



## Press release

### **Eisai initiates submission of application data of lecanemab under the prior assessment consultation system in Japan with the aim of an earlier regulatory approval**

**Stockholm, March 4, 2022 - BioArctic AB:s (publ) (Nasdaq Stockholm: BIOA B) partner Eisai has initiated a submission to the Pharmaceuticals and Medical Devices Agency (PMDA) of application data under the prior assessment consultation system in Japan for the investigational anti-amyloid beta (A $\beta$ ) protofibril antibody lecanemab (BAN2401). The lecanemab Clarity AD Phase 3 clinical study for mild cognitive impairment (MCI) due to Alzheimer's disease (AD) and mild AD (collectively known as early AD) is ongoing.**

The PMDA's process, known as "prior assessment consultation", is conducted at the development stage before the new drug application submission, which is based on available quality, non-clinical and clinical data. By identifying and resolving any potential issues prior to submission, the aim is to shorten application review time.

Based on discussions with the Ministry of Health, Labour and Welfare (MHLW) and PMDA, Eisai applied to PMDA for permission to utilize the "prior assessment consultation" process for lecanemab with the aim of shortening the review period. The agency approved Eisai's request and Eisai has submitted the non-clinical lecanemab data to PMDA. The additional data of the application package will be submitted hereafter. Eisai plans to obtain the primary endpoint data from Clarity AD study in the fall of 2022, and based on the results of the study, aims to file for the manufacturing and marketing approval in Japan before end of March 2023.

In September 2021, Eisai initiated a rolling submission to the U.S. Food and Drug Administration (FDA) of a Biologics License Application (BLA) for lecanemab, an investigational agent under the Accelerated Approval pathway for the treatment of early AD with confirmed amyloid pathology, and expects to complete this rolling submission in the second quarter 2022. Based on the results of the confirmatory Clarity AD study, Eisai plans to submit for full approval of lecanemab to the U.S. FDA before end of March 2023.

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*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 any investigational uses of such product will successfully complete clinical development or gain health authority approval.*

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*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 persons above, on March 4, 2022, at 00:35 a.m. CET.*

#### **Note to editors**

##### **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 Eisai and BioArctic. Lecanemab selectively binds to, neutralize and eliminate soluble toxic A $\beta$  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. Eisai obtained the global rights to study, develop, manufacture, and market lecanemab for the treatment of AD pursuant to an agreement concluded with BioArctic in December 2007. In March 2014, Eisai and Biogen entered into a joint development and commercialization agreement for lecanemab. Currently, lecanemab is being studied in a pivotal Phase 3 clinical study in symptomatic early AD (Clarity AD), following the outcome of the Phase 2b clinical study (Study 201). In July of 2020, the Phase 3 clinical study, AHEAD 3-45, for individuals with preclinical (asymptomatic) AD, meaning they are clinically normal and have intermediate or elevated levels of brain amyloid, was initiated. 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 June 2021, FDA granted lecanemab Breakthrough Therapy designation and in September 2021, Eisai initiated a rolling submission for the US FDA Biologics license application of lecanemab for early Alzheimer's disease under the accelerated approval pathway. In December 2021, FDA granted lecanemab Fast track designation and the second part of the rolling application was submitted. Eisai expects the rolling submission to be completed during the second quarter 2022.

##### **About the collaboration between BioArctic and Eisai**

Since 2005, BioArctic has 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. Eisai is responsible for the clinical development, application for market approval and commercialization of the products for Alzheimer's disease. 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.

##### **About BioArctic AB**

BioArctic AB (publ) is a Swedish research-based biopharma company focusing on disease-modifying treatments and reliable biomarkers and diagnostics for neurodegenerative diseases, such as Alzheimer's disease and Parkinson's disease. 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 partners in the Alzheimer (Eisai) and Parkinson (AbbVie) projects. 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](http://www.bioarctic.com).