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 Studied:	Nurtec® ODT (rimegepant, also called PF-07899801 or BHV-3000)
Protocol Number:	C4951016 (BHV3000-317)
Dates of Study:	05 May 2022 to 18 May 2023
Title of this Study:	A Study of Rimegepant in Adults With Temporomandibular Disorders [A Phase 2/3, Double-Blind, Randomized, Placebo-Controlled Safety and Efficacy Trial of BHV-3000 (Rimegepant) Orally Disintegrating Tablet (ODT) for the Acute Treatment of Temporomandibular Disorders (TMD)]
Date of this Report:	17 May 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 are temporomandibular disorders?

Temporomandibular disorders, or **TMDs**, are a group of medical conditions involving the temporomandibular joint, which is the joint that connects the jawbone to the skull, and the surrounding muscles and tissues. People with TMD may have pain, reduced movement of the jaw, and/or clicking in the joint when moving.

What is rimegepant?

Rimegepant (ri-ME'-je-pant) is a medicine approved for the treatment of migraine (a type of severe headache). 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.

When people experience a migraine attack, they have high levels of a protein called "calcitonin gene related peptide", also called **CGRP**, released from the trigeminal system. Rimegepant works by blocking CGRP effects, such as transmission of pain signals and swelling of blood vessels, that cause migraine attacks.

> The trigeminal system is responsible for carrying information about touch, pain, and temperature from the face and head to the brain.

Researchers thought that rimegepant can also help people with TMD. In this study, rimegepant was considered investigational because it is not approved for treatment of TMD outside of research studies. Rimegepant was taken in this study sublingually, meaning placed under the tongue.

What was the purpose of this study?

The main purpose of this study was to learn if rimegepant can help relieve sudden (also called “acute”) jaw or temple pain in adults with TMD within 2 hours after taking it.

Researchers wanted to know:

- **Did participants feel relief from sudden TMD pain within 2 hours after taking rimegepant?**
- **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 flipping a coin) to take home 1 of the 2 study treatments:

- One (1) tablet of rimegepant 75 milligrams (or mg)
- One (1) tablet of placebo
  A placebo does not have any medicine in it, but it looks just like rimegepant.

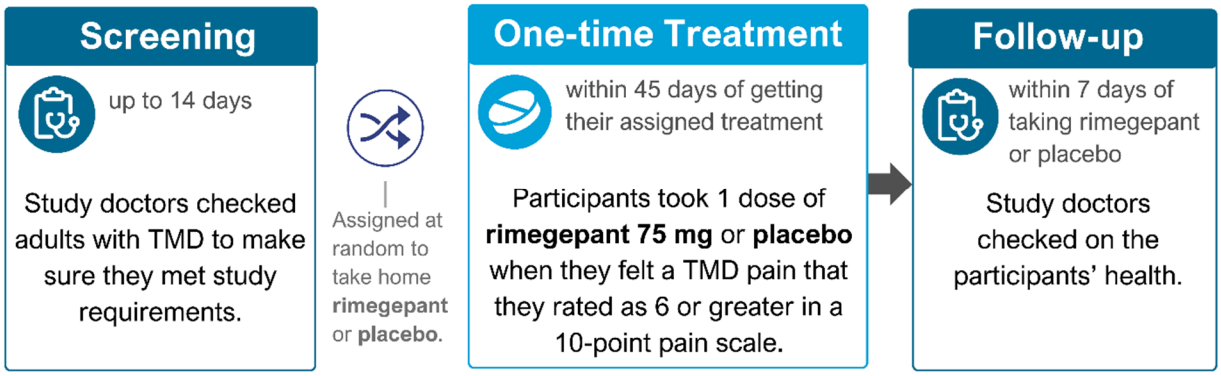
Within 45 days of getting their assigned study treatment, participants were to take their assigned treatment only when they feel a TMD pain that they can rate as 6 or greater on a scale of 0 to 10 (0 means no pain, and 10 means worst pain imaginable).

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

Throughout the study, study doctors checked on the participants’ health and asked the participants to rate their TMD pain.

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 10 locations in the United States.

When did this study take place?

It began on 05 May 2022 and ended on 18 May 2023.

The Sponsor ended the study earlier than planned because their plans for developing rimegepant had changed. This decision was not due to safety concerns with rimegepant.

Who participated in this study?

The study included participants 18 years of age or older who have TMD.

- A total of 16 men and 55 women participated.

- All participants were from 19 to 72 years old.

Of the 87 participants who started the study, 71 participants took a study treatment. All 71 participants finished the study.

How long did the study last?

Study participants were in the study for up to about 2 months. The study was conducted for about 1 year before it was stopped.

When the study ended in May 2023, 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 participants feel relief from sudden TMD pain within 2 hours after taking rimegepant?

To answer this question, researchers asked participants to rate their sudden TMD pain before they take their assigned study treatment and up to 24 hours after treatment. Participants rated their TMD pain using a scale of 0 to 10 (0 means no pain, and 10 means worst pain imaginable).

Researchers then calculated how much the participants' ratings have changed over 2 hours of taking rimegepant or placebo. A drop in ratings would mean participants felt relief from TMD pain, while an increase would mean they felt worsening of TMD pain.

Researchers compared the results of those who took rimegepant to those who took a placebo.

On average, TMD pain ratings:

- **dropped by 4.0 points** within 2 hours of taking rimegepant.
- **dropped by 3.9 points** within 2 hours of taking placebo.

However, these results do not show whether rimegepant can or cannot help relieve, within 2 hours of taking it, sudden TMD pain in adults with TMD. This is because the study ended early, and the number of participants was not enough to have a strong statistical analysis.

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 4 out of 71 participants (6%) in this study had at least 1 medical problem during the on-treatment period of the study.

- In the rimegepant group, 1 participant had a “right bundle branch block”, which is a condition caused by blockage of electrical signals to the right ventricle of the heart. The study doctors believe this condition was not related to rimegepant.
- In the placebo group:
    - One (1) participant had body aches.
    - One (1) participant had high levels of liver enzymes.
    - One (1) participant had numbness.

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.

None of the participants had a serious medical problem or 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 **C4951016**

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

www.clinicaltrials.gov	Use the study identifier **NCT05262517**

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!