Clinical Study Results

Research Sponsor: Eisai Inc.
Drug Studied: Lecanemab, also called BAN2401
Short Study Title: A study to learn about the long-term safety and risks of lecanemab in people with early Alzheimer's disease

Thank you

You took part in this clinical study for the study drug BAN2401, also called lecanemab. Everyone who participated helped researchers learn more about the long-term safety and risks of lecanemab and how it may help people with early Alzheimer's disease (AD). AD is a brain disorder that causes problems with memory, thinking, and behavior.

Eisai, a Japanese pharmaceutical company that was 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 study results with participants.

Eisai has prepared this summary of the study and its results with a medical and regulatory writing organization called Certara.

If you participated in this 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?

It started in December 2018 and ended in December 2024.

The study included 180 participants from 56 sites in the following countries:

Canada	Italy	Japan	South Korea
Spain	Sweden	United States	

All 180 participants received 1 or more doses of lecanemab in this study.

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

Why was the research needed?

Researchers were looking for a different way to treat people who have early AD. Current treatments for early AD include medicines that can help reduce some of its symptoms. But these medicines do not prevent the disease from getting worse.

In the earlier study of lecanemab, researchers found that lecanemab 10 mg/kg every 2 weeks was the most effective dose in slowing down the worsening of AD.

In this study, the researchers wanted to find out the long-term safety and risks of lecanemab in people with early AD. They also wanted to find out if people had any medical problems during the study.

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

- Can participants tolerate lecanemab for a long time?
- What adverse events did participants receiving lecanemab have? An adverse event is a medical problem that may or may not be caused by the study drug.

It is important to know that this study was designed to get accurate answers to the questions listed above. There were other questions the researchers wanted to answer to learn more about how lecanemab works, but these were not the main questions the study was designed to answer.

What kind of study was this?

To answer the main questions above, researchers asked for the help of participants like you who took part in the earlier lecanemab study – regardless of whether they completed it or stopped early. Of these participants, 52% were male and 48% were female. The youngest was 52 years old, and the oldest was 87 years old.

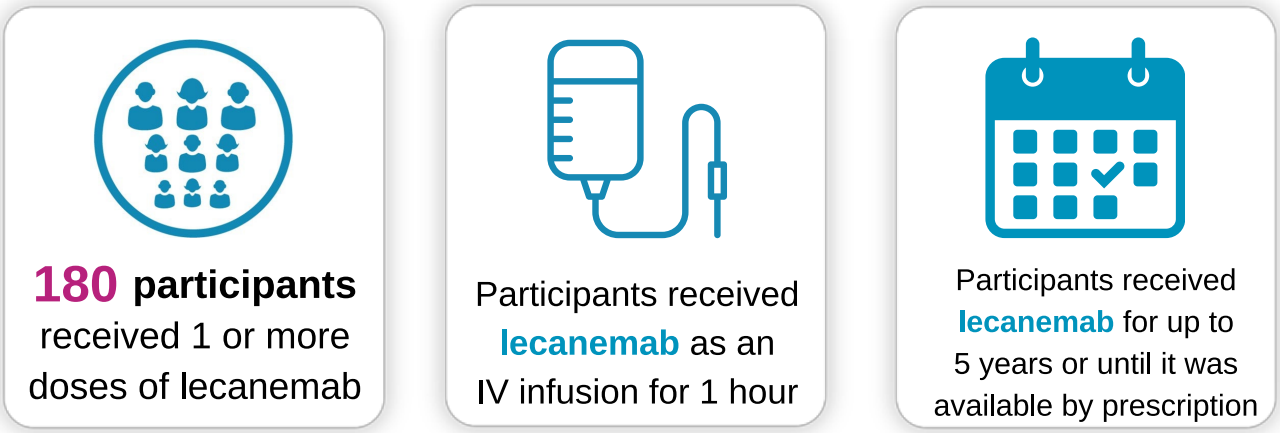
This study was "open-label." This means that the participants, the study doctors and staff, and the sponsor knew that the participants received lecanemab.

Lecanemab was measured in milligrams per kilogram of body weight (mg/kg).

Most participants received lecanemab 10 mg/kg once every 2 weeks as an infusion into the vein (or IV infusion).

Participants received lecanemab in this study for up to 5 years (60 months) or until lecanemab was available by prescription.

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



What happened during the study?

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

The doctors or staff also:

- Confirmed that participants took part in the earlier lecanemab study
- Analyzed blood and urine samples
- Obtained scans of participants' brains
- Completed different surveys to assess participants' early AD

During the treatment period, participants received lecanemab for up to 5 years.

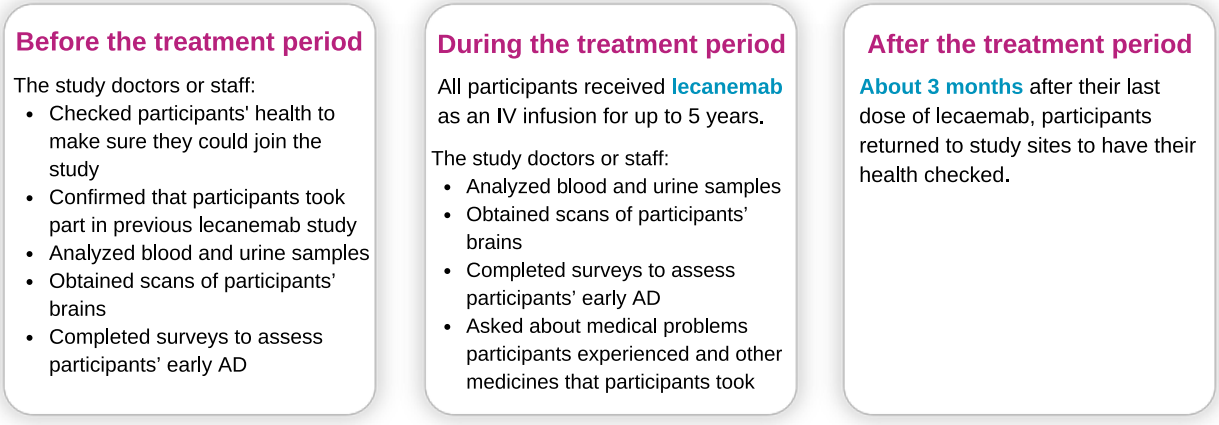
Throughout the study, the doctors:

- Analyzed blood and urine samples
- Obtained scans of participants' brains
- Completed different surveys to assess participants' early AD
- Asked about medical problems that participants experienced and other medicines that participants took

About 3 months after their last dose of lecanemab, participants returned to their study site to have their health checked.

The figure below shows how the study was done.

How did this study work?



What were the results of the study?

This is a summary of the main results of this study up. Each participant's individual results were different and unique to them. Individual results are not given separately in this summary, but all participants' results are summarized together here. A full list of the questions researchers wanted to answer can be found on the websites listed at the end of this summary. A full report of the study results is available and 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 by patients. Other studies may provide new information or different results. Always talk to a doctor before making any treatment decisions.

Can participants tolerate lecanemab for a long time?

To answer this question, researchers looked at all medical problems participants experienced and all abnormal laboratory test results during the study.

Overall, participants tolerated lecanemab well after 5 years of treatment. The results were similar to the safety and risks results from the previous lecanemab study.

What medical problems did participants have?

Medical problems that happen to participants in clinical studies are called "adverse events". If the study doctors thought an adverse event was caused by the study drug, it is called an "adverse reaction". Adverse events or reactions are considered "serious" if the participant needs to be admitted to a hospital, if they are life-threatening, or if they cause lasting health problems.

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

How many participants had adverse events?

Out of 180 participants in this study,

- 173 participants (96%) had adverse events
- 60 participants (33%) had serious adverse events
- 9 participants (5%) had stopped receiving lecanemab because of an adverse event

What were the most common serious adverse events?

The most common serious adverse events – reported by 4 participants or more – were the following:

- Fall – 7 participants (4%)
- Lung infection – 4 participants (2%)
- Mini-stroke – 4 participants (2%)

A total of 5 out of 180 participants (3%) died because of serious adverse events. Study doctors thought that none of the adverse events that led to the death of participants were caused by lecanemab.

What were the most common adverse events?

The top 3 most common adverse events were the following:

- Fall
- Reaction (such as redness) that happened during or soon after IV infusion
- Infection of the parts of the body that collect and pass out urine

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

Most Common Adverse Events in This Study

	Out of 180 participants who received lecanemab
Fall	51 (28%)
Reaction (such as redness) that happened during or soon after IV infusion	40 (22%)
Infection of the parts of the body that collect and pass out urine	36 (20%)
Infection caused by coronavirus-2019	35 (19%)
Small brain bleed seen on scan	30 (17%)
Swelling of the nose and throat	22 (12%)
Feeling worried and nervous	20 (11%)
Joint pain	19 (11%)

How many participants had adverse reactions?

Out of 180 participants in this study,

- 89 participants (49%) had adverse reactions
- 4 participants (2%) had serious adverse reactions
- 1 participant (less than 1%) had stopped receiving lecanemab because of an adverse reaction

What were the most common serious adverse reactions?

The most common serious adverse reaction was brain swelling seen on scan – reported by 2 participants.

Each of the other serious adverse reactions was reported by 1 participant.

What were the most common adverse reactions?

The top 3 most common adverse reactions were:

- Reaction (such as redness) that happened during or soon after IV infusion – 38 participants
- Small brain bleed or iron deposits in the brain seen on scan – 28 participants
- Brain swelling seen on scan – 17 participants

How has this study helped patients and researchers?

In this study, researchers learned more about the long-term safety and risks of lecanemab in people with early AD.

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.

Lecanemab is an approved medicine for the treatment of early AD in many countries worldwide. Further clinical studies with lecanemab for early AD are ongoing.

Where can I learn more about the study?

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

- http://www.clinicalstudiesregister.eu - Once you are on the website, click "**Home and Search**", then type **2012-002843-11** in the search box and click "**Search**".
- http://www.clinicalstudies.gov - Once you are on the website, type **NCT01767311** into the search box and click "**Search**".

Full study title: A Placebo-Controlled, Double-Blind, Parallel-Group, Bayesian Adaptive Randomization Design and Dose Regimen-finding Study With an Open-Label Extension Phase to Evaluate Safety, Tolerability and Efficacy of BAN2401 in Subjects With Early Alzheimer's Disease

Protocol number: BAN2401-G000-201

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 numbers for general information are +1-888-274-2378 (USA) and +44-845-676-1400 (UK).

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

Eisai Co., Ltd. is a global research and development-based pharmaceutical company headquartered in Japan. We define our corporate mission as "to give first thought to patients and the people in the daily living domain, and increase the benefits that health care provides to them as well as meet diverse healthcare needs worldwide", 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 http://www.eisai.com.

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Certara Headquarters 4 Radnor Corporate Center Suite 350 Radnor, PA 19087
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