**AHEAD 3-45 Study**

This is a placebo-controlled, double-blind, 216-week study sponsored by Eisai, Inc. to evaluate the efficacy and safety of treatment with BAN2401 in participants with “preclinical Alzheimer's Disease” and elevated amyloid (A45 trial) and participants with “early preclinical Alzheimer's Disease” and intermediate amyloid (A3 trial). Approximately 1,400 subjects total will be enrolled across sites worldwide – 400 in the A3 trial and 1,000 in the A45 trial. All participants will be randomly assigned on a 1:1 ratio to receive either active study drug (BAN2401) or placebo via intravenous infusion.

**Category:** Alzheimer’s Disease Research

**Study Population:** Adults with “preclinical Alzheimer’s disease” defined by elevated levels of brain amyloid or “early preclinical Alzheimer’s disease” defined by intermediate levels of brain amyloid

**Study Length:** 216 weeks of treatment – A3 arm involves infusions every 4 weeks, A45 arm involves infusions every 2 weeks for 2 years, then every 4 weeks for 2 years.

**Requirements:**

* Adults 55-80 years old
* Must be cognitively normal, but have elevated or intermediate levels of brain amyloid as determined through amyloid PET scan completed during the screening process for the trial.
* Those aged 55-64 must have 1 of the following additional risk factors to be eligible to screen:
  + First degree relative diagnosed with dementia before age 75
  + Known to possess at least 1 apoliprotein E4 variant (APOE-4) allele, or
  + Known before screening to have elevated brain amyloid according to prior PET scan or cerebrospinal fluid (CSF) testing.
* A study partner (family member, close friend, caregiver) who has frequent contact with the patient and can accompany him/her to most study visits is required.
* Must sign an informed consent document indicating that he or she understands the purpose of the study, procedures required, and is willing to participate in the study.

**Benefits:**

There is no guarantee that participating in this research study will help you. We hope the knowledge gained will be beneficial to our society and our understanding of Alzheimer’s disease (AD) and will help with the future prevention of AD dementia. We may learn things about you that could be important to your health or to your care. If we do, this information will be provided to you, and you may decide to talk with your personal doctor about it.

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