Press release

Leqembi® Iqlik™ PDUFA date updated to August 24 in the U.S.

Stockholm, Sweden, May 8, 2026 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai today announced that the U.S. Food and Drug Administration (FDA) has extended the review period by three months for the supplemental Biologics License Application (sBLA) for a once weekly lecanemab irmb subcutaneous injection, also known as Leqembi® Iqlik™, as a starting dose for the treatment of early Alzheimer's disease. The new Prescription Drug User Fee Act (PDUFA) action date is August 24, 2026.

As part of the ongoing review process, the agency requested additional information and has determined that it constituted a major amendment to the sBLA, extending the PDUFA date to allow sufficient time for a full review of the additional materials. The FDA has not raised any concerns to date regarding the approvability of Leqembi Iqlik as a starting dose.

Eisai believes that the comprehensive clinical data package evaluating subcutaneous administration of Leqembi across multiple studies and dosing regimens strongly supports the potential use of Leqembi Iqlik for initiation therapy, following FDA approval of the subcutaneous maintenance dosing regimen on August 26, 2025.

Leqembi has been approved by more than 50 regulatory authorities worldwide, reflecting broad regulatory confidence in Leqembi as a treatment option for early Alzheimer's disease.

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 clinical development, marketing authorization applications 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 currently preparing for a joint commercialization in the region.

This information 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 May 8, 2026, at 8:30 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 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 7 countries, including the United Kingdom, China, the US and Japan, and applications have been filed in 10 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 regarding a subcutaneous starting dose with Leqembi Iqlik was granted Priority Review by the US FDA with a May 24, 2026, PDUFA date. 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.

Please find full Prescribing Information for Leqembi here.

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.