Press release

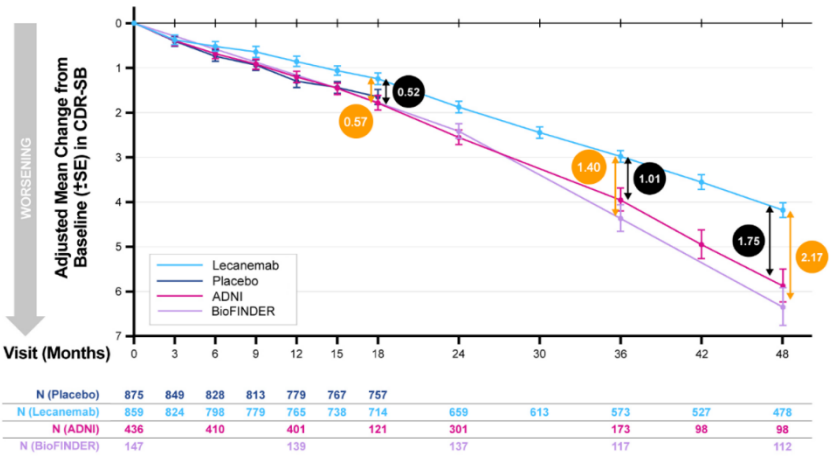
Latest data presented at AAIC 2025 reinforces lecanemab's clinical effect with consistent safety profile

Stockholm, Sweden, July 31, 2025 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai presented the latest findings on lecanemab (Leqembi®) at the Alzheimer's Association International Conference (AAIC), held in Toronto, July 27 to 31. The presentations included four-year treatment data from the phase 3 Clarity AD open-label extension study, data on subcutaneous dosing and interim data from an ongoing real-world evidence study. The data further reinforces the clinical efficacy of lecanemab, with a safety profile in line with the phase 3 Clarity AD core study results.

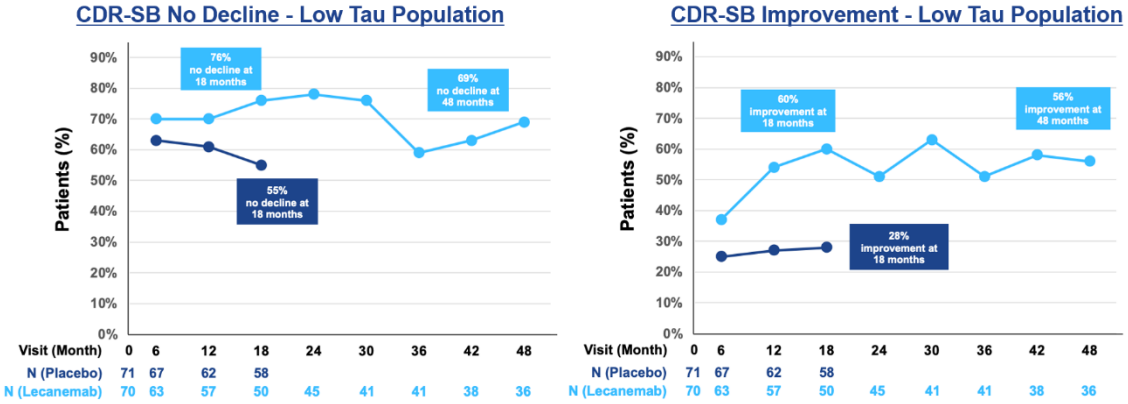
1. Four years of lecanemab treatment helped patients remain in early stage of Alzheimer's disease longer compared to natural disease course, with consistent safety profile

In the core phase 3 study of lecanemab in early Alzheimer's disease, Clarity AD, the mean change from baseline between the lecanemab treated group and the placebo group after 18 months was -0.45 (p=0.00005) on the primary endpoint of CDR-SB global cognitive and functional scale, corresponding to a 27% slowing of clinical decline. A change from 0.5 to 1 on the CDR score domains of Memory, Community Affairs and Home/Hobbies reflect a shift from mild impairment to loss of independence.

Of the patients who completed the core study, 95% chose to continue in the open-label extension study (OLE). Over three years of treatment, including both the core study and the OLE, lecanemab demonstrated 1.01 points less decline, measured by CDR-SB, compared to the Alzheimer's Disease Neuroimaging Initiative (ADNI)[i] cohort. This benefit became more pronounced after four years, with a less decline of 1.75 points. Similarly, when benchmarked against the expected decline in the BioFINDER[ii] cohort, lecanemab showed a 1.40-point difference over three years and 2.17-point difference at the four-year mark. These data indicate that lecanemab treatment slows disease progression by approximately one year compared to no treatment over a four-year period.



The Clarity AD study included a tau PET sub study. Among participants of this sub study with low levels of tau, an indicator for early-stage Alzheimer's disease, 69% showed improvement or no decline, and 56% showed improvement from baseline on the CDR-SB after four years of lecanemab treatment. Similar results were observed on the ADAS-Cog14 scale (51% and 51% respectively) and on the ADCS-MCI-ADL scale (64% and 58% respectively). These findings suggest that initiating and maintaining treatment with lecanemab in early-stage Alzheimer's disease may slow clinical decline and offer sustained long-term benefits.



No new safety findings were observed in the OLE with continued lecanemab treatment over four years. Rates of amyloid-related imaging abnormalities (ARIA) decreased after the initial 12 months and remained consistent throughout four years of continuous treatment.

2. Interim real-world data show 84% of patients on lecanemab either remained stable or clinically improved with a safety profile in line with phase 3 data

A retrospective, multicenter, real-world study in the United States showed that a large majority of patients remained at the same clinical stage or improved from mild dementia to mild cognitive impairment (MCI), with about 77% remaining stable and 7% showing improvement. The results

encompass data from 178 patient case studies across nine diverse U.S. sites. Patients received lecanemab for an average of 375 days and a mean of 25 doses.

The data also revealed that a longer treatment duration correlated with increased effectiveness. Notably, 20% of patients receiving 40 or more doses (around 18 months; n=15) improved from mild Alzheimer's disease to MCI. Furthermore, the interim data showed high retention rates with approximately 87% of patients continuing therapy, as well as safety data in line with the FDA-approved label, with most ARIA cases reported as asymptomatic (1.1% symptomatic ARIA-E and 0% symptomatic ARIA-H).

The full study will include 15 healthcare professionals (HCPs) and 320 patients with early Alzheimer's disease, with final results expected by the end of 2025.

3. Subcutaneous dosing of lecanemab could offer a new option for treatment of early Alzheimer's disease

Several clinical trials investigating subcutaneous (SC) dosing of lecanemab have been conducted, including a sub-study within the open-label extension of the phase 3 Clarity AD study. These trials evaluated various doses administered subcutaneously. Eisai has developed a SC autoinjector to deliver a weekly maintenance dose of 360 mg, and a 500 mg SC autoinjector is currently being developed for initiation dosing.

Data presented at the AAIC demonstrate that transitioning to a weekly 360 mg SC autoinjector dose of lecanemab, following 18 months of initiation dosing with 10 mg/kg (IV) biweekly, maintains clinical and biomarker benefits comparable to continued biweekly intravenous administration. Data also show the 500 mg SC autoinjector provides equivalent exposure to the initial 10 mg/kg intravenous biweekly treatment regimen up to 18 months, with comparable effects on amyloid removal, efficacy, and ARIA-E.

The safety profile of 360 mg weekly SC maintenance dose was consistent with that of IV maintenance therapy, with systemic injection or infusion reactions occurring in less than 1% of patients. Across all SC doses, the rate of systemic injection/infusion reactions was 1% compared to 26% with IV. The 360 mg SC maintenance dose was initiated after 18 months of intravenous treatment, beyond the high-risk period for ARIA. No cases of ARIA-E were observed among 49 treated with the 360 mg SC weekly maintenance dose over an average of six months.

In addition, two studies – one evaluating human factors and another assessing subcutaneous autoinjector device tolerability – found that subcutaneous dosing allows patients to easily use the device at home, shortens treatment time, and enables continuation of therapy without visits to an infusion center, according to patients and care partners. Healthcare professionals reported that the device has the potential to offer a new option for patients benefiting from lecanemab treatment. The SC formulation has the potential to reduce medical preparation and administration time related to

intravenous therapy. These factors suggest that the SC autoinjector may play an important role in the treatment of early Alzheimer's disease.

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 31, 2025, at 01:30 a.m. CET.

For further information, please contact:
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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 46 countries including the U.S., Japan, China, and the European Union 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), and is under regulatory review in 10 countries

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.

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[i] ADNI is a clinical research project launched in 2005 to develop methods to predict the onset and progression of AD and to confirm the effectiveness of treatments. The project involves a multi-year longitudinal observation targeting healthy elderly individuals as well as patients with mild cognitive impairment (MCI) and early stages of AD

[ii] BioFINDER subjects are similar to Clarity AD and ADNI subjects, except all BioFINDER subjects are in the MCI stage and no mild AD subjects are included, and their baseline CDR-SB is lower. BioFINDER is a large-scale, long-term prospective study led by Lund University in Sweden, aiming to establish early diagnosis and elucidate pathophysiology of neurodegenerative diseases. In addition to AD, the study also focuses on conditions including Parkinson's Disease. Individuals participating in the study undergo regular clinical assessments, cognitive function tests, brain imaging (MRI, Aβ PET, Tau PET), and collection of biomarkers from blood and cerebrospinal fluid (CSF).