent migraine headaches that were not prevented by their previous medicines. Researchers have decided that the results are not likely the result of chance.

This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies may have different results.

What medical problems did participants have during the study?

The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could also have been caused by a study treatment or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many treatment groups in many studies, doctors try to understand what effects a study medicine might have on a participant.

DB Treatment

Figure 4 below shows the number of participants who had at least 1 medical problem during DB Treatment.

Figure 4. How many participants had medical problems – DB Treatment?

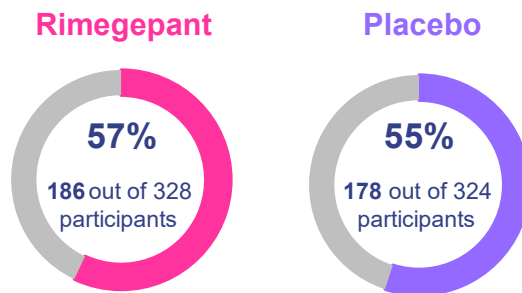


Figure 5 shows the number of participants who stopped taking rimegepant or placebo because of a medical problem during DB Treatment.

Figure 5. How many participants stopped taking rimegepant or placebo because of a medical problem – DB Treatment?

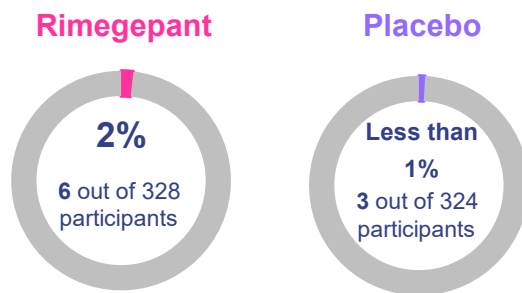


Table 1 below shows the commonly reported medical problems during DB Treatment.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column in Table 1 lists medical problems that were commonly reported during DB Treatment. All medical problems listed were reported by 3% of participants or more in either treatment group.
- The **2nd** column tells the number and percentage of participants who took **rimegepant** and reported the medical problem in Column 1.
- The **3rd** column tells the number and percentage of participants who took **placebo** and reported the medical problem in Column 1.
- Using these instructions, you can see that 29 out of 328 participants (9%) who took rimegepant and 46 out of 324 participants (14%) who took placebo reported common cold (nasopharyngitis).

Table 1. Commonly reported medical problems by study participants – DB Treatment

Medical Problem	Rimegepant (328 Participants)	Placebo (324 Participants)
Common cold (nasopharyngitis)	29 out of 328 participants (9%)	46 out of 324 participants (14%)
Flu (influenza)	16 out of 328 participants (5%)	11 out of 324 participants (3%)
Infection of the nose and throat (upper respiratory tract infection)	7 out of 328 participants (2%)	14 out of 324 participants (4%)
Back pain	17 out of 328 participants (5%)	7 out of 324 participants (2%)
Nausea	15 out of 328 participants (5%)	9 out of 324 participants (3%)
Headache	10 out of 328 participants (3%)	5 out of 324 participants (2%)
Pain in the upper part of the stomach	8 out of 328 participants (2%)	10 out of 324 participants (3%)

OLE Treatment

Figure 6 below shows the number of participants who had at least 1 medical problem during OLE Treatment.

Figure 6. How many participants had medical problems – OLE Treatment?

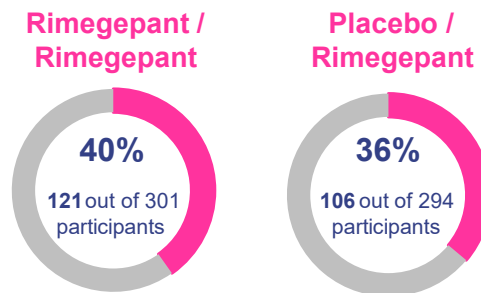


Figure 7 shows the number of participants who stopped taking rimegepant because of a medical problem during OLE Treatment.

Figure 7. How many participants stopped taking rimegepant because of a medical problem – OLE Treatment?

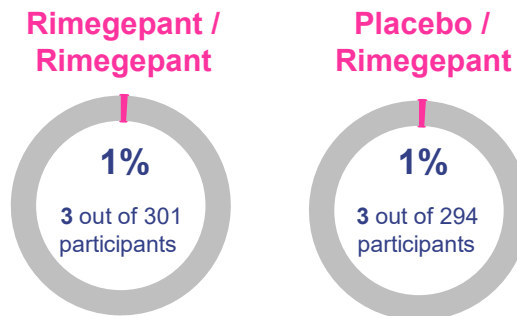


Table 2 below shows the commonly reported medical problems during OLE Treatment.

Below are instructions on how to read Table 2.

Instructions for Understanding Table 2.

- The **1st** column in Table 2 lists medical problems that were commonly reported during OLE Treatment. All medical problems listed were reported by 3% of participants or more in either group.
- The **2nd** column tells the number and percentage of participants who took **rimegepant** during both DB and OLE Treatments and reported the medical problem in Column 1.
- The **3rd** column tells the number and percentage of participants who took **placebo** during DB Treatment and **rimegepant** during OLE Treatment and reported the medical problem in Column 1.
- Using these instructions, you can see that 22 out of 301 participants (7%) who took rimegepant during both DB and OLE Treatments and 12 out of 294 participants (4%) who took placebo during DB Treatment and rimegepant during OLE Treatment reported common cold (nasopharyngitis).

Table 2. Commonly reported medical problems by study participants – OLE Treatment

Medical Problem	Rimegepant / Rimegepant (301 Participants)	Placebo / Rimegepant (294 Participants)
Common cold (nasopharyngitis)	22 out of 301 participants (7%)	12 out of 294 participants (4%)
Flu (influenza)	12 out of 301 participants (4%)	9 out of 294 participants (3%)

Did study participants have any serious medical problems?

A medical problem is considered “serious” when it is life-threatening, needs hospital care, or causes lasting problems.

Figure 8 below shows the number of participants who had at least 1 serious medical problem during DB Treatment.

Figure 8. How many had serious medical problems – DB Treatment?

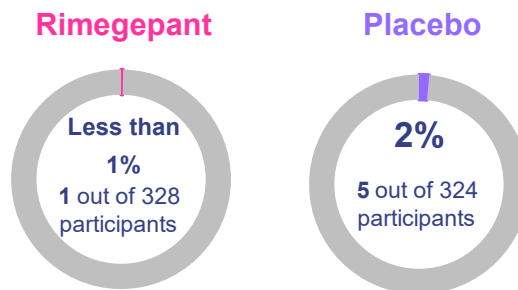
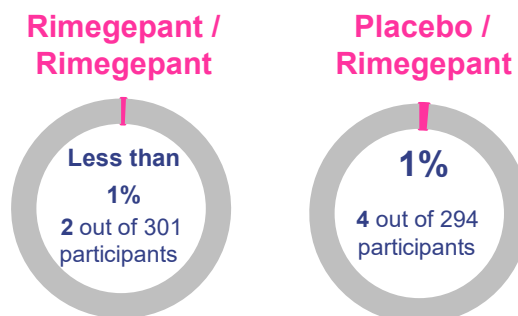


Figure 9 below shows the number of participants who had at least 1 serious medical problem during OLE Treatment.

Figure 9. How many had serious medical problems – OLE Treatment?



No participants died during the study.

Where can I learn more about this study?

If you have questions about the results of your study, please speak with the doctor or staff at your study site.

For more details on your study protocol, please visit:

www.pfizer.com/research/research_clinical_trials/trial_results Use the protocol number **C4951012 (BHV3000-407)**

The full scientific report of this study is available online at:

www.clinicaltrials.gov Use the study identifier **NCT05518123**

<https://euclinicaltrials.eu> Use the study identifier **2024-513270-21-00**

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients.

Again, if you participated in this study,
thank you for volunteering.

We do research to try to find the
best ways to help patients, and you helped
us to do that!

