Press release

Leqembi® Iqlik™ (lecanemab-irmb) supplemental Biologics License Application regarding subcutaneous starting dose granted Priority Review by the US FDA

Stockholm, Sweden, January 26, 2026 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that the supplemental Biologics License Application (sBLA) for Leqembi Iqlik subcutaneous autoinjector (SC-AI) as a weekly starting dose has been granted Priority Review by the U.S. Food and Drug Administration (FDA). Leqembi is indicated for the treatment of Alzheimer's disease in patients with Mild Cognitive Impairment (MCI) or mild dementia stage of disease (collectively referred to as early Alzheimer's disease). A Prescription Drug User Fee Act (PDUFA) action date is set for May 24, 2026. If approved, Leqembi Iqlik would be the first and only anti-amyloid treatment to offer at-home injection options for initiation and maintenance dosing for this progressive, relentless disease.

Should the FDA approve the Leqembi Iqlik 500 mg subcutaneous (SC) dosing regimen (two 250 mg injections), the autoinjector could be used to administer a once-weekly starting dose, as an alternative to the current bi-weekly intravenous (IV) dosing. This would enable patients and care partners to choose SC administration at home for both treatment initiation and the currently approved maintenance therapy (360 mg), offering the option of SC or IV administration throughout the entire treatment journey. The injection time for each Leqembi Iqlik autoinjector takes approximately 15 seconds per each 250 mg injection. The SC formulation also has the potential to reduce healthcare resources associated with IV dosing, such as infusion preparation and nurse monitoring, while streamlining the overall Alzheimer's disease treatment pathway.

The sBLA is supported by data evaluating SC administration of lecanemab across a range of doses and as part of sub-studies within the Phase 3 Clarity Alzheimer's disease open-label extension (OLE) following the 18-month core study in individuals with early Alzheimer's disease. Data show that once-weekly administration of the 500 mg of SC-AI achieved equivalent exposure to once every two weeks IV administration and similar clinical and biomarker benefits. SC administration demonstrated a safety profile similar to IV administration, with less than 2% incidence of systemic injection or infusion-related reactions.

Alzheimer's disease is a progressive, relentless disease, with amyloid beta (Aβ) and tau as hallmarks, that is caused by a continuous underlying neurotoxic process driven by protofibrils* (PF) that begins

before amyloid plaque removal and continues afterward[1,2,3]. Only Leqembi fights Alzheimer's disease in two ways – targeting both PF and amyloid plaque, which can impact tau downstream.

Please see full **Prescribing Information** for Leqembi in the US, including Boxed WARNING.

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 January 26, 2026, at 00:30 CET.

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About lecanemab (Leqembi®)
Lecanemab 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).

Lecanemab is approved in 53 countries and is under regulatory review in 7 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 the United Kingdom, China, the U.S. and other countries, and applications have been filed in 4 countries and regions. In the U.S., Leqembi Iqlik™ is approved for subcutaneous dosing with an autoinjector for maintenance treatment of early Alzheimer's disease (AD). In November 2025, a rolling sBLA application to the U.S. FDA for the subcutaneous initiation dosing with Leqembi Iqlik was also completed and a new drug application for subcutaneous formulation of Leqembi was submitted in Japan. In December 2025, Lecanemab has been included in the "Commercial Insurance Innovative Drug List", recently introduced by the National Healthcare Security Administration (NHSA) of China.

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 AD and related dementias in the U.S., 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 AD (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

[1] Amin L, Harris DA. Aβ receptors specifically recognize molecular features displayed by fibril ends and neurotoxic oligomers. Nat Commun. 2021;12:3451. doi:10.1038/s41467-021-23507-z.
[2] Ono K, Tsuji M. Protofibrils of Amyloid-β are Important Targets of a Disease-Modifying Approach for Alzheimer's Disease. Int J Mol Sci. 2020;21(3):952. doi: 10.3390/ijms21030952. PMID: 32023927; PMCID: PMC7037706.
[3] Hampel H, Hardy J, Blennow K, et al. The amyloid-β pathway in Alzheimer's disease. Mol Psychiatry. 2021;26(10):5481-5503.

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 Leqembi 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.