



## Press release

### Latest lecanemab data to be presented at the AD/PD™ congress

**Stockholm, March 11, 2022 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) announced today that the company and its collaboration partner Eisai will both present data relating to its investigational anti-amyloid beta (A $\beta$ ) protofibril antibody lecanemab (BAN2401), at the 16th International Conference on Alzheimer’s and Parkinson’s Diseases and related neurological disorders, AD/PD™ 2022 in Barcelona and online.**

The International Conference on Alzheimer’s and Parkinson’s Diseases and related neurological disorders is a key scientific event with a focus on improving the treatment of Alzheimer’s, Parkinson’s and other related neurodegenerative diseases.

BioArctic’s founder Professor Lars Lannfelt, will be presenting on the topic of the science of the amyloid-beta cascade as well as the distinct mechanisms of action of lecanemab. His presentation will also include data on lecanemab in comparison with other late-stage anti-amyloid antibodies.

Eisai will present data from the Phase 2b study of lecanemab in early Alzheimer’s disease and the ongoing open-label extension study, including new biomarker data. Eisai will also update on the clinical development of lecanemab including subcutaneous development and the Dominantly Inherited Alzheimer’s Network Trials Unit (DIAN-TU) Tau Nexgen study, where lecanemab will be used as a background treatment in combination with an investigational tau therapy.

Lecanemab was granted Breakthrough Therapy and Fast Track designations by the U.S. Food and Drug Administration (FDA) in June and December 2021, respectively. Eisai anticipates completing lecanemab’s rolling submission of a Biologics License Application for the treatment of early AD to the FDA under the accelerated approval pathway in the second quarter 2022. Additionally, the readout of the Phase 3 confirmatory Clarity AD clinical trial is expected by end of September 2022. Eisai initiated a submission to the Pharmaceuticals and Medical Devices Agency (PMDA) of application data of lecanemab under the prior assessment consultation system in Japan in March 2022.

Session, date and time (CET), presenter	Topic
Symposium: Advances in AD, PD and LBD drug development Thursday March 17 Lecture Time: 10:25 AM - 10:40 AM Presenter: Lon S. Schneider	Dominantly Inherited Alzheimer’s Network Trials Unit (DIAN-TU) Tau Nexgen Platform Trial of the Anti-tau Antibody, E2814 with Background Lecanemab Therapy
Symposium: A $\beta$ targeting therapies in AD 2 Friday March 18 Lecture time: 05:15 PM - 05:40 PM Presenter: Lars Lannfelt	Science of the amyloid- $\beta$ cascade and distinct mechanisms of action of lecanemab



Symposium: A $\beta$ targeting therapies in AD 2 Friday March 18 Lecture time: 05:40 PM - 05:55 PM Presenter: Marwan Sabbagh	Key trial design aspects and clinical outcomes of the lecanemab phase 2 trial and open-label extension in early Alzheimer's disease
Symposium: A $\beta$ targeting therapies in AD 2 Friday March 18 Lecture Time: 05:55 PM - 06:10 PM Presenter: Eric McDade	Biomarker results from the lecanemab phase 2 study: linking disease progression to chronic amyloid treatment
Symposium: A $\beta$ targeting therapies in AD 2 Friday March 18 Lecture Time: 06:10 PM - 06:25 PM Presenter: Michael C. Irizarry	Update on lecanemab clinical development, including new subcutaneous (SC) formulation
Symposium: A $\beta$ and other targeting therapies in AD Sunday March 20 Lecture Time: 09:05 AM - 09:20 AM Presenter: Antonio Cabal	Quantitative Systems Pharmacology Amyloid Platform: Multiscale Computational Modeling of A $\beta$ Biology and Its Interaction with Lecanemab Pharmacology
On demand presentation Presenter: Arnaud Charil	Baseline Tau in Clarity AD: A Phase 3 Placebo-Controlled, Double-Blind, Parallel-Group, 18-Month Study Evaluating Lecanemab in Early Alzheimer's Disease

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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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**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 addition, 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, is ongoing. 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).