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: C4951011 (or BHV3000-405)

Dates of Study: 15 March 2022 to 02 July 2024

Title of this Study: Safety and Tolerability Study of Daily Dosing of Rimegepant in Episodic Migraine Prevention

[A Phase 4, Open-label Study to Evaluate the Safety and Tolerability of Daily Dosing of Rimegepant in Episodic Migraine Prevention]

Date of this Report: 07 July 2025

– Thank You –

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

Pfizer

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 a 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.

The most common form of migraine is called "**episodic migraine**", which means the headaches come in episodes and then go away. People with episodic migraines experience up to 14 migraine attacks in 1 month, with each episode lasting 4 to 72 hours if not treated.

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 or Vydura®, 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 and/or reducing the frequency of migraine attacks.

The recommended dose of rimegepant for the prevention of episodic migraine is 75 milligrams (or mg) ODT every other day taken by mouth (oral). The safety of rimegepant taken more frequently than every other day is being studied.

What was the purpose of this study?

The main goal of this study was to learn if rimegepant taken **once a day** for up to 24 weeks (or 6 months) is safe for the prevention of episodic migraine in adult participants.

Researchers wanted to know:

Were participants able to tolerate rimegepant taken once a day?

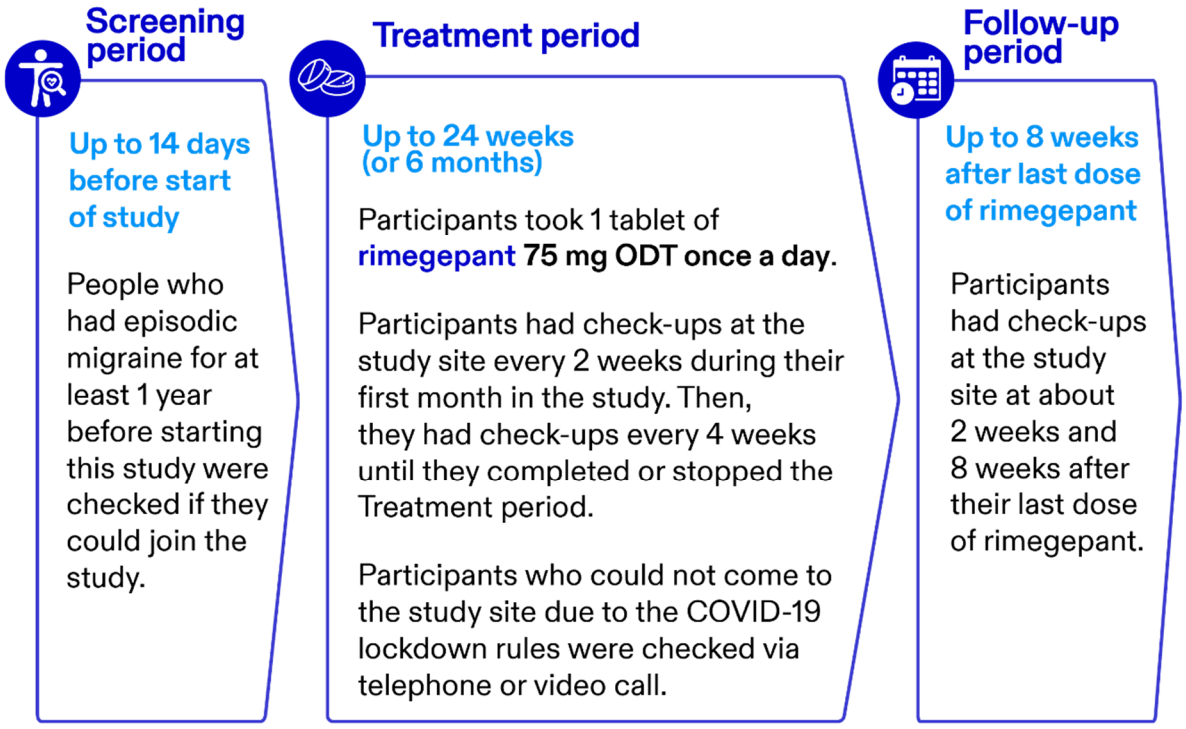
What happened during the study?

How was the study done?

Participants took 1 tablet of rimegepant 75 mg ODT once a day for up to 24 weeks (or 6 months).

Figure 1 below shows what happened in the study.

Figure 1. Study plan



This study was "open-label", which means that study participants and researchers knew that all participants took rimegepant in this study.

Where did this study take place?

The Sponsor ran this study in the United States.

When did this study take place?

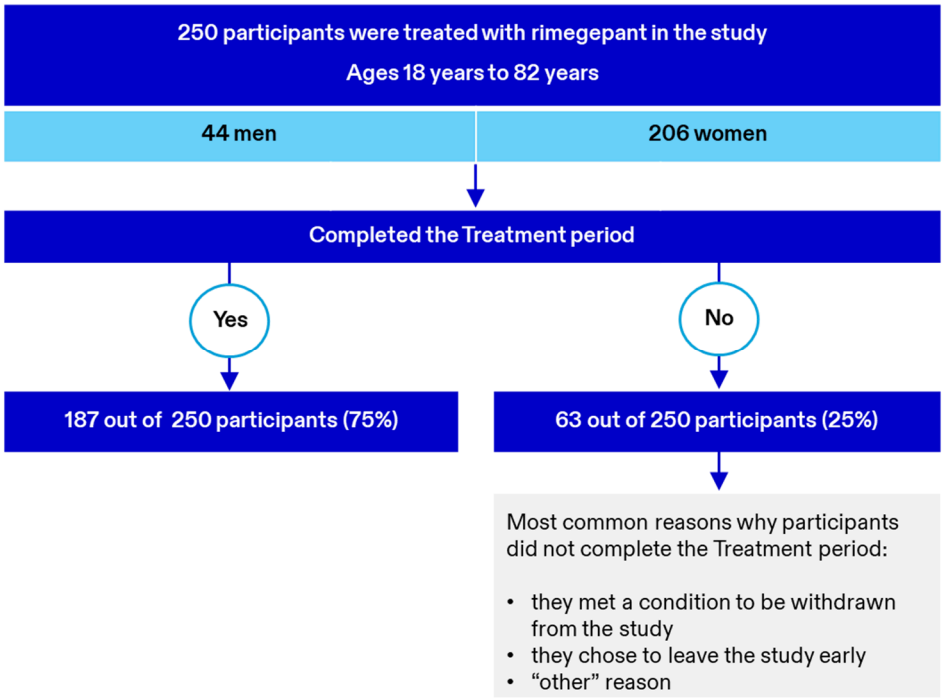
It began on 15 March 2022 and ended on 02 July 2024.

Who participated in this study?

The study included participants aged 18 years and older who had episodic migraine for at least 1 year before starting this study. The participants must have started experiencing migraines before they turned 50 years of age.

Figure 2 below shows how many participants joined the study.

Figure 2. How many participants joined the study



How long did the study last?

Study participants were in the study for up to about 9 months. The entire study took about 2 years and 4 months to complete. The study was completed as planned.

When the study ended in July 2024, 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?

Were participants able to tolerate rimegepant taken once a day?

To answer this question, researchers looked at any medical problems that participants had during the study. Researchers also checked the blood test results of participants during the study.

Researchers found that participants were generally able to tolerate rimegepant taken once a day for up to 24 weeks (or 6 months) for episodic migraine.

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.

During the Treatment period of the study, 134 out of 250 participants (54%) had at least 1 medical problem. A total of 7 out of 250 participants (3%) stopped taking rimegepant because of medical problems.

The most common medical problems during the Treatment period – those reported by more than 5% of participants – are as follows:

- "**Nasopharyngitis**", or inflammation of the nose and throat in 23 out of 250 participants (9%)
- **COVID-19** in 16 out of 250 participants (6%)
- **Nausea** in 15 out of 250 participants (6%)

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.

None of the participants had any serious medical problem during the Treatment period of the study.

During the Follow-up period, 2 participants (less than 1%) had serious medical problems. Researchers do not believe that these reported serious medical problems were related to rimegepant.

None of the 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 **C4951011 (BHV3000-405)**

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

www.clinicaltrials.gov

Use the study identifier **NCT05207865**

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!

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