Press release

FDA grants Breakthrough Therapy designation for lecanemab in Alzheimer's disease

Stockholm, 23 June 2021 - BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for lecanemab (BAN2401), an investigational anti-amyloid beta (Aβ) protofibril antibody for the treatment of Alzheimer's disease.

Breakthrough Therapy designation is an FDA program intended to expedite the development and review of medicines for serious or life-threatening conditions. The benefits of a Breakthrough Therapy designation include more intensive guidance on an efficient development program as well as eligibility for rolling review and potentially priority review.

The FDA's Breakthrough Therapy designation for lecanemab is based on the recently published results of a Phase 2b clinical trial (Study 201) of 856 patients with mild cognitive impairment (MCI) due to Alzheimer's disease and mild Alzheimer's with confirmed presence of amyloid pathology.[1] The proof-of-concept Study 201 explored the impact of treatment with lecanemab on reducing brain amyloid beta (Aβ) and clinical decline. In this study, pre-specified analysis showed consistent reduction of clinical decline across several clinical and biomarker endpoints at the highest doses.

In March 2021, the enrollment of 1,795 patients with early Alzheimer's disease in the Phase 3 study of lecanemab, Clarity AD, was completed. The study's primary endpoint is expected to be completed by the end of September 2022. Additionally, the Phase 3 clinical study, AHEAD 3-45, is currently exploring lecanemab in individuals with preclinical Alzheimer's disease, meaning they are clinically normal and have intermediate or elevated levels of amyloid in their brains. Open label extension data from Phase 2b study (Study 201) detected rapid and increasing reduction of brain Aβ over time in individuals treated with lecanemab and was presented at the 2021 Alzheimer's Disease and Parkinson's Disease Conference.

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.

This information is information that BioArctic AB (publ) is obliged to disclose pursuant to the EU Market Abuse Regulation. The information was released for public disclosure, through the agency of the contact persons above, on June 23, 2021, at 10.10 p.m. CET.

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[1] Alzheimer's Research & Therapy volume 13, Article number: 80 (2021)
https://alzres.biomedcentral.com/articles/10.1186/s13195-021-00813-8

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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.

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.