Press release

New clinical data on the Leqembi® subcutaneous autoinjector presented at AAIC® 2026 support similar efficacy and safety to IV formulation in early Alzheimer's disease

Stockholm, Sweden, July 12, 2026 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai today presented new data at the 2026 Alzheimer's Association International Conference (AAIC), held in London, July 12-15, demonstrating that the Leqembi (lecanemab) subcutaneous autoinjector (SC-AI) formulation offers efficacy and safety comparable to intravenous (IV) administration in people with early Alzheimer's disease. The findings support a fully subcutaneous treatment pathway from initiation through maintenance treatment, offering greater convenience and flexibility for patients and care partners.

Key findings:

The data were presented during the Developing Topics session, "Lecanemab Subcutaneous Formulation in Early Alzheimer's Disease: Emerging Clinical Evidence and Practical Use Considerations" (Session #1-32-FRS-C). The session highlighted findings from the lecanemab SC-AI development program in early Alzheimer's disease, including pharmacokinetic (PK), pharmacodynamic (PD), efficacy, safety and real-world patient and care partner experience data.

Results showed that once-weekly 500 mg SC-AI achieved drug exposure similar to the approved IV initiation regimen (10 mg/kg every two weeks), supporting the expectation of similar clinical efficacy and safety, regardless of the route of administration.

The subcutaneous dosing option may offer a convenient at-home alternative to IV infusion, with the potential to expand treatment access and support more flexible care delivery across healthcare settings.

Data showed:

- **Bioequivalence achieved:** Once-weekly 500 mg SC-AI demonstrated bioequivalence to the IV initiation regimen (10 mg/kg every two weeks), with an exposure ratio of 104% (90% confidence interval [CI]: 99.1%–109%). Exposure remained consistent across body weight quartiles, demonstrating a stable pharmacokinetic profile in a broad patient population.
- **Efficacy driven by exposure, not route of administration:** Amyloid removal measured by amyloid PET, clinical efficacy measured by CDR-SB, and the incidence of ARIA-E were driven by lecanemab exposure rather than the route of administration. The 500 mg SC-AI initiation regimen achieved exposure comparable to the IV initiation regimen, supporting the expectation of a comparable efficacy and safety profile despite the different route of administration.
- **Consistent results across patient populations:** The 500 mg SC-AI initiation regimen demonstrated consistent exposure, amyloid clearance as measured by amyloid PET, clinical efficacy and safety across body weight groups. Amyloid clearance and clinical outcomes were not meaningfully affected by body weight, supporting the use of a fixed-dose regimen.

- **Flexible administration options:** Patients may switch between IV and SC administration as needed, and if a dose is missed, treatment can be administered the following day or up to six days later, providing greater flexibility and convenience in Leqembi administration.

Safety profile of subcutaneous Leqembi aligned with the IV formulation:

- Overall safety profile of SC-AI was generally consistent with that observed for the IV formulation.
- Incidence of ARIA-E with the 500 mg SC-AI initiation regimen was predicted to be similar to that observed with the IV initiation regimen.
- Injection-related reactions were observed with subcutaneous Leqembi, most of which were localized, while systemic reactions were less frequently observed.
- The incidence of anti-drug antibodies was low, at 1.4% in the 500 mg SC-AI group. No neutralizing antibodies were observed, confirming that the low immunogenicity profile was maintained with the SC-AI formulation.

Clinical trial perspectives and real-world evidence: sustained clinical benefit with SC-AI

Data from two US Alzheimer's treatment centers (Alzheimer's Research and Treatment Center, and First Choice Neurology and Visionary Investigators Network) provide early insight into clinical trial and real-world use of subcutaneous Leqembi:

- At Alzheimer's Research and Treatment Center, 28 patients receiving SC administration demonstrated slower cognitive decline as measured by CDR-SB[1] over 36 months relative to a matched Alzheimer's Disease Neuroimaging Initiative (ADNI) natural history cohort. The cohort included 25 patients newly initiated on SC administration and 3 patients who transitioned from IV administration.
- In a separate case series from First Choice Neurology and Visionary Investigators Network, 10 of 11 evaluable patients (91%) showed improvement or remained stable on MMSE[2] compared with baseline before maintenance therapy. At this center, patients who had received maintenance therapy with SC administration for at least 6 months were included in the analysis.
- Patient and care partner surveys conducted at these two sites demonstrated high satisfaction with subcutaneous Leqembi administration, with satisfaction rates ranging from 75% to 97%, convenience ratings from 83% to 97%, and willingness to recommend treatment ranging from 92% to 100%.

Results presented in this session further reinforce the importance of early and continuous treatment, highlighting how Leqembi SC initiation and maintenance administration provides greater optionality for long-term disease management.

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[1] Clinical Dementia Rating–Sum of Boxes (CDR-SB) is a standard scoring system used to quantify the severity of dementia in Alzheimer's disease.

[2] Mini-Mental State Examination (MMSE) is a 30-point questionnaire used to assess cognitive impairment and screen for Alzheimer's disease.

This release discusses investigational uses of an agent in development and is not intended to convey conclusions about efficacy or safety. There is no guarantee that such investigational agents will successfully complete clinical development or gain health authority approval.

The information was released for public disclosure, through the agency of the contact person below, on July 12, 2026, at 5:30 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 for 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, Eisai's supplemental Biologics License Application (sBLA) regarding a subcutaneous starting dose with Leqembi Iqlik was granted Priority Review by the US FDA. The sBLA has been assigned an extended PDUFA date of August 24, 2026. 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.