



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

**Medicine Studied:** Velsipity™ (etrasimod)

**Protocol Number:** C5041006 SSA-P2 (APD334-202 or CULTIVATE)

**Dates of Study:** 06 January 2020 to 23 March 2023

**Title of this Study:** A Study of Etrasimod in Adults With Crohn's Disease  
[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 A]

**Date of this Report:** 06 March 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?

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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.

CD can also damage the gut. Signs of damage caused by CD include narrowing of the gut or sores in its lining. Doctors use a procedure called an endoscopy to monitor CD. During an endoscopy for CD, doctors use a thin tube with a small camera to view the inside of the gut.

### What is etrasimod?

Etrasimod (et –ras' – i – mod), also called Velsipity™, is a medicine in tablet form that is swallowed. It is approved for treatment of 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 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 cells, which 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 certain lymphocytes may reduce inflammation and help with CD symptoms.

## What was the purpose of this study?

The main purpose of this study was to learn if 2 milligrams (or mg) or 3 mg etrasimod could help ease gut inflammation in participants with moderately to severely active CD.

In this study, study doctors used endoscopy to check for reduction of inflammation in the small and large bowels. Successful inflammation reduction was measured by the number of participants who had an endoscopic response.

### Endoscopic response is considered one of the following:

- little to no signs of inflammation, like sores or narrowing, in the small and large bowels.
- at least 50% decrease in signs of inflammation in the small and large bowels.

The other purpose of this study was to learn if etrasimod is safe when given to participants with moderately to severely active CD.

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### Researchers wanted to know:

- **How many participants had an endoscopic response after taking etrasimod 2 mg or 3 mg for 14 weeks?**
  - **What medical problems did participants have during the study?**
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## What happened during the study?

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### How was the study done?

Researchers tested 2 doses of etrasimod on different groups of study participants. They did this to find out if either dose could help participants have an endoscopic response.

Participants were assigned at random to take etrasimod 2 mg or 3 mg. They took their assigned dose 1 time a day for 14 weeks. Neither the participants nor the study doctors knew which dose of etrasimod the participants were taking.

In the middle of the study, the study plan had changed to add a placebo treatment group. A placebo does not have any medicine in it, but it looks just like etrasimod. Then, the study plan changed again to remove this group. Only 1 participant was randomly assigned to take a placebo for 14 weeks.

After 14 weeks of treatment, participants had the chance to continue taking etrasimod for an additional 52 weeks. The participant who took a placebo was assigned to take etrasimod 3 mg in the next 52 weeks.

As shown in Figure 1 on the next page:

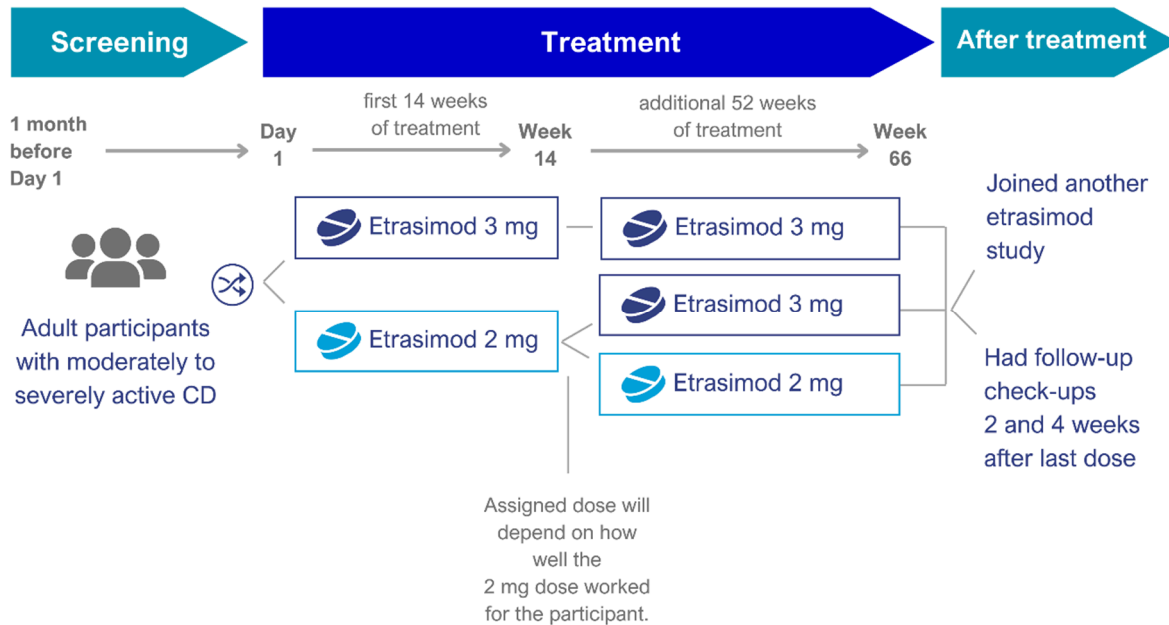
- Those who took etrasimod 3 mg for 14 weeks continued taking etrasimod 3 mg.
- Those who took etrasimod 2 mg took either etrasimod 2 mg or 3 mg in the next 52 weeks.

After a total of 66 weeks of treatment, participants had the chance to join another study on etrasimod. Those who decided not to join had follow-up check-ups 2 and 4 weeks after their last dose of etrasimod.

Study doctors monitored the participants' CD symptoms, overall health, and safety throughout the study.

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 114 locations in 18 countries worldwide.

### When did this study take place?

It began on 06 January 2020 and ended on 23 March 2023.

### Who participated in this study?

The study included adult participants who had moderately to severely active CD. These participants had also tried other CD treatments. But, they could not tolerate the treatment, or the treatments either did not work for them or worked at first but stopped working after some time.

- A total of 43 men and 41 women participated.
- All participants were from 19 to 76 years old.

### **During the 14 weeks of treatment:**

Of the 84 participants who started the study, 68 participants completed 14 weeks of treatment with etrasimod. One (1) participant completed 14 weeks of treatment with a placebo.

A total of 15 participants did not finish treatment. Most of these participants stopped taking part in the study either by their choice or due to a medical problem they had during the study.

### **During the additional 52 weeks of treatment:**

Of the 69 participants who completed 14 weeks of treatment, 65 participants decided to take etrasimod for the additional 52 weeks.

Thirty-eight (38) participants finished the study, and 27 participants did not. Most of the participants who did not finish the study stopped taking part either by their choice or due to a medical problem they had in the study.

### **How long did the study last?**

Study participants were in the study for up to 74 weeks (about 1 year and 5 months). The entire study took around 3 years and 2 months to complete.

When the study ended in March 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?

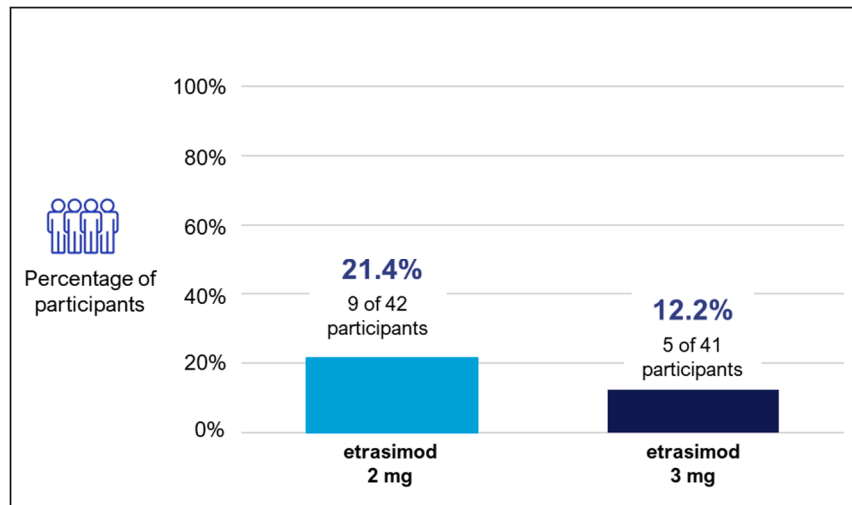
### How many participants had an endoscopic response after taking etrasimod 2 mg or 3 mg for 14 weeks?

To answer the question, study doctors performed an endoscopy on participants before they started taking etrasimod. They performed another endoscopy after 14 weeks of treatment to see any changes in the severity of inflammation in the small and large bowels.

Then, study doctors checked how many participants had an endoscopic response in each treatment group. Results of the participant who took a placebo in the first 14 weeks were not included in this section.

Figure 2 below shows that **21.4%** of participants taking etrasimod 2 mg and **12.2%** of participants taking etrasimod 3 mg had an endoscopic response after 14 weeks of treatment.

**Figure 2. How many participants had an endoscopic response after taking etrasimod 2 mg or 3 mg for 14 weeks?**



Based on these results, the researchers believed that etrasimod 2 mg or 3 mg may help ease gut inflammation in adults with moderately to severely active CD.

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?

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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 medication might have on a participant.

This section shows the results of all 84 participants who took at least 1 dose of etrasimod in the study. For the participant who took a placebo in the first 14 weeks, any medical problems that this participant had during treatment with etrasimod 3 mg for the additional 52 weeks were reported.

Out of 84 participants, 73 participants (86.9%) had at least 1 medical problem during their participation in the whole study (for up to 1 year and 5 months). A total of 15 participants (17.9%) stopped treatment and 13 participants (15.5%) left the study because of medical problems.

The most common medical problems reported by the participants are described in Table 1 on the next page. These medical problems are those reported by at least 10% of participants in any treatment group.

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 in the study. All medical problems reported by at least 10% of participants in any treatment group are listed.
- The **2nd** and **3rd** columns tell how many participants taking etrasimod 2 mg or 3 mg reported each medical problem. Next to each number is the percentage of these participants who reported the medical problem.
- Using these instructions, you can see that 9 out of 42 participants (21.4%) taking etrasimod 2 mg reported worsening of CD. A total of 10 out of 44 participants (22.7%) taking etrasimod 3 mg reported the same medical problem.

Two (2) participants who took etrasimod 2 mg in the first 14 weeks shifted to 3 mg for the additional 52 weeks. These 2 participants were counted in both 2 mg and 3 mg groups in the table below.

**Table 1. Commonly reported medical problems by study participants during the entire study**

<b>Medical Problem</b>	<b>Etrasimod 2 mg (42 Participants)</b>	<b>Etrasimod 3 mg (44 Participants)</b>
<b>Worsening of CD</b>	9 out of 42 participants (21.4%)	10 out of 44 participants (22.7%)
<b>Abdominal pain</b>	3 out of 42 participants (7.1%)	6 out of 44 participants (13.6%)
<b>Nausea</b>	5 out of 42 participants (11.9%)	4 out of 44 participants (9.1%)
<b>COVID-19</b>	5 out of 42 participants (11.9%)	12 out of 44 participants (27.3%)
<b>Headache</b>	7 out of 42 participants (16.7%)	12 out of 44 participants (27.3%)
<b>Joint pain</b>	7 out of 42 participants (16.7%)	13 out of 44 participants (29.5%)
<b>Feeling tired</b>	5 out of 42 participants (11.9%)	5 out of 44 participants (11.4%)
<b>Fever</b>	4 out of 42 participants (9.5%)	6 out of 44 participants (13.6%)

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## 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.

A total of 13 out of 84 participants (15.5%) in the study had at least 1 serious medical problem during their participation in the whole study. The most common serious medical problems reported during the study are listed below:

- 4 participants reported experiencing worsening of CD.
- 2 participants reported having COVID-19.
- 2 participants reported having blockage in the small intestine.

No other serious medical problem was reported by more than 1 participant.

Study doctors do not believe any of the serious medical problems were related to etrasimod.

No participants died during the study.

## 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 SSA-P2**

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!