Clinical Study Results

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 medication 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(s) Studied:	Rimegepant
Protocol Number:	C4951022 (BHV3000-313)
Dates of Study:	09 August 2022 to 19 January 2024
Title of this Study:	Efficacy and Safety Study of Rimegepant for the Acute Treatment of Migraine in Japanese Subjects (Japan Only) [Double-Blind, Randomized, Placebo-Controlled, Dose-Ranging Study to Evaluate the Efficacy and Safety of Rimegepant for the Acute Treatment of Migraine in Japanese Subjects]
Date(s) of this Report:	07 October 2024

– 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. If you have any questions about the study or the results, 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 head pain 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 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 works by blocking CGRP's effects, thereby relieving and/or reducing the frequency of migraine attacks.

What was the purpose of this study?

- The main purpose of this study was to compare taking rimegepant with taking placebo for the acute treatment of migraine in Japanese participants. A placebo looks just like the study treatment, but does not contain any medicine. An acute treatment is one that is taken only at the time of a migraine attack to relieve the current symptoms. This is in contrast to preventative treatment which is taken all the time to reduce the overall frequency and severity of migraine attacks.

Researchers wanted to know:

- **Did acute treatment with rimegepant give pain freedom from migraine 2 hours after treatment?**
- **What medical problems did the participants have during the study?**

What happened during the study?

How was the study done?

At the start of the study, participants were assigned by chance (like rolling dice) to take home 1 of the 3 study treatments:

- One (1) tablet of rimegepant 25 milligrams (or mg)
- One (1) tablet of rimegepant 75 mg
- One (1) tablet of placebo

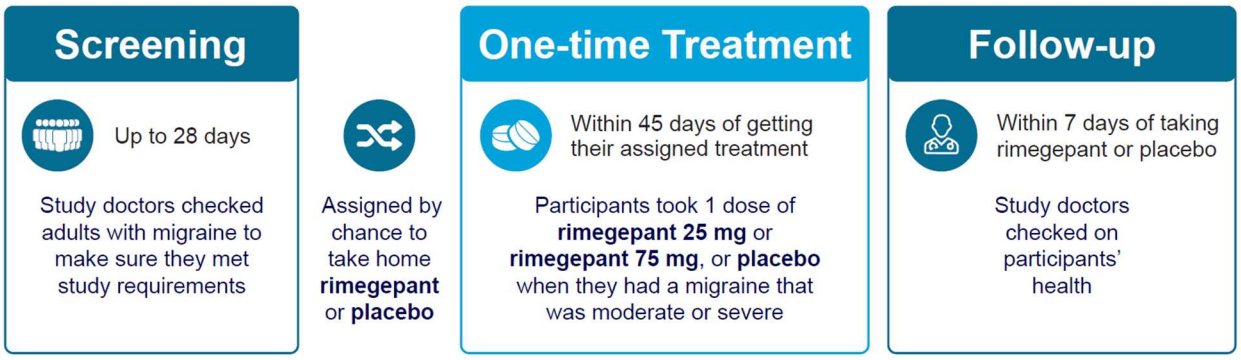
Participants were to take their assigned treatment once. It was only to be taken when they had a moderate to severe migraine. This needed to be within 45 days of taking the treatment home.

The study participants and researchers did not know who took rimegepant and who took placebo. This is known as a “blinded” study.

During the study, study doctors checked on the participants’ health and asked them how they were feeling.

Figure 1 below shows how the study was done.

Figure 1. How was this study done?



Where did this study take place?

The Sponsor ran this study at 50 locations in Japan.

When did this study take place?

It began 09 August 2022 and ended 19 January 2024.

Who participated in this study?

The study included participants who had been having migraines for at least a year. The participants must have started experiencing migraines before they were 50 years old.

- A total of 156 men participated and took the study treatment
- A total of 550 women participated and took the study treatment
- All participants were between the ages of 18 and 72 years.

Of the 706 participants who participated and took the study treatment, 705 finished the study.

One (1) participant in the rimegepant 25 mg group did not finish the study because they could not be contacted.

How long did the study last?

Study participants were in the study for up to about 2 months. The entire study took about 1 year and 5 months to complete.

When the study ended in January 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?

Did acute treatment with rimegepant give pain freedom from migraine 2 hours after treatment?

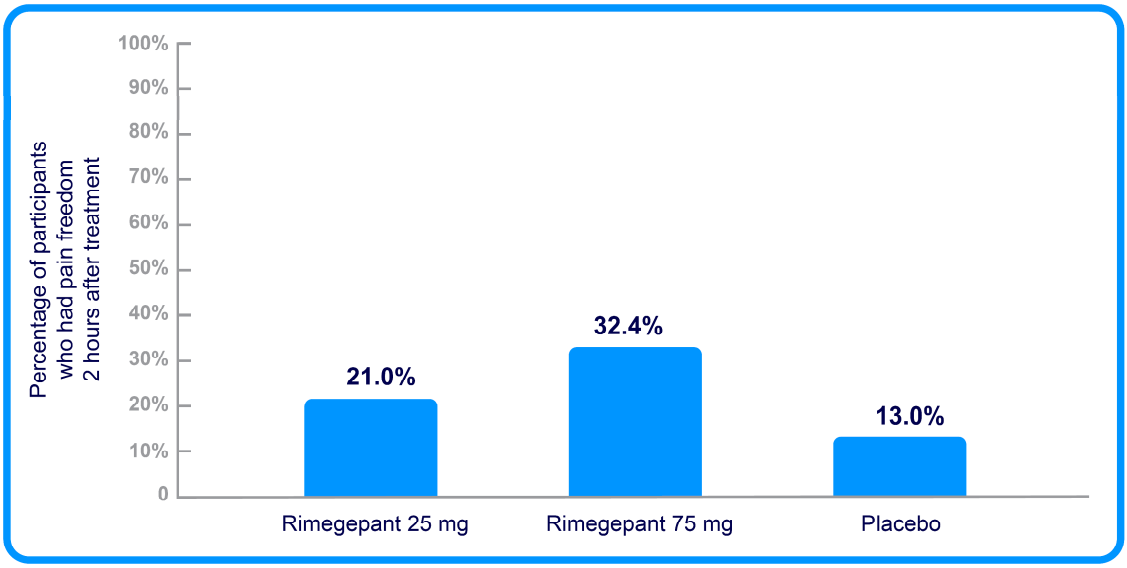
To answer this and other questions, researchers asked participants to rate their migraine pain before they took their assigned study treatment and up to 48 hours after treatment. Participants rated their migraine pain using a 4-grade scale of 0 to 3 (0 = no pain, 1 = mild pain, 2 = moderate pain, 3 = severe pain).

Researchers then calculated the percentage of participants who had pain freedom (no migraine pain) 2 hours after taking rimegepant or placebo. Researchers compared the results of those who took rimegepant to those who took placebo.

The percentage of participants who had pain freedom 2 hours after treatment is shown in Figure 2 below. In total, pain freedom was experienced by:

- 50 out of 238 participants (21.0%) in the rimegepant 25 mg group
- 77 out of 238 participants (32.4%) in the rimegepant 75 mg group
- 30 out of 230 participants (13.0%) in the placebo group.

Figure 2. Pain freedom 2 hours after treatment



The researchers have decided that the results for rimegepant 75 mg compared to placebo are not likely the result of chance. The results show that rimegepant may help migraine pain.

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 medication might have on a participant.

A total of 54 out of 706 participants (7.6%) in this study had at least 1 medical problem after taking the study treatment. This included:

- 17 participants (7.1%) in the rimegepant 25 mg group
- 22 participants (9.2%) in the rimegepant 25 mg group
- 15 participants (6.6%) in the placebo group

The most common medical problem – reported by at least 1% of participants – was inflammation of the nose/throat (nasopharyngitis). This was reported by a total of 8 out of 706 participants (1.1%):

- 3 participants (1.3%) in the rimegepant 25 mg group
- 3 participants (1.3%) in the rimegepant 75 mg group
- 2 participants (0.9%) in the placebo group.

No participant left the study because of a medical problem.

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.

One participant in the rimegepant 75 mg group had a serious medical problem of suicidal thoughts. These suicidal thoughts were thought of as mild and the participant recovered. Researchers do not believe that this serious medical problem was related to the study medication.

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 C4951022

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

www.clinicaltrials.gov	Use the study identifier **NCT05399459**

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!