Press release

Lecanemab receives priority review status in Japan

Stockholm, January 30, 2023 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that the application for manufacturing and marketing approval for lecanemab (generic name, U.S. brand name: LEQEMBI™) in Japan has been designated for Priority Review by the Japanese Ministry of Health, Labour and Welfare (MHLW). Lecanemab is an anti-amyloid-β (Aβ) protofibril[1] antibody for treatment of Alzheimer's disease (AD). Priority Review in Japan is granted to new medicines recognized as having high medical utility for serious diseases, and once designated for Priority Review, the target total review period is shortened.

In Japan, Eisai submitted the manufacturing and marketing approval for lecanemab to the Pharmaceuticals and Medical Devices Agency (PMDA) on January 16, 2023. This application is based on the results of the Phase 3 Clarity AD study and the Phase 2b clinical study, which demonstrated that lecanemab treatment showed a reduction of clinical decline in early AD.

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 New England Journal of Medicine, a peer-reviewed medical journal.

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. In Europe, Eisai submitted a marketing authorization application (MAA) to the European Medicines Agency (EMA) on January 9, 2023, which was accepted on January 26, 2023. In China, Eisai initiated submission of data for a BLA to the National Medical Products Administration (NMPA) in December 2022.

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

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 30, 2023, at 00.30 a.m. CET.

For further information, please contact:
Oskar Bosson, VP Communications and IR
E-mail: oskar.bosson@bioarctic.se
Phone: +46 70 410 71 80

About Priority Review in Japan
Priority review is granted to medicines that meet all of the following requirements. In addition, medicines designated as orphan drugs and pioneering medicines will be given priority for review.
i. the qualifying disease is deemed to be serious; and
ii. the efficacy or safety of the product is recognized to be clearly superior to that of existing medicines, medical devices, or regenerative medical products or treatment methods from a medical point of view.

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. 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.