Press release

New data on lecanemab to be presented at CTAD conference

Stockholm, Sweden, November 19, 2025 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai will present the latest findings on lecanemab (Leqembi®) at the Clinical Trials on Alzheimer's Disease (CTAD) conference, being held in San Diego December 1-4. Presentations will include data on long-term treatment and estimated time savings over 10 years, as well as safety and potential benefits of subcutaneous administration of lecanemab for initiation dosing. In addition, data on the effects of lecanemab on soluble amyloid-beta (Aβ) protofibrils[1] and insights from real-world clinical practice studies, including the US ALZ-NET registry, will also be presented.

Key oral presentations

- Continued treatment: On Tuesday, Dec. 2, at 5:05 PM PT and Wednesday, Dec. 3, at 2:40 PM PT, new analyses will be presented on benefits of continued therapy and estimated time savings over 10 years of lecanemab treatment based on Phase 3 clinical data (LB12, LB21).
- Subcutaneous initiation dosing: On Wednesday, Dec. 3, the late-breaking symposium, "Lecanemab Subcutaneous Formulation for Treatment Initiation in Early Alzheimer's Disease: Optimizing Patient Care with a Potential New Option" (3:10 – 3:50 PM PT), will explore potential benefits of subcutaneous lecanemab initiation dosing as well as pharmacokinetic and safety findings (LB Symposium 2).
- Real-world experience: A presentation on Thursday, Dec. 4, at 11:40 AM PT will share findings from an interim analysis of a post-marketing observational study of lecanemab in Japan (OC30).
- Mechanism-related: A presentation scheduled for Tuesday, Dec. 2, at 1:40 PM PT, will review the effects of lecanemab treatment on soluble Aβ protofibrils in the Clarity AD clinical trial (OC5).

Key lecanemab poster presentation:

Real-world experience: During the poster session on Monday, Dec. 1, at 3:00 PM PT and Tuesday, Dec. 2, at 5:30 PM PT, Poster 055 presents an overview of baseline characteristics and preliminary safety findings from a study of lecanemab in Alzheimer's disease (AD) using the ALZ-NET registry.

[1] Protofibrils are thought to be the most toxic Aβ species that contribute to brain damage in AD and play a major role in the cognitive decline of this progressive and devastating disease. Protofibrils can cause neuronal and synaptic damage in the brain, which can subsequently adversely affect cognitive function through multiple mechanisms. The mechanism by which this occurs has been reported not only by increasing the formation of insoluble Aβ plaques, but also by directly damaging signaling between neurons and other cells. It is believed that reducing protofibrils may reduce neuronal damage and cognitive impairment, potentially preventing the progression of AD.

Additional lecanemab poster presentations

Poster Session Date	Title, Abstract Number
Dec. 1 (Mon.) – Dec. 2 (Tues.)	Characterizing Enrollment Patterns in a Preclinical Alzheimer's Disease Trial (P006)
Dec. 1 (Mon.) – Dec. 2 (Tues.)	Stability and Improvement in Early Alzheimer's Disease with Lecanemab: Sub-analysis from a United States Multicenter, Retrospective Real-World Study (P049)
Dec. 1 (Mon.) – Dec. 2 (Tues.)	Long-Term Benefit of Lecanemab in Patients with Low Baseline Amyloid: Estimation of Time Saved (P052)
Dec. 1 (Mon.) – Dec. 2 (Tues.)	Patient, Care Partner, and Health Care Professional Acceptability of the Autoinjector for the Subcutaneous Delivery of Lecanemab in Patients with Early Alzheimer's Disease in the US (P053)
Dec. 1 (Mon.) – Dec. 2 (Tues.)	Real-World Clinical, Safety and Patient-Reported Outcomes of Treatment with Lecanemab in a New England Alzheimer's Disease Center (P072)
Dec. 1 (Mon.) – Dec. 2 (Tues.)	Comparison of Amyloid-related Imaging Abnormalities Risk for Lecanemab versus Donanemab and the Potential Implications (P096)
Dec. 3 (Weds.)	Binding profiles of lecanemab and other amyloid-beta antibodies to amyloid-beta species isolated from Alzheimer's disease brain (P292)
Dec. 3 (Weds.)	C2N Eligibility, APOE Genotype Identification, Amyloid Confirmation Results from the AHEAD 3-45 Programme at Neuroclin Glasgow (P256)
Dec. 3 (Weds.)	A Simulation of Long-Term Lecanemab Treatment Effect on the Alzheimer's Disease Progression in ApoE4 Non-Carriers and Heterozygous Carriers (P278)
Dec. 3 (Weds.)	Neuro-Dynamic Quantitative Systems Pharmacology (QSP) Model Predicts Increasing Benefits of Continued Lecanemab Treatment with Clarity AD 48-Month Data (P279)
Dec. 4 (Thurs.)	Clinical Outcomes and Patient Experience of Subcutaneous Lecanemab Administration from an Alzheimer's Disease Treatment Center (P342)
Dec. 4 (Thurs.)	Societal Cost and Efficiency Comparison of Subcutaneous vs Intravenous Lecanemab for Early Alzheimer's Disease in the United States (P361)

Leqembi 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 Leqembi for Alzheimer's disease. 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 November 19, 2025, at 00:30 a.m. CET.

For further information, please contact:
Oskar Bosson, VP Communications and Investor Relations
E-mail: oskar.bosson@bioarctic.com
Telephone: +46 704 107 180

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 51 countries and is under regulatory review in 9 countries. Following the initial phase with treatment every two weeks for 18 months, intravenous (IV) maintenance dosing with treatment every four weeks is approved in the United Kingdom, China, the U.S. and other countries, and applications have been filed in 4 countries and regions. In the U.S., Leqembi Iqlik™ is approved for subcutaneous dosing with an autoinjector for maintenance treatment of early Alzheimer's disease. In September 2025, a rolling sBLA application to the U.S. FDA for the subcutaneous initiation dosing with Leqembi Iqlik was also initiated.

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 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.