



Press release

Leqembi® approved for IV maintenance treatment in China

Stockholm, September 29, 2025 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that lecanemab (Leqembi) has been approved for once every four weeks intravenous (IV) maintenance dosing for the treatment of early Alzheimer's disease by the National Medical Products Administration (NMPA) in China.

In January 2024, lecanemab was approved for the treatment of Alzheimer's disease (AD) in patients with mild cognitive impairment (MCI) or mild dementia stage of disease (collectively referred to as early AD) in China. After 18 months of a dosing regimen of 10 mg/kg once every two weeks during initiation phase, a transition to the maintenance dosing regimen of 10 mg/kg once every four weeks may be considered or the regimen of 10 mg/kg once every two weeks may be continued.

AD is a progressive, relentless disease characterized by formation of protein deposits known as plaques made of amyloid-beta aggregates and neurofibrillary tangles made of tau protein in the brains of people living with AD. It is caused by a continuous underlying neurotoxic process that begins before amyloid plaque accumulation and continues after plaque removal.^{i,ii,iii,iv} The data show that A β protofibrils¹ and tau tangles play roles in the neurodegeneration process,^{i,ii} and Leqembi is the only approved therapy that fights AD in two ways – targeting both amyloid plaque and protofibrils, which can impact tau downstream.

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 September 29, 2025, at 08:20 a.m. CET.

¹ Protofibrils are believed to contribute to the brain injury that occurs with AD and are considered to be the most toxic form of A β , having a primary role in the cognitive decline associated with this progressive, debilitating condition. Protofibrils cause injury to neurons in the brain, which in turn, can negatively impact cognitive function via multiple mechanisms, not only increasing the development of insoluble A β plaques but also increasing direct damage to brain cell membranes and the connections that transmit signals between nerve cells or nerve cells and other cells. It is believed the reduction of protofibrils may prevent the progression of AD by reducing damage to neurons in the brain and cognitive dysfunction.



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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 50 countries including the U.S., Japan, China, and the European Union for the treatment of Alzheimer's disease (AD) in patients with Mild Cognitive Impairment (MCI) or mild dementia stage of disease (collectively referred to as early AD) and is under regulatory review in 10 countries. Leqembi Iqlik™ is approved for subcutaneous injection for maintenance dosing for the treatment of early Alzheimer's disease in the US. Following the initial phase with treatment every two weeks for 18 months, intravenous (IV) maintenance dosing with treatment every four weeks is approved in China, the U.S. and others, and applications have been filed in 5 countries and regions.

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 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.

ⁱ Eisai presents full results of lecanemab Phase 3 confirmatory Clarity AD study for early Alzheimer's disease at Clinical Trials on Alzheimer's Disease (CTAD) conference. Available at:

<https://www.eisai.co.jp/news/2022/news202285.html>

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

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

^{iv} 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.