Press release

DIAN-TU enrolls first subject for the Tau NexGen study with lecanemab as back-ground anti-amyloid treatment

Stockholm, January 19, 2022 - BioArctic AB:s (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that the Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU), led by Washington University School of Medicine in St. Louis, has enrolled the first subject in the phase II/III study (Tau NexGen study). The study will assess the safety, tolerability, biomarker and cognitive efficacy of investigational tau-therapies in pre-symptomatic or symptomatic participants who have an Alzheimer's disease-causing gene mutation, while using BioArctic and Eisai's investigational anti-amyloid beta (Aβ) protofibril antibody lecanemab as the background anti-amyloid agent.

People who have genetic mutations of Dominantly Inherited Alzheimer´s Disease (DIAD) are known to develop Alzheimer's disease (AD) and will likely develop symptoms at around the same age their affected parents did, often in their 50s, 40s or even 30s. The major AD pathologies are amyloid plaque that consists of amyloid beta (Aβ) aggregates; neurofibrillary tangles; and intraneuronal aggregates of tau, all of which are believed to spread throughout the brain. In March 2021, DIAN-TU selected Eisai's tau antibody E2814, as the first investigational medicine among anti-tau drugs for the DIAN-TU tau study.

The Tau NexGen study was originally designed to focus on therapies that target tau. With increasing evidence from clinical studies showing that targeting amyloid can reduce biomarkers of AD, the Tau NexGen clinical trial leaders selected BioArctic and Eisai's investigational anti-Aβ protofibril antibody lecanemab as the background anti-amyloid therapy, and the study design was amended in November 2021.

The purpose of the Tau NexGen study is to assess the safety, tolerability, biomarker and cognitive efficacy of investigational therapies in people who have an Alzheimer's disease-causing gene mutation. In the Tau NexGen study, symptomatic participants will be administered lecanemab for six months before being randomly assigned to also receive the anti-tau drug or a placebo. Since amyloid plaques accumulate before tau tangles in AD, this study design allows the researchers to assess whether amyloid removal clears the way for the anti-tau drug to function most effectively. Pre-symptomatic participants will be randomly assigned to receive the anti-tau drug or a placebo for a year before beginning lecanemab administration. By staggering the drugs in this way, the researchers will be able to evaluate the effects of the drug alone before assessing the effects of the two drugs in combination.

This release discusses investigational uses of an agent in development and is not intended to convey conclusions about efficacy or safety. There is no guarantee that any investigational uses of such product will successfully complete clinical development or gain health authority approval.

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The information was released for public disclosure, through the agency of the contact persons above, on January 19, 2022, at 08:00 a.m. CET.

Note to editors

About lecanemab (BAN2401)
Lecanemab is an investigational humanized monoclonal antibody for Alzheimer's disease (AD) that is the result of a strategic research alliance between Eisai and BioArctic. Lecanemab selectively binds to, neutralize and eliminate soluble toxic Aβ aggregates (protofibrils) that are thought to contribute to the neurodegenerative process in AD. As such, lecanemab 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 lecanemab for the treatment of AD pursuant to an agreement concluded with BioArctic in December 2007. In March 2014, Eisai and Biogen entered into a joint development and commercialization agreement for lecanemab. Currently, lecanemab is being studied in a pivotal Phase 3 clinical study in symptomatic early AD (Clarity AD), following the outcome of the Phase 2b clinical study (Study 201). In July of 2020, the Phase 3 clinical study, AHEAD 3-45, for individuals with preclinical (asymptomatic) AD, meaning they are clinically normal and have intermediate or elevated levels of brain amyloid, was initiated. AHEAD 3-45 is conducted as a public-private partnership between the Alzheimer's Clinical Trial Consortium, funded by the National Institute on Aging, part of the National Institutes of Health and Eisai. In June 2021, FDA granted lecanemab Breakthrough Therapy designation and in September 2021, Eisai initiated a rolling submission for the US FDA Biologics license application of lecanemab for early Alzheimer's disease under the accelerated approval pathway. In December 2021, FDA granted lecanemab Fast track designation and the second part of the rolling application was submitted. Eisai expects the rolling submission to be completed during the first half of 2022.

About the collaboration between BioArctic and Eisai
Since 2005, BioArctic has long-term collaboration with Eisai regarding the development and commercialization of drugs for the treatment of Alzheimer's disease. The most important agreements are the Development and Commercialization Agreement for the lecanemab antibody, which was signed in December 2007, and the Development and Commercialization agreement for the antibody BAN2401 back-up for Alzheimer's disease, which was signed in May 2015. Eisai is responsible for the clinical development, application for market approval and commercialization of the products for Alzheimer's disease. BioArctic has no development costs for lecanemab in Alzheimer's disease and is entitled to payments in connection with regulatory filings, approvals, and sales milestones.

About BioArctic AB
BioArctic AB (publ) is a Swedish research-based biopharma company focusing on disease-modifying treatments and reliable biomarkers and diagnostics for neurodegenerative diseases, such as Alzheimer's disease and Parkinson's disease. BioArctic focuses on innovative treatments in areas with high unmet medical needs. The company was founded in 2003 based on innovative research from Uppsala University, Sweden. Collaborations with universities are of great importance to the company together with its strategically important global partners in the Alzheimer (Eisai) and Parkinson (AbbVie) projects. The project portfolio is a combination of fully funded projects run in partnership with global pharmaceutical companies and innovative in-house projects with significant market and out-licensing potential. BioArctic's Class B share is listed on Nasdaq Stockholm Mid Cap (ticker: BIOA B). For more information about BioArctic, please visit www.bioarctic.com.