Press release

Lecanemab (BAN2401) Phase 2b study in early Alzheimer's disease published in peer-reviewed journal, Alzheimer's Research & Therapy

Stockholm April 20, 2021 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai today announced the publication of an article, *A Randomized, Double-Blind Phase 2b Proof of Concept Clinical Trial in Early Alzheimer's Disease with Lecanemab, an Anti-Aß Protofibril Antibody*, in the peer-reviewed journal Alzheimer's Research & Therapy. The manuscript describes results from Study 201, a Phase 2b proof-of-concept study that explored the impact of treatment with lecanemab on reducing brain amyloid beta (Aβ) and clinical decline in patients with early Alzheimer's disease. The manuscript concluded that the analysis showed consistent reduction of clinical decline across several clinical and biomarker endpoints at the highest doses, which the pivotal Phase 3 study Clarity AD aims to confirm.

The lecanemab Clarity AD Phase 3 study completed enrollment last month with 1,795 symptomatic patients with early Alzheimer's disease. Clarity AD is a placebo-controlled, double-blind, parallel-group, 18-month study with an open-label extension phase designed to confirm safety and efficacy of lecanemab in subjects with early Alzheimer's disease. Eisai expects the 18-month results to be available in September 2022. Additionally, the Phase 3 AHEAD 3-45 study is currently exploring lecanemab in individuals with preclinical Alzheimer's disease, defined as persons that are clinically asymptomatic, but have intermediate or elevated brain Aβ levels.

"It's great to see the promising results from the Phase 2b study published. The aim of the Clarity AD study is to confirm these results, thereby offering a disease modifying treatment to millions of Alzheimer's disease patients around the globe, which have no such treatment available today," said Gunilla Osswald, CEO, BioArctic.

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The information was submitted for publication at 08:00 am CET on April 20, 2021.

About lecanemab (BAN2401)
Lecanemab is an investigational humanized monoclonal antibody for Alzheimer's disease 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.

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 BAN2401 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 BAN2401 in Alzheimer's disease.

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.