

# 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:** Arena Pharmaceuticals, Inc. (a wholly owned subsidiary of Pfizer Inc.)

**Medicine Studied:** Velsipity® (also known as etrasimod)

**Protocol Number:** C5041006 SS4 (APD334-202 or CULTIVATE)

**Dates of Study:** 24 March 2022 to 09 June 2025

**Title of this Study:** A Study of Etrasimod in Adults With Crohn's Disease – Substudy 4

[A Multicenter, Randomized, Double-Blind, Parallel-Group Study to Assess the Efficacy and Safety of Oral Etrasimod as Induction and Maintenance Therapy for Moderately to Severely Active Crohn's Disease – Substudy 4]

**Date of this Report:** 01 April 2026

# – 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?

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### What is Crohn's disease?

Crohn's disease (or CD) is a condition caused by inflammation (pain, swelling, and redness) in the gut. CD can affect any part of the gut from the mouth to the anus. This inflammation can lead to symptoms like diarrhea, abdominal pain, blood in the stool, weight loss, and tiredness. Signs of damage caused by CD include narrowing of the gut or sores in its lining.

### What is etrasimod?

Etrasimod (et –ras' – i – mod), also called Velsipity™, is a medicine in tablet form that is swallowed. It is approved for adult patients with moderately to severely active ulcerative colitis, a disease that causes inflammation in the colon (large intestine). In this study, etrasimod is considered investigational because it is not approved for the treatment of CD outside of research studies.

Etrasimod is designed to partially block the movement of certain groups of lymphocytes to areas of inflammation in the gut. Lymphocytes are a type of white blood cell that are a part of the immune system (the body's defense system against infection). Studies show that certain lymphocytes may be involved in causing CD. Researchers think that blocking these lymphocytes may reduce inflammation and help with CD symptoms.



## What was the purpose of this study?

The main purpose of Substudy 4 was to find out whether etrasimod could be safely given for a long time in adult participants with moderately to severely active CD.

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### Researchers wanted to know:

- Can participants safely take etrasimod for a long time?
- What medical problems did participants have during this study?

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This study was stopped early and was not completed as planned. This was because results from an earlier etrasimod study showed that it did not work in improving CD symptoms. This was not because of safety concerns or a request from health authorities.

## What happened during the study?

### How was the study done?

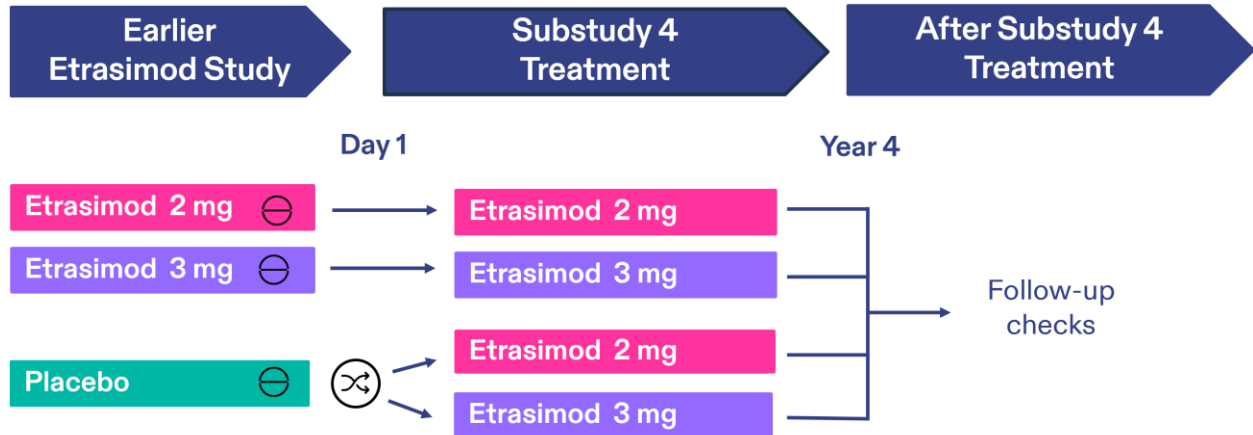
Researchers tested 2 doses of etrasimod to find out whether etrasimod could be safely given for a long time. The study participants and researchers did not know what dose of etrasimod participants took. This is known as a “blinded” study.

Participants assigned to the **etrasimod** group continued with the same etrasimod dose (2 or 3 mg) they had taken during the earlier etrasimod study. Participants who took **placebo** in the earlier etrasimod study were randomly divided (like flipping a coin) into 2 etrasimod groups: 2 or 3 mg. A placebo does not have any medicine in it, but it looks just like the study medicine.

Participants were planned to take their assigned treatment once per day for 208 weeks (about 4 years). Researchers checked the participants' health during the study and asked them how they were feeling.

Figure 1 shows how the study was done.

**Figure 1. How was the study done?**



### Where did this study take place?

The Sponsor ran this study at 197 locations in 38 countries worldwide.

### When did this study take place?

It began on 24 March 2022 and ended on 09 June 2025.

### Who participated in this study?

The study included adult participants who had moderately to severely active CD. These participants had completed at least 52 weeks (about 1 year) of treatment in the earlier etrasimod study.

In total, 143 participants started this study.

- A total of 72 men and 71 women participated.
- All participants were between the ages of 19 and 78 years.

Out of 143 participants who started the study, 72 participants took etrasimod 2 mg and 71 participants took etrasimod 3 mg. A total of 102 participants stopped taking part in the study early because of the Sponsor's decision.

### How long did the study last?

Participants were planned to be in Substudy 4 for about 4 years. But the Sponsor stopped the study early, so it ended 1 year sooner than planned.

The Sponsor decided to stop Substudy 4 early after learning that etrasimod did not work in improving CD symptoms in an earlier study of etrasimod. This decision was not due to safety concerns reported by other etrasimod studies or a request from health authorities.

When Substudy 4 ended in June 2025, 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?

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### Can participants safely take etrasimod for a long time?

To answer this question, researchers looked at all the information collected on the participants' health throughout the study, including any medical problems that participants had.

This study was stopped early and was not completed as planned. Even though the number of participants was smaller and the treatment period was shorter than planned, overall, participants were able to safely take etrasimod during the study.

## What medical problems did participants have during the study?

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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.

Figure 2 shows the number of participants who had at least 1 medical problem in Substudy 4.

**Figure 2. How many participants had medical problems?**

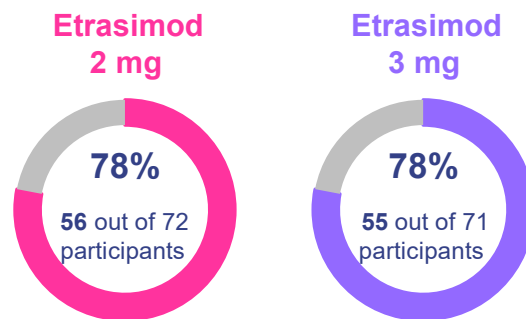
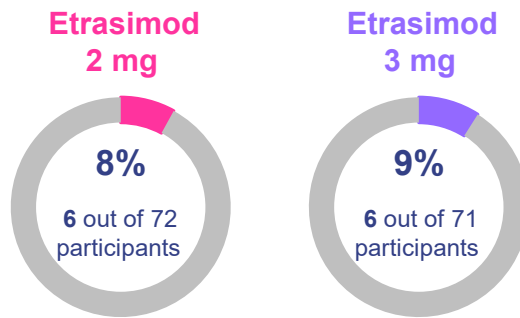


Figure 3 shows the number of participants who stopped taking etrasimod because of a medical problem in Substudy 4.

**Figure 3. How many participants stopped taking etrasimod because of a medical problem?**



Participants who stopped taking etrasimod because of a medical problem also stopped taking part in Substudy 4 early.

The most common medical problems – those reported by 10 participants or more in total of both groups – in Substudy 4 are described in Table 1.

Below are instructions on how to read Table 1.

**Instructions for Understanding Table 1.**

- The **1st** column lists the medical problems that were reported by 10 participants or more in total of both groups.
- The **2nd** column tells the number and percentage of participants who took **etrasimod 2 mg** and reported the medical problem.
- The **3rd** column tells the number and percentage of participants who took **etrasimod 3 mg** and reported the medical problem.
- Using these instructions, you can see that 10 out of 72 participants (14%) who took etrasimod 2 mg and 10 out of 71 participants (14%) who took etrasimod 3 mg reported Crohn’s disease (CD).

<b>Table 1. Commonly reported medical problems by study participants</b>		
<b>Medical Problem</b>	<b>Etrasimod 2 mg (72 Participants)</b>	<b>Etrasimod 3 mg (71 Participants)</b>
<b>Crohn's disease</b>	10 out of 72 participants (14%)	10 out of 71 participants (14%)
<b>Low level of lymphocytes (lymphopenia)</b>	9 out of 72 participants (13%)	7 out of 71 participants (10%)
<b>Common cold (nasopharyngitis)</b>	6 out of 72 participants (8%)	5 out of 71 participants (7%)
<b>Low level of lymphocytes (lymphocyte count decreased)</b>	6 out of 72 participants (8%)	5 out of 71 participants (7%)
<b>Abdominal pain</b>	6 out of 72 participants (8%)	4 out of 71 participants (6%)
<b>Low level of red blood cells (anemia)</b>	7 out of 72 participants (10%)	3 out of 71 participants (4%)

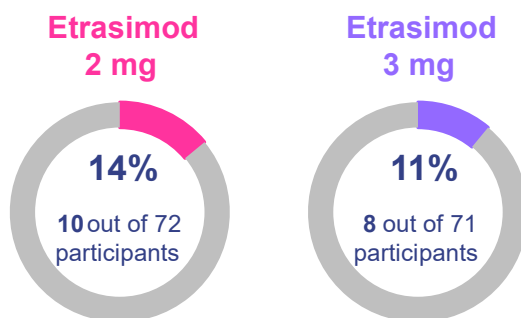
## Did study participants have any serious medical problems?

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A medical problem is considered “serious” when it is life-threatening, needs hospital care, or causes lasting problems.

Figure 4 shows the number of participants who had at least 1 serious medical problem in Substudy 4.

**Figure 4. How many participants had serious medical problems?**



In **etrasimod 2 mg** group, the common serious medical problems were CD and anemia, which were reported by 2 participants each. One (1) participant died because of a medical problem, which was considered not related to etrasimod.

In **etrasimod 3 mg** group, no serious medical problems were reported by more than 1 participant.

## Where can I learn more about this study?

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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](http://www.pfizer.com/research/research_clinical_trials/trial_results) Use the protocol number **C5041006 SS4**

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

[www.clinicaltrials.gov](http://www.clinicaltrials.gov) Use the study identifier **NCT04173273**

[www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu) Use the study identifier **2020-004775-40**

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!