# 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:** Zavzpret™ (zavegepant)

**Protocol Number:** BHV-3500-204 (C5301005)

**Dates of Study:** 18 October 2021 to 04 April 2023

**Title of this Study:** A study to learn about the effect and safety of oral zavegepant in participants with mild allergic asthma

[A Phase 1b, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate Safety and Efficacy of Oral Zavegepant in Subjects With Mild Allergic Asthma]

**Date of this Report:** 23 January 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 allergic asthma?

Asthma is a long-term condition of the airways. Airways are the tubes that carry air to and from the lungs. In asthma, the airways become narrow or blocked. This makes it difficult for the person to breathe. Sometimes, an asthma episode happens when a person breathes in an “allergen”. Allergen is any substance like dust, grass, or pollen, that irritates the airway. This type of asthma is called allergic asthma.

An asthma episode may happen soon after people with allergic asthma breathe in an allergen. Many people may also experience another episode of difficulty in breathing, 3 to 7 hours after they breathed in the allergen. This episode may extend for hours to days. The usual asthma medicine may not help to provide relief.

Researchers measure the lung function using a test. It measures the amount of air a person can breathe out in 1 second. People with allergic asthma experience a decrease in the amount of air breathed out.

## What is zavegepant?

The study medication Zavzpret™ is also called zavegepant. Zavegepant is pronounced as ‘zah-VEJ-ah-pant’.

Zavegepant may help by blocking how the body responds to allergens, so the airways may not become narrow or blocked. Researchers think zavegepant may help people with allergic asthma who experience episodes that happen some hours after breathing in the allergen. In this study, zavegepant was used as a capsule taken by mouth.

## What was the purpose of this study?

- The purpose of the study was to learn about the effect and safety of zavegepant, compared to "'placebo" in participants with mild allergic asthma. A placebo does not have any medicine in it, but it looks just like the study medication.

### Researchers wanted to know:

**After 4 weeks of treatment with zavegepant compared to placebo, what was the maximum reduction in the lung function of the participants who were exposed to the allergen?**

# What happened during the study?

## How was the study done?

Researchers tested zavegepant on a group of study participants to find out the maximum reduction in the lung function when the study participants were exposed to the allergen after they were treated for 4 weeks.

Researchers then compared the results of study participants taking the study medication to the results of study participants taking placebo.

The study participants and researchers did not know who took zavegepant and who took the placebo. This is known as a "blinded" study.

The study had three periods: Screening Period, Treatment Period and Follow-up Period (Figure 1).

**Screening Period:** During the screening period, the researchers checked who could take part in this study. There were 4 visits during this period. During these visits, the researchers did many tests to check for allergies and the lung function. These tests included study participants' breathing in an allergen to check how the lung function changed. The study participants' lung function was also checked with other triggers, like a chemical called methacholine. Researchers use methacholine to check if the study participants have asthma. This took up to 4 weeks.

After these tests, there was a break of 2 to 4 weeks before the treatment started. The time allowed the study participants' lung function to return to how it was before the screening tests were done.

The whole screening period could have taken up to 6 to 8 weeks.

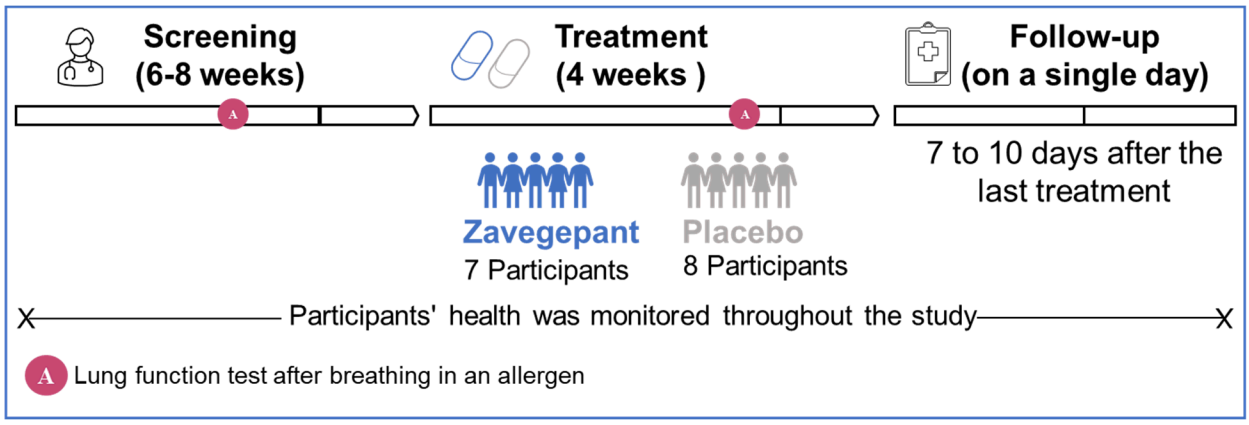
**Treatment Period:** The study participants had their lung function checked again before they were divided into 2 groups. Study participants were assigned to each group by chance alone. They had equal chances to be in the zavegepant group or the placebo group. The total daily dose of zavegepant was 300 milligrams. The study participants took 6 capsules, by mouth, two times in a day. They took capsules once in the morning on an empty stomach and once in the evening for 4 weeks. The study participants were asked not to eat or drink anything other than water for 1 hour after the medication.

During the last 3 days of treatment, the study participants visited the study site every day. During these visits, their lung function was checked to learn if there was any change in the lung function before and after the treatment. The lung function was checked after the study participants were asked to breathe in methacholine and the allergen on separate days during these visits. The allergen was same as the one used during the screening period.

**Follow-up-Period:** The study participants visited the study site for the last time 7 to 10 days after the last day of the treatment. Participants' health was monitored throughout the study.

The study was stopped early. This decision was not due to any safety concerns with zavegepant.

## Figure 1: The different study periods




## Where did this study take place?

The Sponsor ran this study at 6 locations in Canada.

## When did this study take place?

It began on 18 October 2021 and ended on 04 April 2023.

## Who participated in this study?

The study included adult participants who had occasional mild allergic asthma. They had positive response to a lung test to confirm asthma diagnosis. They did not have any other lung disease.

- A total of 3 men and 12 women participated.
- All participants were between the ages of 20 and 61 years.

Participants were to be treated for 4 weeks. Of the 15 participants who started the study, 13 finished the study.

Two participants did not finish the study because:

- one participant had COVID-19, and
- one participant left before the study was over by their choice.

### How long did the study last?

Study participants were in the study for a little more than 3 months. The entire study was conducted for 1 year and 6 months before the sponsors decided to stop the study. This decision was not due to any safety concerns with zavegepant.

When the study ended in April 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?

### After 4 weeks of treatment with zavegepant compared to placebo, what was the maximum reduction in the lung function of the participants who were exposed to the allergen?

To answer this question, after 4 weeks of treatment, the researchers measured the study participants' lung function. They did this at specific times after the study participants were exposed to the allergen. They were looking for the largest drop in the lung function between 3 and 7 hours after the study participants breathed in the allergen.

However, the study was stopped early. As the number of study participants was small, the researchers could not make any conclusion about the effect of zavegepant.

## 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.

Overall, 7 out of 15 [47%] participants in this study had at least 1 medical problem. One participant left the study because of medical problem. The most common medical problems – those reported by the participants – are described below in Table 1.

Below are instructions on how to read Table 1.

### Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists medical problems that were commonly reported during the study. All medical problems reported by participants are listed.
- The **2nd** column tells how many of the 7 participants taking the study medication reported each medical problem. Next to

this number is the percentage of the 7 participants taking the study medication who reported the medical problem.

- The **3rd** column tells how many of the 8 participants taking a placebo reported each medical problem. Next to this number is the percentage of the 8 participants taking a placebo who reported the medical problem.
- Using these instructions, you can see that 2 out of the 7 [29%] participants taking the study medication reported stomach pain. No participants taking a placebo reported stomach pain.

**Table 1. Commonly reported medical problems by study participants**

| Medical Problem | Zavegepant (7 Participants) | Placebo (8 Participants) |
|---|---|---|
| **Stomach pain** | 2 out of 7 participants (29%) | 0 |
| **Blocked airways** | 1 out of 7 participants (14%) | 0 |
| **Cough** | 1 out of 7 participants (14%) | 1 out of 8 participants (13%) |
| **Diarrhea** | 1 out of 7 participants (14%) | 1 out of 8 participants (13%) |

| Table 1. Commonly reported medical problems by study participants | | |
|---|---|---|
| **Medical Problem** | **Zavegepant (7 Participants)** | **Placebo (8 Participants)** |
| **Discomfort in the air-filled spaces around the nasal cavity** | 1 out of 7 participants (14%) | 0 |
| **Feeling tired** | 1 out of 7 participants (14%) | 0 |
| **Fever** | 1 out of 7 participants (14%) | 1 out of 8 participants (13%) |
| **Headache** | 1 out of 7 participants (14%) | 1 out of 8 participants (13%) |
| **Painful, dry, or scratchy feeling in the throat** | 1 out of 7 participants (14%) | 0 |
| **Stuffy Nose** | 1 out of 7 participants (14%) | 0 |
| **COVID-19** | 0 | 1 out of 8 participants (13%) |

| Table 1. Commonly reported medical problems by study participants | | |
|---|---|---|
| **Medical Problem** | **Zavegepant (7 Participants)** | **Placebo (8 Participants)** |
| **Swelling in the stomach area or region** | 0 | 1 out of 8 participants (13%) |

## 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.

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 **BHV-3500-204 (C5301005)** |

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

| | |
|---|---|
| www.clinicaltrials.gov | Use the study identifier **NCT04987944** |

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!