Press release

Biologics License Application for lecanemab designated for Priority Review by China National Medical Products Administration

Stockholm, February 28, 2023 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that the Biologics License Application (BLA) for lecanemab (brand name in the U.S.: LEQEMBI™), an investigational anti-amyloid beta (Aβ) protofibril antibody has been designated for Priority Review by the National Medical Products Administration (NMPA) in China. The Priority Review and Approval procedure was implemented by the NMPA with the aim of accelerating research, development and launch of new medicines that have significant clinical value. Under this procedure the assessment period is expected to be shortened.

In China, Eisai initiated submission of data for BLA to the NMPA in December 2022. Eisai initially submitted a package that includes data from the Phase 2b clinical trial and the top-line data of the large global Phase III Clarity AD study 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. 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 aggregates (protofibrils) that are thought to contribute to the neurotoxicity 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 Clarity AD study of lecanemab 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 peer-reviewed medical journal New England Journal of Medicine.

In the U.S., lecanemab was granted accelerated approval as a treatment for AD by the Food and Drug Administration (FDA) on January 6, 2023. On the same day, Eisai submitted a Supplemental Biologics License Application (sBLA) to the FDA for approval under the traditional pathway. In Europe, Eisai submitted marketing authorization application (MAA) to the European Medicines Agency (EMA) on January 9, 2023, which was accepted on January 26, 2023. In Japan, Eisai submitted a marketing authorization application to the Pharmaceuticals and Medical Devices Agency (PMDA) on January 16, 2023, and Priority Review was designated by the Ministry of Health, Labour and Welfare on January 26, 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.

BioArctic has no development costs for lecanemab in Alzheimer's disease and is entitled to payments in connection with regulatory approvals and sales milestones as well as royalties on global sales.

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 February 28, 2023, at 00.30 a.m. CET.

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About lecanemab
Lecanemab (Brand Name in the U.S.: LEQEMBI™) is the result of a strategic research alliance between BioArctic and Eisai. Lecanemab is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid-beta (Aβ). In the U.S., LEQEMBI was granted accelerated approval by the U.S. Food and Drug Administration (FDA) on January 6, 2023. LEQEMBI is indicated for the treatment of Alzheimer's disease (AD) in the U.S. Treatment with LEQEMBI should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication is approved under accelerated approval based on reduction in Aβ plaques observed in patients treated with LEQEMBI. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial. Eisai has submitted a sBLA in the USA for LEQEMBI based on the data from the Phase 3 confirmatory Clarity AD clinical trial.

Please see LEQEMBI US Prescribing Information.

Eisai has completed a LEQEMBI subcutaneous bioavailability study and subcutaneous dosing is currently being evaluated in the Clarity AD open label extension study.

Since July 2020 Eisai's Phase 3 clinical study (AHEAD 3-45) for individuals with preclinical AD, meaning they are clinically normal and have intermediate or elevated levels of amyloid in their brains, is ongoing. AHEAD 3-45 is conducted as a public-private partnership between the Alzheimer's Clinical Trial Consortium that provides the infrastructure for academic clinical trials in AD and related dementias in the U.S, funded by the National Institute on Aging, part of the National Institutes of Health and Eisai.

Since January 2022, the Tau NexGen clinical study for Dominantly Inherited AD (DIAD) is ongoing, where lecanemab is given as a background anti-amyloid treatment when exploring combination therapies with anti-tau treatments. The study is conducted by Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU), led by Washington University School of Medicine in St. Louis.

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 Large Cap (ticker: BIOA B). For more information about BioArctic, please visit www.bioarctic.com.