BIOARCTIC

Press release

FDA approves Leqembi Iqlik® (lecanemab-irmb) subcutaneous injection as a starting dose for early Alzheimer's disease

Stockholm, Sweden, July 13, 2026 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai today announced that the US Food and Drug Administration (FDA) has approved a supplemental Biologics License Application (sBLA) for a once weekly lecanemab irmb subcutaneous injection (US brand name: Leqembi Iqlik®) as a starting dose for the treatment of early Alzheimer's disease. The US launch is planned for late August 2026.

Leqembi Iqlik is a first-of-its-kind anti-amyloid treatment worldwide, offering at-home dosing for initiation and maintenance. It is administered via an autoinjector, offering a convenient alternative to intravenous (IV) infusion from the start of treatment. For initiation, the approved regimen is 500 mg once weekly, delivered as two 250 mg injections, each administered in approximately 15 seconds.

Leqembi Iqlik is already approved for maintenance dosing in the US at 360 mg once weekly, once 18 months of IV or subcutaneous treatment has been completed. Patients can now receive Leqembi either as an IV infusion or as a subcutaneous injection (SC) with Leqembi Iqlik throughout the entire treatment course - from initiation through maintenance and may switch between administration methods as needed, providing greater flexibility and convenience.

Leqembi is indicated in the US for the treatment of adults with mild cognitive impairment (MCI) or mild dementia due to Alzheimer's disease, collectively referred to as early Alzheimer's disease. MCI due to Alzheimer's disease represents the earliest symptomatic stage of the disease and may be associated with subtle changes in memory, thinking, language, or daily functioning.

Clinical data supporting FDA approval of subcutaneous initiation dosing
The FDA approval of Leqembi Iqlik for treatment initiation is supported by a comprehensive clinical data package evaluating SC administration of lecanemab across multiple studies and dosing regimens. Data from sub-studies within the Phase 3 Clarity AD long-term extension (LTE), conducted following the 18-month core study in individuals with early Alzheimer's disease, showed:

- Once-weekly subcutaneous administration achieved exposure equivalent to intravenous dosing, supporting similar clinical (efficacy) and biomarker (amyloid removal) benefits.
- The rate of exposure-related adverse events such as ARIA-E with SC administration is expected to be comparable with IV administration. There was no increase in isolated ARIA-H (i.e., ARIA-H in patients who did not also experience ARIA-E) for Leqembi compared to placebo.
- The overall safety profile of SC administration was generally similar to intravenous administration. Injection-related reactions were observed with subcutaneous Leqembi, most of which were localized, while systemic reactions were less frequently observed.

"This approval represents another important step forward in the treatment of Alzheimer's disease," said Gunilla Osswald, CEO of BioArctic. "By providing a new administration option from the start of

treatment, patients, caregivers and healthcare professionals gain greater flexibility in how therapy is delivered. As the Alzheimer's treatment landscape continues to advance, innovations that simplify access and support individualized care will be increasingly important. We are encouraged to see Eisai's diligent work to meet the diverse needs of people living with this difficult disease."

Expanding treatment flexibility across the Alzheimer's disease care pathway
The approval of Leqembi Iqlik as a subcutaneous starting dose provides patients and care partners with the only at-home administration option throughout the Alzheimer's disease treatment journey which could support access and delivery of care across healthcare settings. Subcutaneous administration may:

- Reduce the burden of clinic visits for patients and care partners
- Reduce reliance on infusion and associated healthcare resources
- Decrease treatment preparation and administration time, and nursing monitoring requirements
- Preserve infusion capacity for patients who prefer or require intravenous therapy

Insights from an autoinjector acceptability study indicated that 94% of patients with early Alzheimer's disease and their care partners found the Leqembi Iqlik device easy to use, with high levels of satisfaction and confidence in using it in an at-home setting[1].

Please see full Prescribing Information for Leqembi, including Boxed WARNING.

This is information that BioArctic AB (publ) is obliged to disclose pursuant to the EU Market Abuse Regulation. The information was released for public disclosure, through the agency of the contact person below, on July 13, 2026, at 11:55 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

[1]Based on in-person interviews of 50 patients with early Alzheimer's Disease and 50 care partners currently assisting people with early AD. Participants were given the opportunity to interact with a training autoinjector device (containing no needles or medication) and an injection pad, then asked to answer computer-based surveys about their experience, including "How difficult or easy was it to use the self-injection device?"

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.