## Press release

# New Leqembi-data presented at CTAD 2025 suggests potential to delay disease progression by up to 8.3 years with continued treatment

**Stockholm, Sweden, December 4, 2025 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai presented the latest findings on time saved with continued treatment with lecanemab (Leqembi®) at the 18th Clinical Trials in Alzheimer's Disease (CTAD) conference, held in San Diego December 1-4. Data suggests potential to delay disease progression from Mild cognitive impairment (MCI) to moderate Alzheimer's disease (AD) by up to 8.3 years in the low-amyloid group who started treatment at an early stage.**

Additionally, a scientific symposium was held on the subcutaneous formulation with an autoinjector (SC-AI), which was approved for maintenance treatment in the United States in August 2025, and the rolling supplemental Biologics License Application (sBLA) for initiation treatment was completed in November 2025. The application for a subcutaneous injectable formulation in Japan was submitted in November 2025.

Real-world data from different clinics and countries were also presented at the congress, demonstrating continued clinical benefit with lecanemab treatment and a safety profile consistent with the phase 3 Clarity AD study.

The presentations in summary:

**Estimating the 10-year time-savings benefits of lecanemab treatment** (Presentation: December 3) Based on data from the Clarity AD open-label extension (OLE) and 16 clinical studies of monoclonal antibodies for Alzheimer's disease (AD), this analysis estimated long-term disease progression over 10 years and the slowing effect of continued lecanemab treatment. The analysis evaluated estimated "time savings" (slowing of disease progression) compared to natural decline based on ADNI[1] (Alzheimer's Disease Neuroimaging Initiative) data (untreated group), using Clinical Dementia Rating - Sum of Boxes (CDR-SB). These results suggest that early initiation and long-term lecanemab treatment may continue to slow AD progression and help maintain cognitive function over a longer period.

Findings from each group:

- Time Savings from Mild Cognitive Impairment (MCI) Due to AD to Mild AD
  - The time to progression from MCI due to AD to mild AD was 7.2 years in the untreated group, whereas with continued Leqembi treatment to the onset of moderate AD, progression to mild AD took 9.7 years, indicating a time savings of 2.5 years.

[1] 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.

- In the low-amyloid group (patients who started treatment at an early stage: amyloid PET <60 centiloids), the time to progression from MCI to mild AD was 13.2 years with continued Leqembi treatment to the onset of moderate AD, suggesting a time savings of 6.0 years.

- Time Savings from MCI due to AD to Moderate AD
  - The time to progression from MCI due to AD to moderate AD was 10.1 years in the untreated group, whereas with continued Leqembi treatment to the onset of moderate AD, progression to moderate AD took 13.6 years, indicating a time savings of 3.5 years.
  - In the low-amyloid group, the time to progression with continued Leqembi treatment to the onset of moderate AD was 18.4 years, suggesting a time savings of 8.3 years.

These findings indicate that earlier initiation of Leqembi treatment may provide a greater delay in disease progression. Furthermore, each additional year on Leqembi could further delay disease progression compared to stopping treatment, even long after plaque is expected to have been cleared.

**Lecanemab Subcutaneous Formulation for Treatment Initiation in Early Alzheimer's Disease: Optimizing Patient Care with a Potential New Option** (Symposium presentation: December 3)
In this symposium, the latest data from the lecanemab subcutaneous clinical development program were presented focusing on treatment initiation, including results from the subcutaneous (SC) formulation subcohort (n=273) in the Clarity AD trial OLE. It was shown that weekly administration of lecanemab SC-AI at 500 mg (two 250 mg injections) demonstrated bioequivalence in drug exposure compared to intravenous (IV) dosing of 10 mg/kg every two weeks (exposure ratio: 104%, 90% CI: 99.1%–109%).

Based on clinical data and modeling analysis, the effect on amyloid removal in the brain and safety (ARIA-E incidence) was shown to be independent of the route of administration and explained by exposure, suggesting that weekly 500 mg SC dosing provides similar efficacy and safety to biweekly 10 mg/kg IV dosing. Additionally, ARIA-E incidence was also predicted to be comparable between SC and IV administration (12.4% overall, 30.9% in ApoE4 homozygotes).

In this sub-cohort which had prior exposure to lecanemab, safety evaluation showed systemic infusion reactions occurred in 0% of patients receiving 500 mg SC, all of whom had previously received IV lecanemab. For patients who initiated treatment on 720 mg lecanemab SC by vial, 1.4% showed systemic infusion reactions. This should be compared with systemic infusion reactions of 26.4% in those treated with IV. Immunogenicity assessment indicated a low incidence of anti-drug antibodies (ADA) at 1.4%.

These results indicate that the subcutaneous formulation of lecanemab, designed with consideration for the convenience of patients and their care partners, maintains efficacy with a low incidence of systemic infusion reactions, and is otherwise equivalent to conventional IV administration.

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.

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*The information was released for public disclosure, through the agency of the contact person below, on December 4, 2025, at 07:45 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 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 (AD). In November 2025, a rolling sBLA application to the U.S. FDA for the subcutaneous initiation dosing with Leqembi Iqlik was also completed and a new drug application for subcutaneous formulation of Leqembi was submitted in Japan.

Since July 2020, Eisai's Phase 3 clinical study (AHEAD 3-45) with lecanemab in individuals with preclinical Alzheimer's disease 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.