Press release

Lecanemab four-year efficacy and safety data to be presented at AAIC 2025

Stockholm, Sweden, July 22, 2025 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai will present the latest findings on lecanemab (Leqembi®), including four-year efficacy and safety data and data on the subcutaneous formulation for maintenance dosing, at the Alzheimer's Association International Conference (AAIC), being held in Toronto and virtually from July 27 - 31.

Key oral lecanemab presentations at AAIC

- **Four-year data:** On Wednesday, July 30, as part of the "Developing Topics Session: Innovative Therapeutic Approaches" (8:00 – 8:45 AM EDT), initial four-year findings will be presented on lecanemab from the Phase 3 Clarity AD Open-Label Extension in Early Alzheimer's Disease trial.
- **Subcutaneous maintenance dosing:** A Featured Research Session on Wednesday, July 30 (9:00 – 10:30 AM EDT) will include data on the potential of a new and convenient option for ongoing lecanemab treatment, the subcutaneous formulation for maintenance dosing.
- **Real world case studies:** A Developing Topics Session on Sunday, July 27 (9:00 – 10:30 AM EDT) will include data on real-world case studies and patient pathway learnings from diverse U.S. clinical settings two years post-approval of lecanemab.

Key Lecanemab Poster Presentation at AAIC

- A Poster Presentation on Monday, July 28 (viewing available from 7:30 AM – 4:15 PM EDT) will share findings on cerebrospinal fluid (CSF) samples collected from the Clarity AD trial and analyzed using the novel, sensitive immunoassay developed to measure Aβ protofibrils in CSF.

Eisai serves as the lead of Leqembi 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 Leqembi in the Nordic region together with Eisai and the two companies are preparing for a joint commercialization in the region.

The information was released for public disclosure, through the agency of the contact person below, on July 22, 2025, at 8:00 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, the United Arab Emirates, the United Kingdom, Mexico, Macau, Oman, Taiwan, European Union, Qatar, Singapore and Thailand for the treatment of Alzheimer's disease (AD) in patients with Mild Cognitive Impairment (MCI) or mild dementia stage of disease (collectively referred to as early AD). Eisai has submitted applications for approval of lecanemab in 11 countries and regions.

Since July 2020, Eisai's Phase 3 clinical study (AHEAD 3-45) with lecanemab in individuals with preclinical AD, meaning they are clinically normal and have intermediate or elevated levels of amyloid in their brains, is ongoing. The study was fully recruited in October 2024. AHEAD 3-45 is a four-year study conducted as a public-private partnership between Eisai, Biogen and 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. 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 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.