Press release

BioArctic's partner Eisai initiates BLA submission of data for lecanemab in China

Stockholm, December 23, 2022 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that they have initiated submission of data for Biologics License Application (BLA) to the National Medical Products Administration (NMPA) of China for lecanemab (development code: BAN2401), an investigational anti-amyloid beta (Aβ) protofibril antibody.

The registration category of lecanemab was designated as a Category 1 drug (innovative biologics not approved in China or any other countries). The data submitted in this package includes data from the Phase IIb clinical trial (Study 201) in mild cognitive impairment (MCI) due to Alzheimer's disease (AD) and mild AD (collectively known as early AD) with confirmed Aβ accumulation in the brain and the top-line data of the large global Phase III Clarity AD study. Eisai will submit additional data including full data of the Clarity AD study, as directed by the NMPA.

Lecanemab selectively binds and eliminates soluble, toxic Aβ 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. The large global Phase 3 study, Clarity AD, of lecanemab in early AD met its primary endpoint and all key secondary endpoints with highly statistically significant results. In November 2022, the results of the Clarity AD study were presented at the 2022 Clinical Trials on Alzheimer's Disease (CTAD) conference, and simultaneously published in the New England Journal of Medicine, one of the world's most prestigious peer-reviewed medical journals.

In the U.S., lecanemab was granted Breakthrough Therapy and Fast Track designations by the U.S. Food and Drug Administration (FDA) in June and December 2021, respectively. In July 2022, the FDA accepted Eisai's Biologics License Application (BLA) for lecanemab under the accelerated approval pathway and granted it Priority Review. The Prescription Drug User Fee Act (PDUFA) action date is January 6, 2023. Eisai aims to file for traditional approval in the U.S. and for marketing authorization applications in Japan and Europe by the end of the first quarter 2023.

Eisai serves as the lead of lecanemab development and regulatory submissions globally with both Eisai and Biogen co-commercializing and co-promoting the product and Eisai having final decision-making authority. BioArctic has right to commercialize lecanemab in the Nordic under certain conditions and is currently preparing for commercialization in the Nordics together with Eisai.

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 such an investigational agent will successfully gain health authority approval.

The information was released for public disclosure, through the agency of the contact person below, on December 23, 2022, at 00:30 a.m. CET.

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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 BioArctic and Eisai. Lecanemab selectively binds and eliminates 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. Currently, lecanemab is being developed as the only late-stage anti-Aβ antibody that can be used for the treatment of early AD without the need for titration, enabling full treatment effect from day one.

The Clarity AD open-label extension is underway with treatment initiated after completion of the Core period to further evaluate the safety and efficacy of lecanemab. In addition, the lecanemab Phase 3 clinical study AHEAD 3-45 is ongoing for individuals with preclinical (asymptomatic) AD, meaning they are clinically normal and have intermediate or elevated levels of brain amyloid. 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 2021, lecanemab was selected for the Tau NexGen clinical study for Dominantly Inherited Alzheimer's disease (DIAD), as a background anti-amyloid treatment when exploring combination therapies with anti-tau treatments. The study, which is ongoing, is conducted by Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU), led by Washington University School of Medicine in St. Louis. Furthermore, Eisai has performed a lecanemab subcutaneous dosing Phase 1 study and the subcutaneous formulation is currently being evaluated in the Clarity AD open label extension study.

About the collaboration between BioArctic and Eisai
Since 2005, BioArctic has a 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. In March 2014, Eisai and Biogen entered into a joint development and commercialization agreement for lecanemab. Eisai is responsible for the clinical development, application for market approval and commercialization of the products for Alzheimer's disease. BioArctic has right to commercialize lecanemab in the Nordic under certain conditions and is currently preparing for commercialization in the Nordics together with Eisai. BioArctic has no development costs for lecanemab in Alzheimer's disease and is entitled to payments in connection with regulatory filings, approvals, and sales milestones as well as royalties on global sales.

About BioArctic AB
BioArctic AB (publ) is a Swedish research-based biopharma company focusing on disease-modifying treatments for neurodegenerative diseases, such as Alzheimer's disease, Parkinson's disease and ALS. 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 partner Eisai in Alzheimer disease. 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.