Press release

European Medicines Agency accepts Marketing Authorization Application for lecanemab as treatment for early Alzheimer's disease

Stockholm, January 27, 2023 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that the European Medicines Agency (EMA) has accepted a marketing authorization application (MAA) for lecanemab (Brand Name in the U.S.: LEQEMBI™), an investigational anti-amyloid beta (Aβ) protofibril antibody[1], for the treatment of Early Alzheimer's disease (mild cognitive impairment due to Alzheimer's disease (AD) and mild AD dementia) with confirmed amyloid pathology, for review following a standard timeline. In conjunction with EMA's acceptance of the file, BioArctic is entitled to a milestone of MEUR 5.

In the U.S., lecanemab was granted accelerated approval as a treatment for AD by the U.S. 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 based on the results from the Phase III Clarity AD confirmatory study. In Japan, Eisai submitted a marketing authorization application to the Pharmaceuticals and Medical Devices Agency (PMDA) on January 16, 2023. In China, Eisai has initiated submission of data for a BLA to the National Medical Products Administration (NMPA) of China in December 2022.

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 filings, approvals, and sales milestones as well as royalties on global sales.

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 person below, on January 27, 2023, at 00.30 a.m. CET.

[1] Protofibrils are large Aβ aggregated soluble species of 75-500 Kd.

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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). Lecanemab selectively binds and eliminates Aβ protofibrils that are thought to contribute to the neurotoxicity in Alzheimer's disease. As such, lecanemab may have the potential to have an effect on disease pathology and to slow down the progression of the disease. 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 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. The Clarity AD study of lecanemab met its primary endpoint and all key secondary endpoints with highly statistically significant results. Please see LEQEMBI US Prescribing Information.

Eisai has completed a lecanemab 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.

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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.