BIOARCTIC

Press release

New three-year real-world data on Leqembi® presented at CTAD 2026

Stockholm, Sweden, November 18, 2026 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai today presented new results from the real-world Lecanemab in Early Alzheimer's Disease (LEADER) study[1]. The data showed that patients treated with Leqembi had a 76% lower rate of progression to moderate or severe Alzheimer's disease dementia compared with a matched natural history cohort through 36 months of treatment. The new analysis included 560 patients treated with Leqembi across 13 clinical sites in the US.

The data were presented at the 19th Clinical Trials on Alzheimer's Disease (CTAD) conference in Boston and represent the largest analysis of the ongoing LEADER study reported to date. The results provide further insights into treatment with Leqembi in clinical practice, including disease progression, amyloid clearance, treatment persistence, expanded subcutaneous maintenance treatment experience and safety. The findings were presented alongside an international real-world meta-analysis of approximately 5,000 patients treated with Leqembi.

LEADER study key findings

LEADER patients showed slower progression compared to ADNI control[2]:

- In a pre-specified comparison of patients in LEADER (N=504) with an ADNI-weighted external control cohort (N=573), patients treated with Leqembi had a 76% lower rate of progression to moderate or severe Alzheimer's disease dementia through 36 months (HR 0.24; 95% CI, 0.15–0.39).

More than 8 in 10 patients remained stable or improved[3]:

- Among 546 patients whose change in disease stage could be assessed after an average of approximately 18 months of treatment, 81.1% were reported as stable or improved compared with baseline. Of these patients, 75.8% remained stable and 5.3% improved.
- Results were generally consistent across groups defined by sex, race, ethnicity, APOE genotype and concomitant antithrombotic use.
- At the time of chart extraction, 87.5% of the 560 patients remained on Leqembi treatment, with an average treatment duration of approximately 19 months.

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[1] 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 U.S. clinical settings for patients with early AD. The study integrated deidentified chart and electronic medical record (EMR) data from 13 U.S. sites, HCP surveys and HCP interviews. This updated analysis included 560 patients with early AD who, as of September 2026, received at least seven LEQEMBI initiation infusions. The maintenance therapy analysis included patients who received biweekly IV initiation treatment for 18 months, followed by at least three months of IV or SC maintenance therapy.

[2] 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.

[3] Change in clinical disease stage was defined as:

- Stable: Patient remaining in the same clinical 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.

Most patients estimated to remain in early Alzheimer's disease:

- Among all 560 patients in the study, 95.0% were estimated to remain in the early stages of Alzheimer's disease through three years of treatment, based on statistical modeling of observed real-world patient data.

New real-world evidence shows amyloid clearance:

- Among 43 patients across six sites performing both baseline and follow-up amyloid PET scans, 77% (33) became amyloid-negative at a median follow-up of 18.1 months. (IQR 16.4–18.7 months).

Expanding experience with Leqembi maintenance therapy:

- Of the patients who reached 18 months of treatment, 91.7% remained on Leqembi. A total of 218 patients transitioned to intravenous (IV) maintenance treatment once-every-four-weeks., Following approval of once-weekly subcutaneous (SC) maintenance treatment, 64 patients transitioned to that regimen.
- Among patients receiving monthly IV maintenance treatment, 71.1% remained stable after an average of 26 months from treatment initiation. Among patients receiving weekly SC maintenance treatment, 76.6% remained stable after an average of 25.1 months.
- All 64 patients receiving SC maintenance treatment remained on therapy at the time of chart extraction.
- No ARIA[4] events were reported during the subcutaneous maintenance period, and there were no other safety events of significance. Isolated ARIA-H was reported in 0.5% of patients during the IV maintenance period.

Clinical outcomes consistent between women and men

- 79.3% of women (N=300) and 83.3% of men (N=246) in the study were reported as stable or improved[3].
- Treatment duration and persistence were similar across sexes, with 86.0% of females and 88.9% of males remaining on therapy at time of chart extraction.
- ARIA incidence and severity were generally consistent between female and male patients: any ARIA (14.7% females vs. 17.0% males), ARIA-E (7.5% females vs. 5.5% males), ARIA-H (9.8% females vs. 12.6% males), isolated ARIA-H (7.2% females vs. 11.5% males).

Safety findings consistent with other real-world experience:

Overall safety findings in LEADER were consistent with the independent ALZ-NET registry and the US prescribing information for Leqembi.

- ALZ-NET is a North American voluntary health care provider-enrolled patient network that collects longitudinal clinical, imaging, and safety data in patients treated with FDA-approved AD therapies. Over 1,700 patients taking Leqembi were included in ALZ-NET at the time of data extraction.
- ARIA-E was observed in 6.6% of patients in LEADER compared with 6.3% in ALZ-NET, while ARIA-H was observed in 11.1% and 10.1% of patients, respectively.
- Observed ARIA rates were generally consistent regardless of APOE ε4 status, concomitant antithrombotic use, race and ethnicity.

[4] 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).

Additional real-world analysis of approximately 5,000 patients[5]:
A separate post hoc exploratory analysis presented at CTAD evaluated 16 published real-world Leqembi cohorts across six countries, representing approximately 5,000 patients treated in routine clinical practice.

- Across the 16 studies, the pooled total ARIA rate was 12.4%, compared with 21.5% in the Phase 3 Clarity AD study. ARIA-E occurred in 4.0% compared with 12.6% in Clarity AD, while ARIA-H occurred in 9.4% compared with 17.3%.
- Symptomatic ARIA was reported in 0.8% compared with 2.8% in Clarity AD.
- Treatment discontinuation due to adverse events was 3.2%.

Limitations of Real-World Studies
Retrospective real-world studies can be valuable in providing additional information to complement clinical trial data; however, there are potential limitations to consider, including: potential for biases, data completeness and consistency, lack of a control group, interpretation of data due to lack of placebo-controlled arms, and confounding variables, and data inconsistency. Data inconsistency may be mitigated by providing site access to standardized electronic case-report forms.

The information was released for public disclosure, through the agency of the contact person below, on November 18, 2026, at 5.15 pm CET.

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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 six countries and regions. Following the initial phase with treatment every two weeks for 18 months, intravenous (IV) maintenance dosing with treatment every four weeks is approved in nine countries and regions, including the US, Japan, China and the United Kingdom, and applications have been filed in eleven 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. Subcutaneous initiation treatment was approved in China and Japan in September 2026, and applications are under review in four countries.

Eisai's Phase 3 clinical study (AHEAD 3-45) with lecanemab in individuals with preclinical Alzheimer's disease has been ongoing since July 2020. These individuals are clinically normal and have intermediate or elevated levels of amyloid in their brains. 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

[5] The meta-analysis on ARIA rates and safety profiles in clinical practice included centers located in the U.S., China, South Korea, Japan, Italy and Israel. Patients were treated between 2023 and 2026 and received at least six months of LEQEMBI treatment.

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
BioArctic has a long-term collaboration with Eisai since 2005 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 in 2007, and the Development and Commercialization agreement for the antibody lecanemab back-up for Alzheimer's disease, which was signed in 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 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 therapies 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.