Press release

Leqembi® Pen subcutaneous formulation approved in Japan

Stockholm, Sweden, September 16, 2026 – BioArctic AB (publ)'s (Nasdaq Stockholm: BIOA B) partner Eisai announced today that the subcutaneous autoinjector formulation of Leqembi (known as Leqembi Pen in Japan) has been approved as a new route of administration for the treatment of early Alzheimer's disease.

Leqembi Pen enables patients or care partners to self-administer treatment, with two injections (totaling 500 mg) given once weekly. This approval in Japan provides people living with early Alzheimer's disease with an additional treatment option, allowing once-weekly subcutaneous administration at home[1], complementing the existing intravenous (IV) formulation, which is administered every two weeks in a hospital setting.

Leqembi Pen may reduce the time required for treatment administration compared with IV infusions, with each injection taking approximately 15 seconds. The option for at-home administration may reduce the burden of clinic visits for patients and their care partners and provide a treatment option that better fits their lifestyles.

The subcutaneous treatment option is expected to lower barriers to initiating and continuing treatment and has the potential to reduce healthcare resources associated with IV administration, such as nurse monitoring and maintaining infusion capacity. This may help streamline the overall Alzheimer's disease treatment pathway.

As with IV administration, monitoring for ARIA (amyloid-related imaging abnormalities) involves brain magnetic resonance imaging (MRI) before treatment is initiated and at specified time points thereafter.

Japan is the third country globally to approve the subcutaneous formulation of Leqembi. This approval is based on the integrated results of data and associated modeling and simulation from the 18-month core study of the Phase 3 Clarity AD study of Leqembi in patients with mild cognitive impairment (MCI) due to AD or mild AD dementia (collectively referred to as early AD), as well as multiple subcutaneous administration sub-studies in its subsequent long-term extension (LTE). Once-weekly administration of the 500 mg subcutaneous formulation demonstrated similar exposure to IV administration once every two weeks and supported the expectation that the subcutaneous formulation provides efficacy comparable to that of the IV formulation. The overall safety profile of subcutaneous administration was generally similar to that of IV administration, while systemic

[1] At-home, self-administration using Leqembi Pen will be possible after it is listed in the injectable drug list designated by the Minister of Health, Labour and Welfare that health insurance doctors can administer (or prescribe), following deliberation and approval by the Central Social Insurance Medical Council, in principle within 60 days after approval. In addition, the following points are stipulated to be observed when self-administering.
• When initiating administration, treatment must be administered by a physician or under the direct supervision of a physician at a medical facility.
• With regard to the applicability of self-administration, the appropriateness thereof shall be carefully considered, and only after providing thorough education and training, and confirming that the patient or family member/caregiver understands the risks associated with administration of this drug and how to respond to them, and that the patient or family member/caregiver is able to reliably administer it themselves, shall self-administration be implemented under the management and guidance of a physician.

injection/infusion-related reactions were observed less frequently with subcutaneous administration (1.4%)[2] compared with IV administration.

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 September 16, 2026, at 08:05 am CEST.

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

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 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 had 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.

[2] Incidence in participants newly initiated on Leqembi treatment via SC administration, based on clinical data obtained from once-weekly subcutaneous administration of Leqembi 720 mg using vial formulations.

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.