GROUND-BREAKING ALZHEIMER'S STUDY ADMINISTERS FIRST DOSE

AHEAD Study, the first trial that aims to help prevent Alzheimer's disease, is recruiting participants as young as 55 at risk for dementia and using a new personalized medicine approach

Study launched during World Alzheimer's Month

San Diego, CA—The first infusion of an investigational drug that aims to delay or help to prevent the earliest memory loss due to Alzheimer's disease took place in September at Butler Hospital in Providence, R.I., researchers announced.

Funded by the National Institutes of Health (NIH) and Eisai Inc., a US subsidiary of Eisai Co., Ltd. (Headquarters: Tokyo), the AHEAD Study is the first Alzheimer's disease trial to recruit people as young as 55 years old who are at risk of developing symptoms of Alzheimer's disease as they get older. It introduces a personalized medicine approach that will tailor treatment dose levels to a participant's particular risk of memory loss related to Alzheimer's disease.

"We know that changes in the brains of people with Alzheimer's disease begin up to 20 years before a person notices symptoms, but until now most clinical trials have included older patients who already have symptoms," said Reisa Sperling, MD, director of the Center for Alzheimer's Research and Treatment at Brigham and Women's Hospital, Harvard Medical School and co-principal investigator for the AHEAD Study. "By inviting younger participants, we hope to help individuals who are at higher risk—such as people with family history—get ahead of the disease with early intervention. We also want to reach diverse communities to learn more about why people of color may be at higher risk of cognitive decline."

The AHEAD Study consists of two different clinical trials testing the same investigational drug (known as BAN2401). Participants are enrolled in one of the two trials based on the level of amyloid in their brain. Amyloid is a protein that builds up in people who can go on to have memory problems and develop Alzheimer's disease. The trial is led by experts at the University of Southern California's Alzheimer's Therapeutic Research Institute, the Alzheimer's Clinical Trials Consortium, Brigham and Women's Hospital, Massachusetts General Hospital, and Harvard Medical School.

"The personalized approach for people years before memory loss has begun has the potential to be a breakthrough in Alzheimer's prevention," said Stephen Salloway, MD, MS, and director of the Memory and Aging Program at Butler Hospital. "This new tailored approach can potentially serve as a model to improve clinical trials in Alzheimer's research and other diseases."

The sixth leading cause of death in the United States, Alzheimer's is the only disease among the top 10 causes of death that cannot be prevented, cured, or slowed. Currently, 5.6 million Americans 65 and older are living with Alzheimer's and this number is expected to nearly triple by 2050. Communities of color experience higher incidence of the disease than White communities, yet they remain underrepresented in clinical research.

"Both of my parents were diagnosed with Alzheimer's disease. I can't run away from that, but I can help find a potential treatment," said Dave Kalberer, recipient of the first AHEAD infusion at Butler Hospital. "I'm proud to be at the front of the line for this exciting opportunity and am hopeful this trial can change not just my life, but millions more."

The AHEAD Study seeks 1,165 participants from North America. The study has more than 100 study locations worldwide, including North America, Japan, Singapore, Australia, and Europe.

For more information on eligibility requirements or to find a trial site location, visit AHEADstudy.org.

Research reported in this press release was supported by the NIH's National Institute on Aging under award numbers R01AG054029 and R01AG061848. The AHEAD Study (Clinical Trial number NCT04468659) received funding from NIH and from nongovernmental sources. The content is solely the responsibility of the researchers and does not necessarily represent the official views of the National Institutes of Health.

###

CONTACT: Tiffanie Thomas, TThomas@MessagePartnersPR.com, 703-400-0459

About AHEAD / BAN2401

The AHEAD Study is made up of two different clinical trials testing the same investigational drug (known as BAN2401) at different doses. During the study, participants will receive intravenous (IV) infusions of BAN2401 tailored to their risk of developing memory loss, or a placebo, an inactive substance designed to mimic the appearance of the drug.

At different points in the study, participants have a PET scan (or Positron Emission Tomography brain scan) to look at amyloid and tau (another protein) in the brain. The PET scan takes pictures of participants' brains, allowing researchers to see and track changes in amyloid and tau levels.

About BAN2401

BAN2401 is a humanized monoclonal antibody for Alzheimer's disease (AD) that is the result of a strategic research alliance between Eisai and BioArctic AB (Headquarters: Sweden). BAN2401 selectively binds to neutralize and eliminate soluble, toxic Aβ aggregates (protofibril) that are thought to contribute to the neurodegenerative process in AD. As such, BAN2401 may have the potential to have an effect on disease pathology and to slow down the progression of the disease. Eisai obtained the global rights to study, develop, manufacture and market BAN2401 for the treatment of AD pursuant to an agreement concluded with BioArctic in December 2007. Currently, a global clinical Phase III study (Clarity AD) of BAN2401 in early AD is underway. Now also in a Phase III trial (AHEAD 3-45) for preclinical AD. BAN2401 is being jointly developed by Eisai and Biogen Inc. (Headquarters: Cambridge, M.A.).

About the Alzheimer's Clinical Trials Consortium

The Alzheimer's Clinical Trial Consortium (ACTC) is a state-of-the-art infrastructure network established with funding by the NIA to support the conduct of clinical trials across the continuum of Alzheimer's Disease (AD). The ACTC leverages the depth and breadth of AD clinical research teams at USC, Harvard, and the Mayo Clinic, as well as the considerable experience of investigators at 35 expert AD trial sites to provide an optimal infrastructure, utilizing centralized resources and shared expertise, to accelerate the development of effective interventions for Alzheimer's disease and related disorders (ADRD).

About Butler Hospital

Butler Hospital, a member of Care New England, is the only private, nonprofit psychiatric and substance abuse hospital serving adults, seniors and adolescents in Rhode Island and southeastern New England. Founded in 1844, it was the first hospital in Rhode Island and has earned a reputation as the leading provider of innovative psychiatric treatments in the region. The Major Affiliated Teaching Hospital for Psychiatry and Behavioral Health at The Warren Alpert Medical School of Brown University, Butler is recognized worldwide as a pioneer in conducting cutting-edge research.