Press release

BioArctic and Eisai presented latest data regarding lecanemab at AD/PD 2021

Stockholm, March 15, 2021 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) today announced data on the drug candidate lecanemab (BAN2401), which were presented by the company and its partner Eisai at the 15th International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders, AD/PD™. The presentations included findings suggesting that lecanemab could be of potential benefit for adults with Down's syndrome with signs of functional or cognitive deterioration. Preliminary results presented from the ongoing open-label extension of the Phase 2b study in early Alzheimer's disease continue to support the effect of lecanemab on brain amyloid levels.

BioArctic presented data that confirmed that similar to adults with Alzheimer's disease, individuals with Down's syndrome with dementia show significantly elevated levels of soluble amyloid-beta (Aβ) aggregates, so called protofibrils, compared to control groups. The presentation also demonstrated for the first time that lecanemab binds to these Aβ aggregates and Aβ plaques in this Down's syndrome population with dementia. These combined findings suggest that targeting toxic soluble Aβ aggregates with lecanemab could help preserve brain function in adults with Down's syndrome with dementia.

Eisai presented updated results from subjects who participated in the amyloid imaging sub studies in both the Core and the ongoing open-label extension of the Phase 2b study of lecanemab in early Alzheimer's disease. The results showed that the effects of lecanemab on reducing amyloid in the brain on average persist for at least two years following discontinuation of lecanemab dosing. In participants who were treated with placebo in the core study and started on 10 mg/kg biweekly lecanemab in the open label extension, showed rapid reduction in brain amyloid levels as early as three months of lecanemab treatment, with continued reduction over 12 months of treatment. Lecanemab, dosed at 10 mg/kg biweekly, was also shown to reduce brain amyloid to negative levels[1] in more than 80 percent of patients who participated in the core and open-label extension study, as early as 12 months into treatment.

"The latest data further support the effects of lecanemab, and I'm encouraged to see the continued progress of both Eisai's broad ongoing clinical trial programs in Alzheimer's disease, as well as our own research related to Down's syndrome. We look forward to the continued development of lecanemab as a potential disease-modifying treatment," said BioArctic's CEO Gunilla Osswald.

BioArctic's poster as well as Eisai's presentation from the AD/PD conference, which were presented virtually as a consequence of the COVID-19 pandemic, are available on www.bioarctic.com.

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[1] The patient does no longer show Alzheimer's disease pathology regarding amyloid levels in the brain

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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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Note to editors

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.