Press release

New drug application for subcutaneous formulation of Leqembi® submitted in Japan

Stockholm, Sweden, November 28, 2025 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that they have filed a new drug application for Leqembi (lecanemab) for a subcutaneous formulation (subcutaneous autoinjector: SC-AI) as a new route of administration to Japan's Pharmaceuticals and Medical Devices Agency (PMDA). If approved, lecanemab would be the first and only anti-amyloid treatment in Japan to offer an at-home injection from the initiation of treatment for this progressive, deadly disease.

The application is based on data from multiple subcutaneous (SC) administration sub-studies of lecanemab conducted as part of the Phase 3 Clarity AD open-label extension (OLE), following the 18-month core study in individuals with Mild Cognitive Impairment (MCI) due to Alzheimer's disease (AD) or mild stage of AD dementia (collectively referred to as early AD). It was confirmed that the once-weekly administration of SC-AI 500 mg resulted in equivalent exposure to once every two weeks intravenous (IV) administration and similar clinical and biomarker benefits. Subcutaneous administration demonstrated a safety profile similar to IV administration, with less than 2 percent incidence of systemic injection/infusion-related reactions.

If approved, the SC-AI of 500 mg (two 250 mg injections) 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.

A similar application for initiation dosing with subcutaneous injection of lecanemab was recently submitted to the U.S. Food and Drug Administration (FDA). 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™.

Alzheimer's disease is a progressive, deadly disease with amyloid beta (Aβ) and tau as hallmarks that is caused by a continuous underlying neurotoxic process that begins before amyloid plaque removal and continues afterward.[1,2,3] Leqembi fights Alzheimer's disease in two ways – targeting both amyloid plaque and protofibrils, which can impact tau downstream.

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[1] Amin L, Harris DA. Aβ receptors specifically recognize molecular features displayed by fibril ends and neurotoxic oligomers. Nat Commun. 2021;12:3451. doi:10.1038/s41467-021-23507-z

[2] Ono K, Tsuji M. Protofibrils of Amyloid-β are Important Targets of a Disease-Modifying Approach for Alzheimer's Disease. Int J Mol Sci. 2020;21(3):952. doi: 10.3390/ijms21030952. PMID: 32023927; PMCID: PMC7037706.

[3] Hampel H, Hardy J, Blennow K, et al. The amyloid pathway in Alzheimer's disease. Mol Psychiatry. 2021;26(10):5481-5503.

Leqembi is currently approved in 51 countries and regions and is under regulatory review in 9 countries.

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 November 28, 2025, at 06:30 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 51 countries and is under regulatory review in 9 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.

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.