## Press Release

# Marketing Authorisation Application for lecanemab submitted in Great Britain

**Stockholm, May 22, 2023 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that they have submitted a Marketing Authorisation Application (MAA) for lecanemab, an investigational anti-amyloid beta (Aβ) protofibril[1] antibody, for the treatment of early Alzheimer's disease[2] (AD) with confirmed amyloid pathology in the brain, to the UK Medicines and Healthcare products Regulatory Agency (MHRA) in Great Britain. Lecanemab has been designated by the MHRA for the Innovative Licensing and Access Pathway (ILAP).**

The MAA is based on the results of the confirmatory 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, and is subject to a validation to determine whether it will be accepted by the MHRA. 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.

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 the right to commercialize lecanemab in the Nordic region and currently Eisai and BioArctic are preparing for a joint commercialization in the region.

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*The information was released for public disclosure, through the agency of the contact person below, on May 22, 2023, at 01.30 a.m. CET.*

[1] Protofibrils are large Aβ aggregated soluble species of 75-5000 Kd
[2] Mild cognitive impairment due to Alzheimer's disease (AD) and mild AD dementia

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**About the Innovative Licensing and Access Pathway (ILAP) in the UK**
The ILAP is a program offered by the MHRA (UK) for development programs with the goal of reducing the time to market for innovative medicines that treat life-threatening or seriously debilitating conditions and/or conditions for which there is a significant unmet patient need. The ILAP aims to achieve this goal by enabling enhanced coordination between sponsors, the MHRA and reimbursement bodies such as National Institute for Health and Care Excellence (NICE), leading up to Marketing Authorisation Application (MAA) submissions to support accelerated access.

**About lecanemab**
Lecanemab 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 (protofibril) and insoluble forms of amyloid-beta (Aβ).

In the US, lecanemab was granted accelerated approval for Alzheimer's disease by the US 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. This application was accepted, and has been granted Priority Review, with a Prescription Drug User Fee Act (PDUFA) action date of July 6, 2023. In Europe, Eisai submitted a marketing authorisation application (MAA) to the European Medicines Agency (EMA) on January 9, 2023, which was accepted on January 26, 2023. In Japan, Eisai submitted an application for manufacturing and marketing approval 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 (MHLW) on January 26, 2023. In China, Eisai initiated submission of data for a BLA to the National Medical Products Administration (NMPA) of China in December 2022, which was designated for Priority Review on February 27, 2023. In Canada, Eisai submitted a New Drug Submission (NDS) to Health Canada on March 31, 2023, and was accepted on May 15 of the same year.

Lecanemab is indicated for the treatment of AD in the U.S. Treatment with lecanemab 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 the accelerated approval based on reduction in Aβ plaques observed in patients treated with lecanemab. Continued approval may be contingent upon verification of lecanemab's clinical benefit in a confirmatory trial.

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 the right to commercialize lecanemab in the Nordic region and currently Eisai and BioArctic are preparing for a joint commercialization in the region. 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.

**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.