Press release

BLA for subcutaneous formulation of Leqembi® accepted in China

Stockholm, Sweden, Januari 6, 2026 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that the Biologics License Application (BLA) for the subcutaneous formulation (subcutaneous autoinjector: SC-AI) of Leqembi (lecanemab) for treatment of early Alzheimer's disease has been accepted by the National Medical Products Administration (NMPA) in China. If approved, lecanemab may become the first and only anti-amyloid treatment in China to offer an at-home injection from the initiation of treatment for this progressive, relentless disease.

If approved, the SC-AI of 500 mg could be used to administer a once-weekly dose at home from the initiation of treatment, as an alternative to the current IV administration every two weeks dose in the hospital setting. The injection time for each autoinjector (250mg injection) is approximately 15 seconds. The SC formulation also has the potential to reduce healthcare resources associated with IV dosing, such as preparation for infusion and nurse monitoring, while streamlining the overall AD treatment care pathway.

Similar applications for initiation dosing with subcutaneous injection of lecanemab was recently submitted to the U.S. Food and Drug Administration (FDA) and to Japan's Pharmaceuticals and Medical Devices Agency (PMDA). Lecanemab has previously been approved for subcutaneous injection for maintenance dosing for the treatment of early Alzheimer's disease in the United States under the brand name Leqembi Iqlik™.

Eisai estimates that there were 17 million patients with mild cognitive impairment (MCI) or mild dementia due to Alzheimer's disease in China in 2024, which is expected to increase with the aging of the population.

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 market approval and commercialization of Leqembi for Alzheimer's disease. BioArctic has the right to commercialize Leqembi 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 6, 2026, at 12:00 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 52 countries and is under regulatory review in 8 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 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.