BIOARCTIC

Press release

First patient treated with Leqembi® (lecanemab) in Sweden

Stockholm, Sweden, September 22, 2026 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) announced today that Leqembi is now available at a private clinic in Sweden and that the first patient has started treatment. This is the first time a patient in Sweden has been treated outside of a clinical study since Leqembi received EU approval in April 2025.

"I am very happy that we are now starting to help people diagnosed with early Alzheimer's disease in Sweden as well. There is a significant unmet need for new treatment options that slow the progression of Alzheimer's disease from its early stages and reduce the overall burden for patients affected by the disease, their care partners, healthcare providers and society," said Gunilla Osswald, CEO of BioArctic. "It is great to see that this innovation, based on Professor Lars Lannfelt's research at Uppsala University, is finally, after more than 20 years of research and development, beginning to help patients in Sweden, where it all started."

Leqembi was approved in the EU in April 2025 as the first therapy that targets an underlying cause of Alzheimer's disease (AD). It is indicated for the treatment of adult patients with a clinical diagnosis of mild cognitive impairment (MCI) and mild dementia due to AD (early AD) who are apolipoprotein E ε4 (ApoE ε4[1]) non-carriers or heterozygotes with confirmed amyloid pathology.[2]

Following the EU approval, Eisai and BioArctic have worked to enable patient access in Sweden. However, in April 2026, the New Therapies Council, NT-rådet, gave a negative recommendation for inclusion of Leqembi in the publicly funded health care system. Following NT-rådet's recommendation, Executive Health in Stockholm, where the first patient was treated today, has been working to offer treatment to patients with 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 the clinical development, applications for regulatory approval and global commercialization of Leqembi for Alzheimer's disease. BioArctic has the right to commercialize Leqembi in the Nordic region together with Eisai.

The information was released for public disclosure, through the agency of the contact person below, on September 22, 2026, at 4:10 pm CEST.

For further information, please contact:
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[1] Apolipoprotein E is a protein involved in the metabolism of lipid in humans. It is implicated in AD. People with only one (heterozygous) or no copy (non-carriers) of the ApoE ε4 gene are less likely to experience ARIA than people with two ApoE ε4 copies (homozygous).[ii] ARIA is a recognized important side effect with lecanemab that involves swelling and potential bleeding in the brain.
[2] European Medicines Agency Summary of Product Characteristics (SmPC)

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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 and regions. Following the initial phase with treatment every two weeks for 18 months, intravenous (IV) maintenance dosing with treatment every four weeks is approved in nine countries and regions, including the US, Japan, China and the United Kingdom, and applications have been filed in eleven 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. Subcutaneous initiation treatment was approved in China and Japan in September 2026, and applications are under review in two countries.

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 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 therapies 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.