Clinical Study Results

Research Sponsor: Eisai Inc.
Drug Studied: Lenvatinib
Short Study Title: A long-term safety study in participants with cancer receiving lenvatinib in an Eisai-sponsored study

Thank you!

You took part in this clinical study for the study drug called lenvatinib. All of the participants helped researchers learn more about lenvatinib and how it may help people with cancer. Cancer refers to conditions characterized by the development of abnormal cells that divide uncontrollably and can spread throughout the body.

Eisai, a Japanese pharmaceutical company and the sponsor of this study, thanks you for your help. Eisai is committed to improving health through continuing research in areas of unmet need and sharing the results of the study with you.

Eisai prepared this summary with a medical and regulatory writing organization called Certara Synchrogenix.

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

What has happened since the study started?

The study started in August 2018 and ended in February 2024.

The study included 40 participants from 28 study sites in the following countries:

Australia	Belgium	China	Germany
Italy	Netherlands	Poland	Romania
South Korea	Thailand	United States	

The sponsor of the study reviewed the data collected and created a report of the primary results. This is a summary of that report.

Why was the research needed?

In this study, researchers were looking for a different way to treat people who have cancer. The standard treatments for people with cancer include surgery, chemotherapy, and other treatments that may help shrink tumors. However, these treatments may not help all people with cancer, especially in the later stages of their cancer.

Researchers thought that lenvatinib might help participants with cancer by targeting and blocking specific proteins that help cancer cells survive and grow.

The researchers in this study wanted to find out whether lenvatinib was safe to be given for a long time to participants with cancer. They do this by looking at medical problems that participants may have had during the study.

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

- What medical problems did participants have while taking lenvatinib for a long time?

It is important to know that this study was designed to get accurate answers to the questions listed above.

What kind of study was this?

To answer the main questions, researchers asked for the help of participants enrolled in an Eisai-sponsored lenvatinib study.

Of these participants, 47.5% were men, and 52.5% were women. The youngest was 31 years old, and the oldest was 78 years old.

The participants were to be divided into groups depending on their treatment during the previous lenvatinib study.

In this study, all participants continued to take lenvatinib by itself.

This study was "open-label." This means that the participants, the study doctors and staff, and the sponsor know which group participants were in.

The figure below shows how the treatment was given in your study.

40
participants
continued to take study treatment

The study treatment participants took was based on their treatment during the previous lenvatinib study.

Participants continued to take study treatment until they had an intolerable medical problem.

What happened during the study?

Before the study started, the study doctors did a full check-up to make sure each participant could join the study.

The study doctors or staff also:

- Confirmed that participants have cancer and were from a previous lenvatinib study
- Took blood and urine samples for analysis

During the treatment period, the participants continued to take their assigned study treatment.

Throughout the study, the study doctors or staff:

- Took blood and urine samples for analysis
- Asked about medical problems participants had experienced and medicines participants were taking

Each participant could continue taking their study treatment until:

- Their cancer got worse
- They had intolerable medical problems
- They chose to leave the study
- The sponsor chose to end the study

After the treatment period, the study doctors or staff followed all participants for 30 days to know about the medical problems they had experienced and the medicines they were taking.

The figure below shows how the study was done.

How did this study work?

Before the study started

The study doctors or staff:

- Checked each participant's health to make sure they could join the study
- Confirmed participants were from a previous lenvatinib study
- Took blood and urine samples for analysis

During the treatment period

All 40 participants continued to take their assigned study treatment.

The study doctors or staff:

- Took blood and urine samples for analysis
- Asked about medical problems participants had and medicines participants were taking

After the treatment period

The study doctors or staff followed all participants for **30 days** to know about medical problems they had experienced and medicines they were taking.

What were the results of the study?

This is a summary of the main results of this study. The results each person had individually may be different. But the results each person had are part of the summary of results. A full list of the questions researchers wanted to answer can be found on the websites listed at the end of this summary. If a full report of the study results is available, it can also be found on these websites.

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

What medical problems did participants have while taking lenvatinib for a long time?

To answer this question, researchers looked at the adverse events that happened to participants during the study.

Overall, no new safety concerns were found during the study.

More information on the safety of lenvatinib is shown below.

What medical problems did participants have?

Medical problems that happen in clinical studies are called “adverse events.” An adverse event may or may not be caused by the study drug. An adverse event is called “serious” when it is life-threatening or fatal, causes lasting problems, or the participant needs to be admitted to a hospital.

This section is a summary of the adverse events that happened during this study. The websites listed at the end of this summary may have more information about the medical problems that happened in this study. A lot of research is needed to know whether a drug causes a medical problem.

Results in this section were from participants who received at least 1 dose of any study treatment and had adverse events during the study treatment period.

How many participants had adverse events?

The table below shows how many participants had adverse events in this study.

Adverse Events During the Study Treatment Period

	Out of 40 participants who took study treatment
How many participants had adverse events?	38 (95%)
How many participants had serious adverse events?	21 (53%)
How many participants died because of adverse events	5 (13%)
How many participants stopped taking lenvatinib because of adverse events?	5 (13%)

What were the most common adverse events?

The most common adverse events in this study were the following:

- Diarrhea
- Excess protein in the urine

The table below shows the adverse events in 10% of participants or more in the study. There were other adverse events, but these happened in fewer participants.

Most Common Adverse Events During the Study Treatment Period

	Out of 40 participants who took study treatment
Diarrhea	7 (18%)
Excess protein in the urine	7 (18%)
Increased level of ALT[a]	5 (13%)
Increased level of AST[a]	5 (13%)
COVID-19	5 (13%)
Decreased weight	5 (13%)
Excess protein called albumin in the urine	4 (10%)
Cough	4 (10%)
Blood in the urine	4 (10%)

Abbreviations: ALT = alanine aminotransferase; AST = aspartate aminotransferase

[a] ALT and AST are enzymes in the liver that doctors use to check the health of the liver. An increase in levels of ALT or AST could mean there is a problem with liver function.

What were the most common serious adverse events?

The most common serious adverse events in this study were the following:

- Infection of the lungs
- Coronavirus disease 2019 (also called COVID-19)
- Infection of the parts of the body that collect and pass out urine

Other serious adverse events happened in 1 participant each.

How many participants had adverse events the study doctors thought were caused by study treatment?

In this study, 29 out of 40 participants (73%) had adverse events the study doctors thought were caused by study treatment.

The most common adverse events (10% of participants or more) the study doctors thought were caused by study treatment were:

- Excess protein in the urine
- Diarrhea
- Excess protein called albumin in the urine

Other adverse events the study doctors thought were caused by study treatment happened in fewer participants.

In this study, 6 out of 40 participants (15%) had serious adverse events the study doctors thought were caused by study treatment.

Study doctors thought none of the adverse events that resulted in death were caused by study treatment.

How has this study helped participants and researchers?

In this study, researchers learned more about how lenvatinib may have helped people with cancer.

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

Further clinical studies with lenvatinib are planned.

Where can I learn more about the study?

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

- http://www.clinicaltrialsregister.eu - Once you are on the website, click "**Home and Search**", then type **2017-003668-11** in the search box and click "**Search**".
- https://www.clinicaltrials.gov - Once you are on the website, type **NCT03477175** into the search box and click "**Search**."

Full study title: An open-label, multi-center, roll-over study to assess long term safety of lenvatinib monotherapy or lenvatinib combination regimen or comparator treatment arm to cancer patients in Eisai sponsored lenvatinib trials

Protocol number: E7080-G000-604

Eisai, the sponsor of this study, has headquarters in Tokyo, Japan, and regional headquarters in Nutley, New Jersey, USA and Hatfield, Hertfordshire, UK. The phone number for general information is 44-845-676-1400 (UK) and 1-888-274-2378 (USA).

Thank you

Eisai would like to thank you for your time and interest in participating in this clinical study. Your participation has provided a valuable contribution to research and improvement in health care.

Eisai Co., Ltd. is a global research and development-based pharmaceutical company headquartered in Japan. We define our corporate mission as "giving first thought to patients and the people in the daily living domain and to increasing the benefits health care provides," which we call our human health care (hhc) philosophy. With over 10,000 employees working across our global network of R&D facilities, manufacturing sites, and marketing subsidiaries, we strive to realize our hhc philosophy by delivering innovative products in multiple therapeutic areas with high unmet medical needs, including Oncology and Neurology. For more information, please visit https://www.eisai.com.

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Certara Synchrogenix Headquarters 100 Overlook Center, Suite 101, Princeton, NJ 08540
https://www.certara.com • 1-415-237-8272