



Press release

Eisai presented latest data from the lecanemab clinical program at AAIC 2021

Stockholm, July 30, 2021 - BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai held several presentations at the Alzheimer's Association International Conference (AAIC) in Denver, Colorado July 26 to 30, 2021. The presentations included the latest data for the investigational anti-amyloid beta antibody lecanemab (BAN2401), for which the FDA recently granted Breakthrough Therapy designation.

In an oral presentation, baseline characteristics and results from the preliminary screening of the Phase 3 clinical study, AHEAD 3-45, for preclinical (asymptomatic) Alzheimer's disease, were presented. Eligibility for the two trials A3 and A45 are dependent on the levels of amyloid in the brain as measured by PET. The results showed that inclusion of subjects for the two trials appear consistent with projections based on existing observational data. The initial experience with screening and randomization from the study also suggests that for trials targeting the underlying pathology of Alzheimer's disease, it is feasible to identify participants across the stages of preclinical Alzheimer's disease where patients are at-risk for further amyloid accumulation and the onset of cognitive decline.

For the first time, clinical outcome data from a small cohort of the large Phase 2b open label extension study were presented. These early results regarding treatment response on clinical outcomes such as ADCOMS, CDR-SB and ADAS-Cog in newly lecanemab-treated and previously treated early Alzheimer's disease subjects, provide further support for the prior observed placebo-controlled efficacy results in the core study. The data also indicate the need for continuous treatment.

A poster presentation on the ongoing confirmatory Phase 3 Clarity AD study, showed that the baseline characteristics after randomization of 1536 subjects are highly consistent with the Phase 2b study as well as representative of an early Alzheimer's disease population. In March, Eisai finished recruitment of 1795 patients for Clarity AD, and the readout of the primary endpoint is expected by the end of September 2022.

In another poster presentation results suggested a potential to use the plasma A β 42/40 ratio to monitor for drug effects in individual patients. The approach will be further assessed in the ongoing lecanemab pivotal studies, Clarity AD & AHEAD 3-45.

"It's very encouraging to see that Eisai's broad clinical program for lecanemab continues to deliver data in support of the effects on both amyloid in the brain and cognitive outcomes. 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.

Eisai's presentations and posters from the AAIC congress are available on www.bioarctic.com.



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 July 30, 2021, 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 A β 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.

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.

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.