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 (rimegepant sulfate, also known as PF-07899801 or BHV-3000)

Protocol Number: C4951015 (BHV3000-316)

Dates of Study: 17 February 2022 to 02 April 2024

Title of this Study: Safety and Efficacy Study of BHV-3000 (Rimegepant) Orally Disintegrating Tablet for the Acute Treatment of Chronic Rhinosinusitis

[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 Chronic Rhinosinusitis (CRS) With or Without Nasal Polyps]

Date of this Report: 30 March 2025

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– 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 chronic rhinosinusitis?

Rhinosinusitis is when the soft layer of tissue in the nose and head, called sinuses, becomes inflamed or swollen. Chronic rhinosinusitis (or **CRS**) lasts for more than 3 months, even with treatment. People with CRS often have facial pain/pressure/fullness, blocked or stuffy nose, runny nose, and/or reduced sense of smell.

What is rimegepant?

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

Researchers thought that rimegepant could help people with CRS by blocking a protein called **CGRP receptors**, which plays a role in "inflammation" (swelling) and pain.

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What was the purpose of this study?

The main purpose of this study was to learn whether rimegepant can help relieve facial pain/pressure/fullness in participants with CRS.

Researchers wanted to know:

- **Did rimegepant reduce participants' facial pain/pressure/fullness within 2 hours of treatment?**
- **What medical problems did 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 to 1 of 2 treatment groups (**rimegepant** or **placebo**). A placebo looks just like rimegepant, but it does not have any medicine in it.

Within 45 days of being assigned to a treatment group, participants took 1 dose of rimegepant or placebo when their facial pain/pressure/fullness was rated 6 or higher.

> Participants rated their facial pain/pressure/fullness from **0** (no facial pain/pressure/fullness) to **10** (worst imaginable facial pain/pressure/fullness) using a tool called the Numerical Rating Scale (NRS).

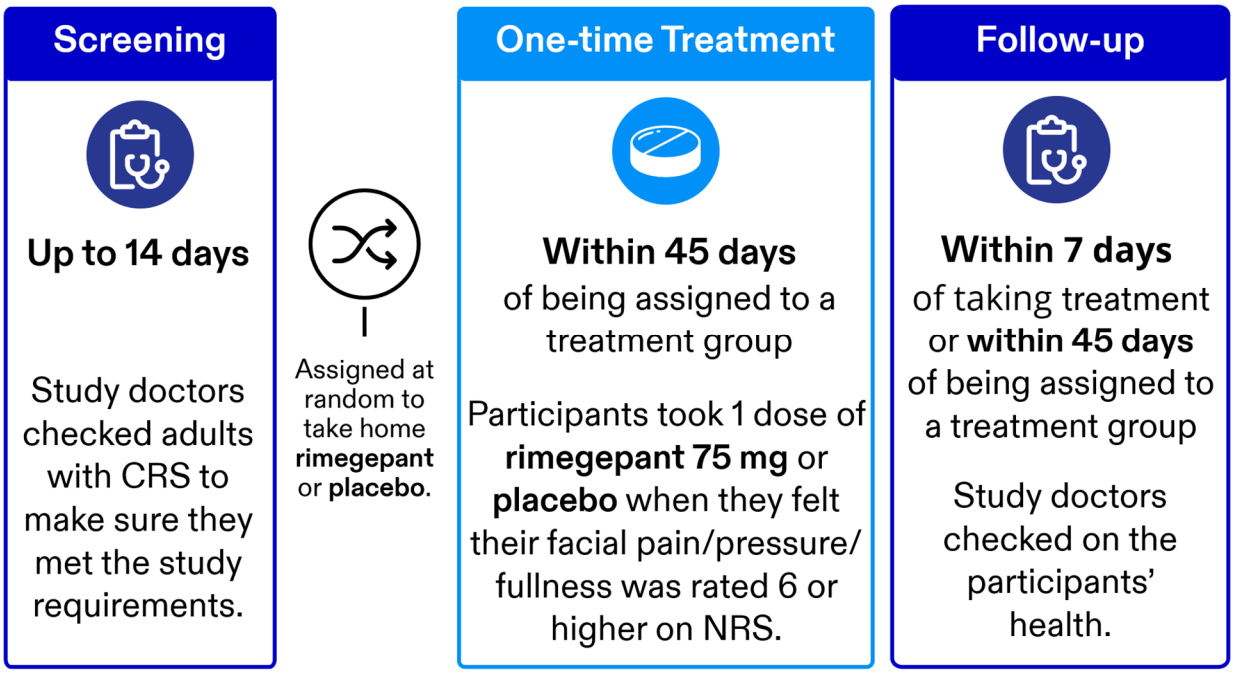
Participants were asked not to take their assigned treatment if they had facial pain/pressure/fullness that did not reach a rating of 6 or higher.

The study participants and researchers did not know whether participants were assigned to take rimegepant or placebo. This is known as a "**double-blind**" study.

Throughout 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 in the United States.

When did this study take place?

It began on 17 February 2022 and ended on 02 April 2024.

Who participated in this study?

The study included participants 18 years of age or older who had CRS with or without growths in the lining of the nose ("nasal polyps").

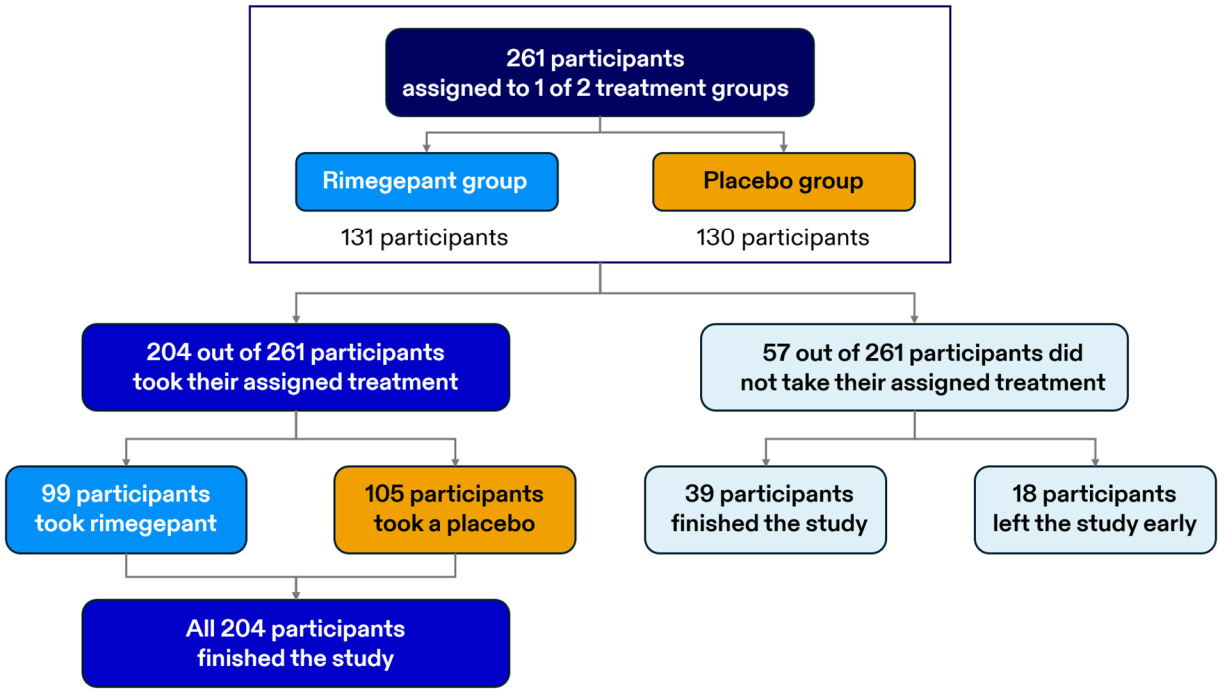
- A total of 116 men and 145 women participated.
- All participants were between the ages of 18 years and 79 years.

Of the 261 participants who started the study, 204 took their assigned treatment: 99 took rimegepant and 105 took a placebo. All 204 participants finished the study.

A total of 57 participants were not treated: 18 left the study early, and 39 finished the study without treatment because their facial pain/ pressure/fullness never reached an NRS score of 6 or higher.

Figure 2 shows the number of participants who took part in this study.

Figure 2. How many participants took part in the study?



How long did the study last?

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

When the study ended in April 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 rimegepant reduce participants' facial pain/pressure/fullness within 2 hours of treatment?

To answer this question, researchers asked participants to rate their facial pain/pressure/fullness using the NRS before taking their assigned treatment and after treatment.

Researchers then calculated how much the participants' ratings had changed over 2 hours of taking the study treatment. A drop in ratings means the participants felt reduced facial pain/pressure/fullness. A rise in ratings means the participants felt worsened facial pain/pressure/fullness.

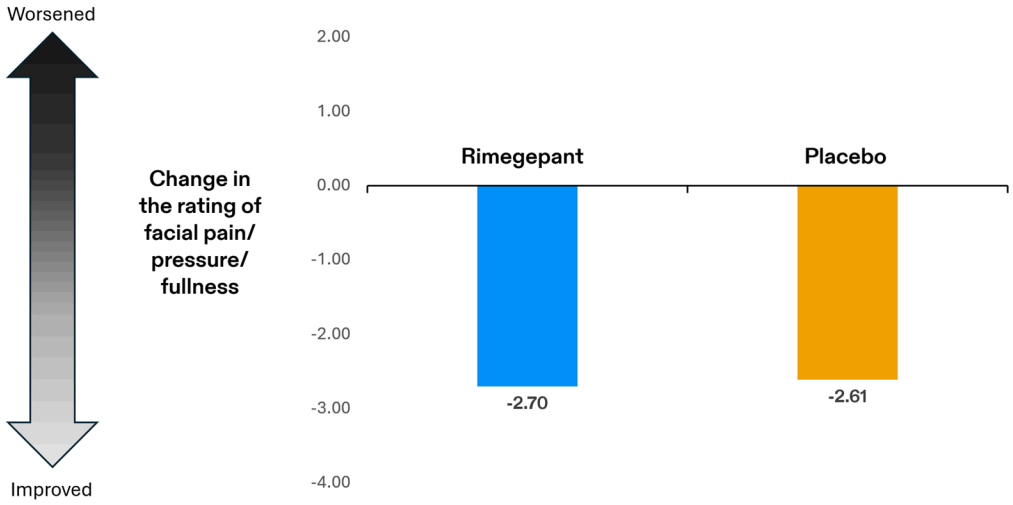
Researchers compared the results from those who took rimegepant with those who took placebo.

On average, the study result showed that,

- In **rimegepant group**, the participants' facial pain/pressure/fullness ratings **dropped by 2.70 points** within 2 hours of taking rimegepant.
- In **placebo group**, the participants' facial pain/pressure/fullness ratings **dropped by 2.61 points** within 2 hours of taking placebo.

Figure 3 below shows these results.

Figure 3. How did the participants' rating of facial pain/pressure/fullness change after 2 hours of taking the study treatment?



Based on these results, the researchers have decided that the results are likely the result of chance. This means the study results did not show that one treatment had a greater effect than another at relieving facial pain/pressure/ fullness.

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.

- Four (4) out of 99 participants (4%) who took **rimegepant** each had at least 1 medical problem during the study. The medical problems were high levels of liver enzymes ("AST increased"), high levels of a muscle enzyme in the blood ("blood creatine phosphokinase increased"), nose and throat infection ("upper respiratory tract infection"), head injury, and dry throat.
- Five (5) out of 105 participants (5%) who took **placebo** each had 1 medical problem during the study. The medical problems were diarrhea; feeling sick ("nausea"); a faster-than-normal electrical signal between the heart's upper and lower chambers, shown on an electrocardiogram (ECG, which measures the electrical activity of the heart); high levels of liver enzymes in the blood ("hypertransaminasemia"); and back pain.
- No participants left the study because of medical problems.

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.

No participants had serious medical problems 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 **C4951015 (BHV3000-316)**

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

www.clinicaltrials.gov	Use the study identifier **NCT05248997**

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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