BIOARCTIC

Press release

Leqembi® subcutaneous formulation approved for initiation treatment in China

Stockholm, Sweden, September 3, 2026 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that the National Medical Products Administration (NMPA) of China has approved the Leqembi subcutaneous autoinjector formulation (Leqembi SC-AI) as an initiation treatment for mild cognitive impairment (MCI) due to Alzheimer's disease (AD) or mild AD dementia (collectively referred to as early AD).

The application was accepted by the NMPA in January 2026 and was subsequently granted Priority Review designation. Launch in China is planned during Eisai's Fiscal Year 2026 which ends on March 31, 2027.

Leqembi SC-AI is a self-administered autoinjector formulation. The approved regimen is 500 mg given once weekly as two consecutive 250 mg injections. With this approval, Leqembi treatment now offers a new option of once-weekly SC administration at home, as an alternative to intravenous (IV) administration every two weeks in a hospital setting. Patients may also switch between IV and SC administration during treatment.

Leqembi SC-AI may significantly reduce the time required for IV infusions (approximate injection time of 15 seconds per injection). In addition, at-home administration may reduce the burden of clinic visits for patients and their care partners and enable treatment options that better fit their lifestyles. The subcutaneous treatment option is expected to lower barriers to initiating and continuing treatment. Furthermore, Leqembi SC-AI also has the potential to reduce healthcare resources associated with IV dosing, such as nurse monitoring and maintaining infusion capacity. For ARIA (amyloid-related imaging abnormalities) monitoring, as with IV administration, brain magnetic resonance imaging (MRI) is performed prior to initiating treatment and at specified time points after treatment initiation.

This marks the second country globally to approve Leqembi SC-AI. 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 early Alzheimer's disease, as well as multiple subcutaneous administration sub-studies (including the Chinese cohort) in its subsequent long-term extension (LTE). Once-weekly administration of SC-AI 500mg demonstrated exposure equivalent to IV administration once every two weeks, with similar clinical and biomarker outcomes. The overall safety profile of SC administration was generally similar to that of IV administration. Injection-related reactions were observed with subcutaneous Leqembi, most of which were localized, while systemic reactions were less frequently observed.

Eisai estimates that there were 17 million patients with MCI or mild dementia due to Alzheimer's disease in China in 2024, a number that is expected to increase as the population ages. Leqembi was launched in China in June 2024.

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 3, 2026, at 06:00 am CEST.

For further information, please contact:
Oskar Bosson, Chief Investor Relations & Communications Officer
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. Following the initial phase with treatment every two weeks for 18 months, intravenous (IV) maintenance dosing with treatment every four weeks is approved in 8 countries, including the United Kingdom, China, the US and Japan, and applications have been filed in 12 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. In November 2025, a new drug application for subcutaneous formulation of Leqembi for initiation treatment 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.

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 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.