Clinical Study Protocol Synopsis

A study to confirm the safety and efficacy of lecanemab in participants with early Alzheimer's disease

Full Study Title:	A Placebo-Controlled, Double-Blind, Parallel-Group, 18-Month Study With an Open-Label Extension Phase to Confirm Safety and Efficacy of BAN2401 in Subjects With Early Alzheimer's Disease		
EU Clinical Study Number:	2018-004739-58	**US Clinical Study Number:**	NCT03887455
Study Sponsor:	Eisai, Inc., Nutley, NJ, USA	Telephone number:	+1 201-692-1100

Why is this research needed?

Researchers are looking for a different way to treat people who have early Alzheimer's disease. **Alzheimer's disease** (or **AD**) is a brain disorder that causes problems with memory, thinking, and behavior. Current treatments for AD include medicines that can help reduce some of its symptoms. These medicines do not prevent the disease from getting worse.

BAN2401 (also known as **lecanemab**) may be able to help people with early AD by removing brain amyloid. Amyloid is one of the toxic proteins in the brain thought to cause AD.

In this study, researchers want to learn about the safety and efficacy of lecanemab in participants with early AD.

What treatment is being studied?

All participants will receive lecanemab or placebo for 18 months as an injection through the vein. This type of injection is called an intravenous infusion (or IV infusion).

A placebo looks like lecanemab but does not have any medicine in it.

Doses of lecanemab will be measured in milligrams per kilogram of body weight.

No one involved in the study will know which treatment participants will receive. This is called a double-blind study.

What are the goals of this study?

The primary objective is to investigate how well lecanemab may work in slowing the worsening of AD compared to placebo after 18 months of treatment.

The secondary objectives are to investigate using more tests how well lecanemab may work in treating early AD compared to placebo after 18 months of treatment and to investigate the safety of lecanemab.

What are the measurements in this study?

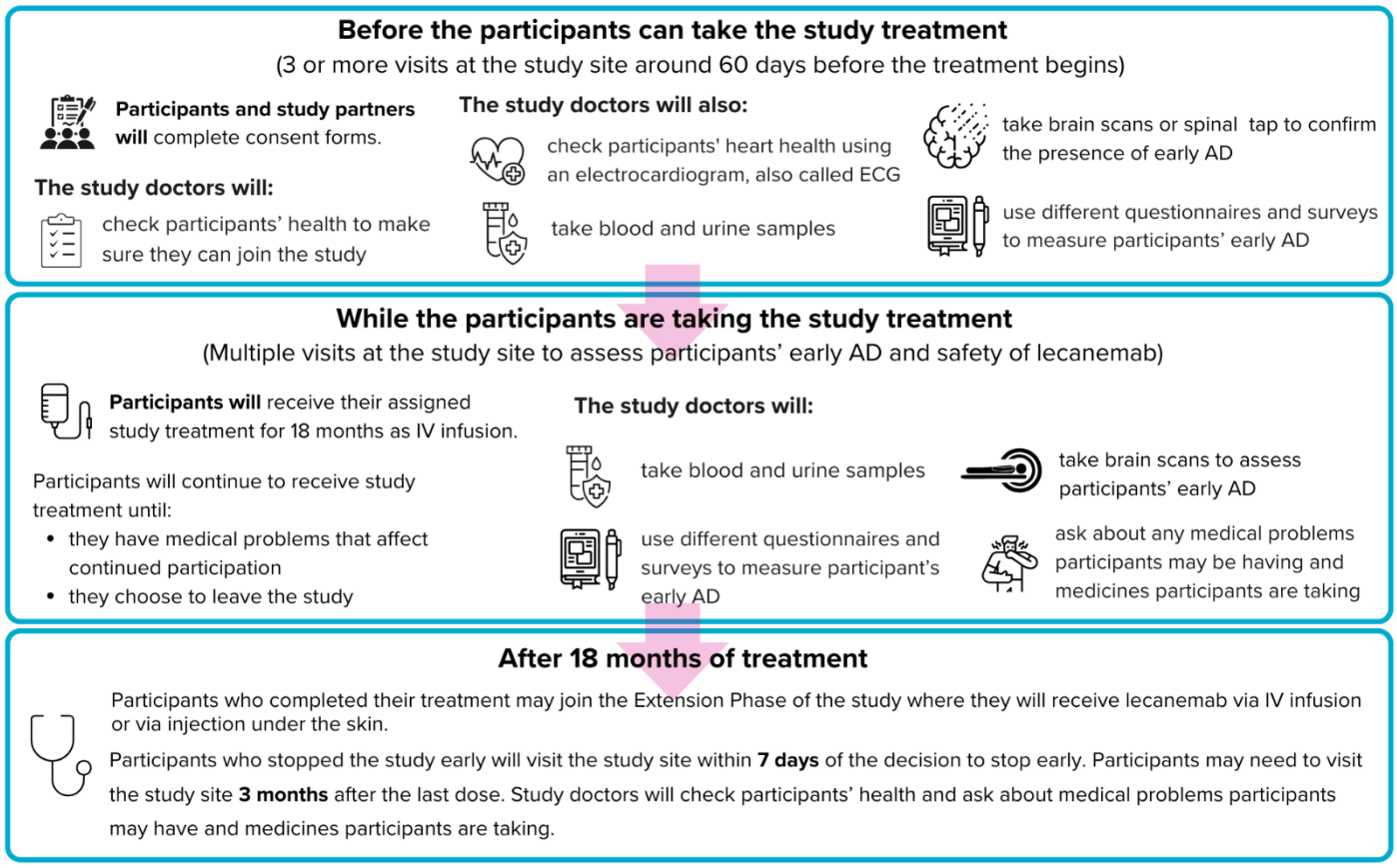
1. **Main measurement:** To investigate the primary objective, researchers will use a questionnaire that measures memory, thinking, and behavior.
2. **Secondary measurements:** To investigate the secondary objectives, researchers will use other questionnaires and surveys that measure memory, thinking, and behavior. They will also collect information on any medical problems that participants may have during the study and measure the levels of brain amyloid.

The researchers will also collect other information about lecanemab. The measurements described above are the most important for this study.

What will happen during the study?

Before participants take part in the study, the doctors will explain the study to the participants and their study partners and answer any questions they may have.

The chart below shows what will happen in the study.



Who can and cannot take part in this study?

People can take part in this study if they:

- Are 50 to 90 years old
- Have been diagnosed with early AD
- Have increased levels of brain amyloid

People cannot take part in this study if they:

- Have abnormality on brain scan or blood test that can suggest a diagnosis other than AD
- Have any medical conditions that may affect study assessments/treatments or pose a safety risk

These are just some of the main requirements. Study doctors will check all requirements to see if a person can safely join this study. Participation in this study is voluntary. Participants can leave the study at any time.

What are the potential benefits and risks of taking part in this study?

Potential Benefits (Advantages): Lecanemab may help in treating participants' early AD. The information collected in this study may help doctors learn more about lecanemab and AD, which could help people with early AD.

Potential Risks (Disadvantages): Lecanemab may not help in treating participants' early AD, or participants might have side effects from lecanemab. There may be additional risks, which are unknown and unexpected.