Press release

Eisai increases the number of participants in Clarity AD study

Stockholm, February 3, 2021 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that they have increased the participant target number by approximately 200 in the pivotal Phase 3 study, Clarity AD, of drug candidate lecanemab (BAN2401) for the treatment of early Alzheimer's disease. The decision was taken proactively to ensure a robust dataset and to mitigate the potential impact of patients who temporarily missed doses due to the COVID-19 pandemic. It was based on a collaborative consultation with the FDA and in accordance with FDA and EMA COVID-19 regulatory guidance. Eisai also confirmed that the screening of participants was completed in January and that time for data readout for Clarity AD remains unchanged and is still expected by September 2022.

During the past year, Eisai has continuously worked to mitigate the challenges posed by the COVID-19 pandemic for the Phase 3 Clarity AD study of drug candidate lecanemab for the treatment of early Alzheimer's disease, prioritizing patient safety, continuity of dosing, and quality of data. Efforts have included home infusion options and online assessment alternatives. Even so, the pandemic posed a risk that participants in the study would not receive all planned doses or that there could be a lack of data at some assessment time points. Eisai has therefore, after FDA consultation, decided to increase the target number of participants by approximately 200 to ensure a robust dataset. Clarity AD is a double-blind study, and the addition of participants has been implemented without unblinding of any clinical results, and prior to completing enrollment of the original 1566 patient target.

"This past year has been very challenging for everybody, not the least for clinical studies, and I am glad that Eisai has taken the decision to increase the number of participants for the Clarity AD study, to ensure a solid dataset. More than 30 million people around the world suffer from Alzheimer's disease and we want to do everything we can to provide them with an effective and safe treatment. We look forward to the continued development of lecanemab as a potential disease-modifying treatment for patients with Alzheimer's disease," said BioArctic's CEO Gunilla Osswald.

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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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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 (protofibril) 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 amyloid in their brains, 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 (grant number R01AG061848 and grant number R01AG054029), 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 on the lecanemab antibody, which was signed in December 2007, and the development and commercialization agreement on 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.

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.