Press release

Eisai submits Marketing Authorisation Variation to EMA for intravenous maintenance dosing every four weeks with Leqembi® (lecanemab)

Stockholm, Sweden, January 26, 2026 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that they have submitted a proposed Marketing Authorisation Variation to the European Medicines Agency (EMA) for a once every four weeks intravenous (IV) infusion maintenance dosing for lecanemab.

In the EU, lecanemab is indicated for the treatment of patients with a clinical diagnosis of mild cognitive impairment (MCI) or mild dementia due to Alzheimer's disease (early Alzheimer's disease) who are apolipoprotein E ε4 (ApoE ε4[1]) non-carriers or heterozygotes with confirmed amyloid pathology.[2] Lecanemab is currently licensed as an IV infusion with a dosing regimen of once every two weeks (10 mg/kg). Eisai's submission states that following the initial dosing regimen of once every two weeks, after 18 months, patients will be transitioned to the maintenance dosing regimen of once every four weeks. Treatment with lecanemab should be discontinued once the patient progresses to moderate Alzheimer's disease.

Lecanemab 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, applications for market approval and commercialization of lecanemab for Alzheimer's disease. BioArctic has the right to commercialize lecanemab in the Nordic region together with Eisai and the two companies are 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 January 26, 2026, at 22:00 CET.

For further information, please contact:
Oskar Bosson, VP Communications and Investor Relations
E-mail: oskar.bosson@bioarctic.com
Telephone: +46 704 107 180

Jenny Ljunggren, External Communications and Investor Relations Manager
E-mail: jenny.ljunggren@bioarctic.com
Telephone: +46 76 013 86 08

[1] Apolipoprotein E is a protein involved in the metabolism of fats in humans. It is implicated in, and is a major risk factor for, AD.

[2] Lecanemab European Union Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/leqembi-epar-product-information_en.pdf. Last accessed: January 2026.

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. 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.

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 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.