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Press release

More than 75% of Leqembi®-treated patients remained stable and nearly 7% improved over an average of 17 months of treatment in real-world LEADER study data presented at AAIC® 2026

Stockholm, Sweden, July 14, 2026 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai today presented results from the real-world Lecanemab in Early Alzheimer's Disease (LEADER) Study showing that nearly 83% of patients with early Alzheimer's disease (AD) enrolled in the study remained stable (75.9%) or improved (6.6%) while receiving Leqembi over an average of 17 months. The results were consistent across sex, race, ethnicity and APOE genotype.

The data were presented during the session "*Developing Topics Session #3-33-DEV-A: Lecanemab Three Years Post-Approval: A Comprehensive Multicenter, Real-World, Retrospective Study (LEADER) in Diverse US Clinical Settings*" at the Alzheimer's Association International Conference® (AAIC®) 2026 in London. These findings support long-term benefits of continuous treatment with Leqembi and provide important insights into treatment experience outside of a clinical trial setting.

LEADER study design
The three-year LEADER study is a multicenter, retrospective real-world study designed to examine Leqembi utilization, treatment persistence, transition to maintenance therapy, safety, cognitive and functional assessments, and healthcare professional (HCP) implementation learnings in diverse US clinical settings for patients with early AD. The study integrated deidentified chart and electronic medical record (EMR) data from 13 US sites, HCP surveys and HCP interviews. This interim analysis included 432 patients with early AD who received at least seven Leqembi infusions as of May 2026.

Patient characteristics at baseline:

- Mean age: 74 years
- Female Patients: 55.8%

Disease stage at baseline:

- Mild cognitive impairment (MCI) due to AD: 63.9%
- Mild AD dementia: 36.1%

Treatment:

- The mean duration of Leqembi treatment was 520 days
- The mean number of Leqembi doses was 26
- Change in disease stage was defined as:
  - Stable: Patient remaining in the same disease stage (MCI due to AD or mild AD dementia) from baseline throughout the course of Leqembi treatment.
  - Improvement: Patient transitioning from mild AD dementia at baseline to MCI due to AD over the course of Leqembi treatment.
  - Progression: Patient advancing from MCI at baseline to mild/moderate AD dementia or from mild AD dementia at baseline to moderate AD dementia throughout the course of Leqembi treatment.

LEADER study key findings

1. Real-world evidence shows long-term benefit with continuous Leqembi treatment across sex, race, ethnicity and APOE genotype
2. Real-world safety consistent with US FDA-approved label

Overall study population findings

- Of the 432 participants enrolled in the LEADER Study, disease stage could be evaluated in 427. Among these patients with early Alzheimer's disease, 82.5% remained stable or improved while receiving Leqembi, with consistent results across sex, race, ethnicity, and APOE genotype groups.
- 75.9% remained stable compared with baseline, meaning they remained in the same disease stage throughout treatment.
- 6.6% improved from baseline, moving from mild AD dementia to MCI due to AD.
- Nearly 87% of patients chose to remain on Leqembi treatment.
- In analyses by APOE ε4 status, clinician-evaluated stable or improved disease stage was observed in:
  - 81.7% of APOE ε4 heterozygotes (stable: 73.8%; improved: 7.9%)
  - 81.0% of APOE ε4 homozygotes (stable: 75.9%; improved: 5.2%).

Maintenance Dosing Population Findings

- Of the 432 participants in the LEADER study, 155 transitioned to once-every-four-weeks intravenous (IV) maintenance treatment, and 14 transitioned to once-weekly subcutaneous (SC) maintenance treatment.
- Among the 155 participants who transitioned to IV maintenance therapy, nearly 81% remained stable (72.3%) or improved (8.4%).
- Of the 14 patients who transitioned to SC maintenance treatment, 12 (85.7%) maintained their disease stage.

Overall safety observations in this real-world study were consistent with the US FDA-approved label.

- ARIA[1] was observed in 12.3% of patients overall; ARIA-E was observed in 6.3% and ARIA-H in 7.9% and isolated ARIA-H in 6.0%. Most ARIA cases were asymptomatic and mild in radiographic severity.
- No new ARIA-E events, macrohemorrhages or intracerebral hemorrhages greater than 1cm were reported during once-every-four-weeks IV maintenance therapy.

APOE ε4 status safety observations were consistent with the overall cohort and the US FDA-approved label.

- ARIA-E was observed in 5.3% of APOE ε4 noncarriers, 6.1% of APOE ε4 heterozygotes and 10.3% of APOE ε4 homozygotes.
- ARIA-H was observed in 12.1%, 4.8% and 12.1%, respectively.
- In APOE ε4 homozygotes, no severe ARIA was reported, and all graded ARIA cases were mild to moderate in radiographic severity.

[1] ARIA refers to amyloid-related imaging abnormalities that can be observed with anti-amyloid beta antibody treatment and includes ARIA-E, which involves edema/effusion, and ARIA-H, which involves hemosiderin deposition, including cerebral microhemorrhage, cerebral macrohemorrhage and superficial siderosis, as observed on brain magnetic resonance imaging (MRI)

Antithrombotic therapy, including anticoagulants or antiplatelet medications, was used by 106 patients, representing 24.5% of the study population.

- Of these, 11 patients were receiving an anticoagulant, either alone or with an antiplatelet medication, and 95 patients were receiving antiplatelet therapy only.
- Among patients receiving antithrombotic therapy, the incidence of ARIA was not meaningfully different from that observed in patients not receiving antithrombotic therapy.

The information was released for public disclosure, through the agency of the contact person below, on July 14, 2026, at 5:15 pm CEST.

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About 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).

Leqembi is approved in 53 countries and is under regulatory review in 6 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 8 countries, including the United Kingdom, China, the US and Japan, and applications have been filed in 12 countries and regions. In the US, Leqembi Iqlik® is approved for subcutaneous dosing with an autoinjector as a starting dose and maintenance treatment of early Alzheimer's disease. In November 2025, a new drug application for subcutaneous formulation of Leqembi was submitted in Japan. In December 2025, Leqembi was included in the "Commercial Insurance Innovative Drug List", recently introduced by the National Healthcare Security Administration (NHSA) of China. In January 2026, the Biologics License Application for subcutaneous formulation of Leqembi was accepted in China and in February, the application was designated for priority review.

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 Alzheimer's disease and related dementias in the US, 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 Alzheimer's disease (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 lecanemab 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.