Press release

Long-term treatment data for lecanemab to be presented at AAIC 2024

Stockholm, July 23, 2024 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) today announced that its partner Eisai will present the latest findings on lecanemab (generic name, brand name Leqembi®) at the Alzheimer's Association International Conference (AAIC) 2024. The conference will be held in Philadelphia and virtually from July 28 to August 1, 2024. Data presented will include three-year efficacy and safety data, as well as data supporting the importance of continued treatment of Alzheimer's disease. In addition, BioArctic will present a poster on the Nordic Healthcare system's readiness to introduce new Alzheimer's disease treatments.

Eisai presentations of the latest data on lecanemab, will focus on the importance of continued treatment for Alzheimer's disease (AD). Key presentations include three-year efficacy and safety data from Phase 2 and Phase 3 studies, the mechanism of action of lecanemab in targeting toxic soluble aggregated amyloid-beta species (protofibrils), and the importance of maintenance treatment based on neurodegenerative biomarkers in plasma. Featured sessions will delve into the long-term imaging and fluid biomarkers, and the evidence supporting the rationale for continued lecanemab dosing. Presenters such as Dennis Selkoe, M.D., and Charlotte Teunissen, Ph.D., will provide insights into the ongoing benefits of lecanemab treatment, highlighting its potential to slow the progression of AD by clearing amyloid-beta protofibrils.

In addition, BioArctic will present a poster of a study highlighting deficiencies in the healthcare system's ability to diagnose and treat Alzheimer's disease in the Nordic countries. The poster will be displayed by Mats Ekelund, Head of Market Access at BioArctic.

Date	Time (EDT)	Presentation Title/Poster Title	Presenter(s)/Abstract ID
July 30	2:00 PM - 3:30 PM	**Featured Research Session:** Beyond Amyloid Removal with Lecanemab Treatment: Update on Long-Term Imaging and Fluid Biomarkers - Amyloid Plaque Reduction as a Biomarker of Efficacy - Lecanemab Slows Tau PET Accumulation - "Paradoxical" Cerebral Volume Changes in Anti-Amyloid Immunotherapy Trials - Long-Term Effects of Lecanemab on Biomarkers of Neurodegeneration in Plasma - Panel discussion and Q&A	Brian Willis, Ph.D., Arnaud Charil, Ph.D., Nick Fox, M.D., FRCP, FMedSci, Charlotte Teunissen, Ph.D.
July 30	4:15 PM - 5:45 PM	**Perspectives Session:** Does the Current Evidence Base Support Lecanemab Continued Dosing for Early Alzheimer's Disease?	Dennis Selkoe, M.D., Youfang Cao, Ph.D., Larisa Reyderman, Ph.D., Christopher van Dyck, M.D.

		- Does the Current Evidence for Lecanemab Mechanism Support a Rationale for Continued Lecanemab Dosing? - How Does the Latest Clinical Pharmacology Data & Modeling Support Continued Lecanemab Dosing? - Neuro-Dynamic Quantitative Systems Pharmacology (QSP) Model Supports Continued Lecanemab Treatment with Maintenance Dosing For Alzheimer's Disease - Is there Evidence for a Continued Benefit for Long-Term Lecanemab Treatment? A Benefit/Risk Update from Long-Term Efficacy, Safety and Biomarker Data - Panel discussion and Q&A	
July 30	2:42 PM – 2:49 PM	**Oral presentation:** Examining Lecanemab-Associated Amyloid-Beta Protofibril as a Proximal Biomarker of Neurodegeneration Unlike Other Plaque-Associated Biomarkers	Kenjiro Ono, M.D. Abstract ID #94585
July 30	2:49 PM – 2:56 PM	**Oral Presentation:** Lecanemab, Amyloid-Induced Tau Pathology as Supported CSF MTBR-tau243 in Clarity AD	Abstract ID #95507
July 28		**Poster presentation:** Model-Based Assessment of Lecanemab Maintenance Dosing Regimen and Potential for Continued Suppression of Amyloid Plaque, Disease Progression	Brian Willis, Ph.D, Eisai Abstract ID #89308
July 30		**Poster presentation:** Expected challenges for memory clinics introducing disease modifying treatments in the Nordics	Mats Ekelund, Ph.D., BioArctic

Lecanemab is the result of a long-standing collaboration between BioArctic and Eisai, and the antibody was originally developed by BioArctic based on the work of Professor Lars Lannfelt and his discovery of the Arctic mutation in Alzheimer's disease. Eisai is responsible for the clinical development, applications for market approval and commercialization of lecanemab for Alzheimer's disease. BioArctic has no development costs for lecanemab in Alzheimer's disease and is entitled to payments in connection with certain regulatory approvals, and sales milestones as well as royalty of 9 percent on global sales. In addition, BioArctic has the right to commercialize lecanemab in the Nordic region, pending European approval, and currently Eisai and BioArctic are preparing for a joint commercialization in the region.

The information was released for public disclosure, through the agency of the contact persons below, on July 23, 2024, at 08:00 a.m. CET.

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About lecanemab (generic name, brand name: Leqembi®)
Lecanemab (Leqembi) 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, and Israel. (See full US prescribing information including boxed waring.)

Lecanemab approvals were based on the large global Phase 3 Clarity AD study. In the Clarity AD study, lecanemab met its primary endpoint and all key secondary endpoints with 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.

Eisai has also submitted applications for approval of lecanemab in 12 other countries and regions, including the European Union (EU). A supplemental Biologics License Application (sBLA) for intravenous maintenance dosing was submitted to the U.S. Food and Drug Administration (FDA) in March 2024. The rolling submission of a Biologics License Application (BLA) for maintenance dosing of a subcutaneous injection formulation, which is being developed to enhance convenience for patients, was initiated in the U.S. under Fast Track status in May 2024.

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.