# **Clinical Study Results**



Research Sponsor: AstraZeneca AB

**Drug Studied:** Savolitinib

**Study Title:** A study to learn how midazolam acts in the bodies of healthy men

when taken with savolitinib

## Thank you!

Thank you to the participants who took part in the clinical study for the study drug savolitinib. AstraZeneca AB sponsored this study and thinks it is important to share the results. An independent non-profit organization called CISCRP helped prepare this summary of the study results.

If you participated in the study and have questions about the results, please speak with the study doctor or staff at your study site.

## Who took part in the study?

The researchers asked for the help of healthy men. The participants in this study were 18 to 58 years old when they joined.

The study included 14 participants in the United States.

# Why was the research needed?

Researchers are looking for a better way to treat tumors. Before a drug can be approved for people to take, researchers do clinical studies to find out how safe it is and how it works.

Cancer is a disease that happens when the body cannot control the growth of cells. The extra cells can form tumors, which can start in any part of the body.

The study drug, savolitinib, is being developed as a treatment for tumors. Researchers think that savolitinib may also slow down the removal of certain substances from the body, such as the drug midazolam. Midazolam is a drug prescribed by doctors to relax people before minor surgery.

In this study, the researchers wanted to learn how midazolam acts in the body when taken with savolitinib. They wanted to learn if savolitinib slows down the removal of midazolam from the body. Also, the researchers wanted to find out if the participants had any medical problems during the study.

# What was the purpose of this study?

The main questions the researchers wanted to answer in this study were:

- How did midazolam act in the body when taken with savolitinib?
- What medical problems happened during the study?

The answers to these questions are important to know. Other studies are being done to find out if savolitinib helps improve the health of people who have tumors.

## What treatments did the participants take?

The participants in this study took midazolam and savolitinib.

The participants took midazolam as a liquid by mouth, and savolitinib as a pill by mouth.

This was an "open-label" study. This means the participants, researchers, study doctors, and other study staff knew what each participant was taking.

Study treatment happened in 2 parts. The same participants were in both parts. The chart below shows the treatments the participants took.

	First part of treatment (14 participants)	Second part of treatment (14 participants)
What study treatment did the participants take?	All of the participants took midazolam as a liquid by mouth	<ul> <li>All of the participants took:</li> <li>midazolam as a liquid by mouth</li> <li>savolitinib as a pill by mouth</li> </ul>
How often did the participants take study treatment?	• 1 time	<ul><li>Midazolam 1 time</li><li>Savolitinib 1 time</li></ul>

# What happened during the study?

The study started in December 2019 and ended in March 2020.

**Before the participants took treatment,** they visited their study site 1 time over the course of about 1 month. During this visit, the study doctors checked to make sure the participants could join the study. The study doctors:

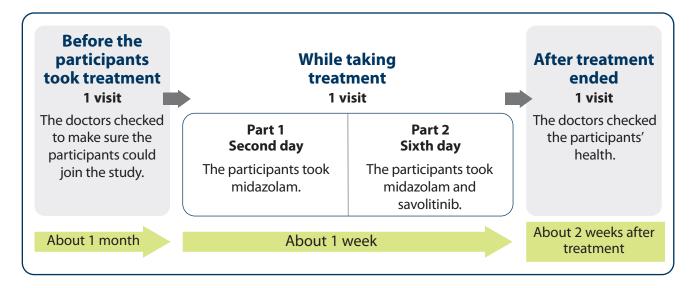
- did a physical examination
- took blood and urine samples
- checked the participants' heart health using an electrocardiogram, also called an ECG
- asked the participants about their medical history, how they were feeling, and what medicines they were taking

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While the participants took treatment, they visited their study site 1 time and stayed overnight. They stayed for 1 week and took treatment in 2 parts. During this time, they took midazolam on the second day. Then, they took midazolam and savolitinib on the sixth day.

**About 2 weeks after their last treatment,** the participants visited their study site 1 more time. At this visit, the study doctors again checked the participants' health and asked them how they were feeling.

The chart below shows what happened during the study.



## What were the results of the study?

This is a summary of the main results from this study overall. The results each participant had might be different and are not in this summary.

Researchers look at the results of many studies to decide which treatments work best and are safest. Other studies may provide new information or different results. Always talk to a doctor before making any treatment changes.

The websites listed at the end of this summary may have more information about the study results.

### How did midazolam act in the body when taken with savolitinib?

To answer this question, the study doctors took blood samples from the participants after both parts of treatment.

In these samples, they measured:

- the average total amount of the study drugs in the blood
- the average highest amount of the study drugs in the blood

The researchers compared the results from when the participants took midazolam only to when they took midazolam and savolitinib. This information may help future researchers determine what other drugs can be given with savolitinib.

The researchers found that the average total and highest amounts of midazolam in the blood were similar when taken with and without savolitinib.

# What medical problems happened during the study?

This section is a summary of the medical problems the participants had during the study that the study doctors thought might be related to the study drugs. These medical problems are called "adverse reactions". An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems, or requires hospital care.

These adverse reactions may or may not be caused by the study drugs. A lot of research is needed to know whether a drug causes an adverse reaction. These adverse reactions have been, and will continue to be, reviewed together with all of the available data for the study drugs.

The websites listed at the end of this summary may have other information about adverse reactions or other medical problems that happened during this study.

#### Did any adverse reactions happen during this study?

There were 21.4% of participants who had adverse reactions during this study that the study doctors thought might be related to midazolam. This was 3 out of 14 participants.

None of the participants had adverse reactions during this study that the study doctors thought might be related to savolitinib.

None of the participants left the study due to adverse reactions.

### What serious adverse reactions happened during this study?

None of the participants had serious adverse reactions during this study.

None of the participants died due to serious adverse reactions during this study.

### What adverse reactions happened during this study?

There were 3 different adverse reactions that happened during this study. The study doctors thought that each adverse reaction might be related to midazolam. Some participants may have had more than 1 adverse reaction. These adverse reactions are listed below:

- Feeling sleepy happened in 14.3% of the participants. This was 2 out of 14 participants.
- Headache happened in 7.1% of the participants. This was 1 out of 14 participants.
- Pain in the stomach area happened in 7.1% of the participants. This was 1 out of 14 participants.

### How has this study helped patients and researchers?

This study helped researchers learn how midazolam acted in the body in healthy male participants when taken with savolitinib.

Researchers look at the results of many studies to decide which treatments work best and are safest. This summary shows only the main results from this one study. Other studies may provide new information or different results.

Further clinical studies with savolitinib are planned.

# Where can I learn more about this study?

You can find more information about this study on the websites listed below. If more information about the study results is available, it can also be found here.

- www.clinicaltrials.gov. Once you are on the website, type "NCT04187456" into the search box, and click "Search".
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type
   "D5084C00004" into the search box, and click "Find a Study".

**Full Trial Title:** An Open-label, 2-period, Fixed-sequence Study to Assess the Effect of Savolitinib on the Pharmacokinetics of Oral Midazolam (a CYP450 3A Probe) in Healthy Subjects

AstraZeneca Protocol Number: D5084C00004

**AstraZeneca AB** sponsored this study and has its headquarters at 151 85 Södertälje, Sweden.

The phone number for the AstraZeneca Information Center is +1-877-240-9479.

### Thank you!

Clinical study participants belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for patients.



The Center for Information & Study on Clinical Research Participation (CISCRP) is a non-profit organization focused on educating and informing the public about clinical research participation. CISCRP is not involved in recruiting participants for clinical studies, nor is it involved in conducting clinical studies.

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