



## Press release

### **Lifetime Achievement Award, lecanemab and biomarkers in focus at CTAD**

**Stockholm, October 24, 2024 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) founder Lars Lannfelt will be presented with the Lifetime Achievement Award in Alzheimer's Disease Therapeutic Research at the Clinical Trials for Alzheimer's Disease Conference (CTAD) held in Madrid, Spain, and virtually from October 29 to November 1. Lars Lannfelt will be one of the keynote speakers at the conference. In addition, BioArctic's partner Eisai present lecanemab data in two oral and one poster presentation at the meeting and three symposia will focus on lecanemab. Data shared will include the importance of continued treatment of Alzheimer's disease, a progressive neurodegenerative disease that begins before plaque deposition and continues after plaque removal.**

At CTAD 2024, Eisai will present the latest information on the use of lecanemab in clinical practice and the use of plasma biomarkers in the AHEAD 3-45 trial to screen for preclinical Alzheimer's disease. The full list of presentations related to lecanemab can be found below.

#### **CTAD Lifetime Achievement Award** October 29, 4:20 p.m. to 4:55 p.m. (CET)

- CTAD Lifetime Achievement Award Alzheimer's Disease Therapeutic Research
- KEYNOTE 1: Professor Lars Lannfelt. Lecanemab: from a mutation to a treatment for Alzheimer's disease

#### **Late Breaking Symposium 1 – The AHEAD 3-45 Study: Design and Results of a Novel Screening Process for a Preclinical AD Trial**

From 6:10 to 6:50 p.m. (CET) on October 29 (Tuesday). This late breaking symposium will present the design of the AHEAD 3-45 trial focused on lecanemab in pre-clinical Alzheimer's disease and the findings on use of plasma biomarkers, amyloid and tau PET imaging in screening.

#### **Late Breaking Symposium 2 – One-Year Experience on the Use of Lecanemab in Clinical Practice**

From 3:30 to 4:10 pm (CET), on October 30 (Wednesday). This symposium will discuss real-world evidence from clinical practice with lecanemab in the U.S. and Japan.

#### **Symposium 1 – Does the Current Evidence Base Support Continued Dosing with Lecanemab for Early Alzheimer's Disease?**

From 9:40 to 10:20 p.m. (CET) on October 30 (Wednesday). This symposium is an update of [Perspectives sessions conducted at AAIC 2024](#).



**Roundtable – Advancing Combination Therapy: Discussion on Key Considerations, Perspectives, and Promising Avenues for the Future of Alzheimer's Treatments**

From 1:45 to 2:15 p.m. (CET) on October 30 (Wednesday)

**Oral Presentations**

<b>Asset/Project, Presentation Time (CET)</b>	<b>Presentation Number, Title</b>
<b>Lecanemab</b> Oct 30 (Wed) 11:20 – 11:35 a.m.	LB6 Lecanemab for the Treatment of Mild Cognitive Impairment and Mild Dementia Due to Alzheimer's Disease in Adults That Are Apolipoprotein E ε4 Heterozygotes or Non-Carriers
<b>Lecanemab</b> Oct 30 (Wed) 3:35 – 3:50 p.m.	LB18 AI-Derived Prognostic Covariates Enhance the Precision of Lecanemab Efficacy Assessments and Optimize Alzheimer's Disease Clinical Trials

**Poster Presentations**

<b>Asset/Project</b>	<b>Presentation Number, Title</b>
<b>Lecanemab</b> Oct 29 (Tue) – Oct 30 (Wed)	LP017 Transitioning from Clinical Trial to Clinical Practice for Long-Term Lecanemab Treatment in Early Alzheimer's Disease: Perspectives from an Alzheimer's Disease Treatment Center

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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 such an investigational agent will successfully complete clinical development or gain health authority approval.*

*The information was released for public disclosure, through the agency of the contact person below, on October 24, 2024, at 08.00 a.m. CET.*

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**About lecanemab (Leqembi®)**

Lecanemab is the result of a strategic research alliance between BioArctic and Eisai. It is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble (protofibril) and insoluble forms of amyloid-beta (Aβ).

Lecanemab is approved in the U.S., Japan, China, South Korea, Hong Kong, Israel, UAE and Great Britain for the treatment of MCI due to AD and mild AD dementia. Lecanemab's approvals in these countries were primarily based on Phase 3 data from Eisai's global Clarity AD clinical trial, in which it met its primary endpoint and all



key secondary endpoints with statistically significant results. The most common adverse events (>10%) in the lecanemab group were infusion reactions, ARIA-H (combined cerebral microhemorrhages, cerebral macrohemorrhages, and superficial siderosis), ARIA-E (edema/effusion), headache, and fall.

Lecanemab marketed in the U.S., Japan and China. Eisai has also submitted applications for approval of lecanemab in 10 countries and regions, including the European Union.

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), that is conducted by Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU), led by Washington University School of Medicine in St. Louis, is ongoing and includes lecanemab as the backbone anti-amyloid therapy.

#### **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 2007, and the Development and Commercialization agreement for the antibody Leqembi back-up for Alzheimer's disease, which was signed 2015. In 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 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 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 innovative treatments that can delay or stop the progression of neurodegenerative diseases. The company invented Leqembi® (lecanemab) – the world's first drug proven to slow the progression of the disease and reduce cognitive impairment in early Alzheimer's disease. Leqembi has been developed together with BioArctic's partner Eisai, who are responsible for regulatory interactions and commercialization globally. In addition to Leqembi, BioArctic has a broad research portfolio with antibodies against Parkinson's disease and ALS as well as additional projects against Alzheimer's disease. Several of the projects utilize the company's proprietary BrainTransporter™ technology, which has the potential to actively transport antibodies across the blood-brain barrier to enhance the efficacy of the treatment. BioArctic's B share (BIOA B) is listed on Nasdaq Stockholm Large Cap. For further information, please visit [www.bioarctic.com](http://www.bioarctic.com).