Press release

Health Canada Grants Authorization for Leqembi® (lecanemab)

Stockholm, October 27, 2025 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that Health Canada has issued a Notice of Compliance with Conditions (NOC/c) for Leqembi® (lecanemab) for the treatment of adult patients with a clinical diagnosis of mild cognitive impairment or mild dementia due to Alzheimer's disease (early AD) who are apolipoprotein E ε4 (ApoE ε4[1]) non-carriers or heterozygotes and who have confirmed amyloid pathology. LEQEMBI is the first treatment for early AD that targets an underlying cause of the disease, to be authorized in Canada.

Leqembi selectively binds to soluble Aβ aggregates (protofibrils[i]), as well as insoluble Aβ aggregates (fibrils) which are a major component of Aβ plaques, thereby reducing both Aβ protofibrils and Aβ plaques in the brain. Leqembi is the first approved treatment shown to reduce the rate of disease progression and to slow cognitive and functional decline in adults with Alzheimer's disease. Leqembi is approved in 51 countries and regions including Japan, the United States, Europe, China, South Korea, Taiwan, and Saudi Arabia, and applications have been filed in 9 countries.

The approval of Leqembi is based on the large global Phase 3 Clarity AD study. In the Clarity AD study, Leqembi met its primary endpoint and all key secondary endpoints with statistically significant results.[2,3] Leqembi has been issued market authorization in Canada with conditions, pending the results of trials to verify its clinical benefit. Eisai plans to submit clinical assessment data captured from participants in real-world clinical practice.

Alzheimer's Disease is the most common form of dementia, accounting for 60 to 80% of all cases.[4] As of January 1, 2025, it is estimated there are more than 771,000 patients with dementia in Canada, which is expected to increase to approximately 1 million in 2030 and over 1.7 million in 2050.[5] In addition, annual care provided by family and friends for those with dementia is equivalent to 290,000 full-time jobs, which is expected to increase to 690,000 full-time jobs in 2050.[5]

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[1] Apolipoprotein E is a protein involved in the metabolism of lipid in humans. It is implicated in AD. People with only one (heterozygous) or no copy (non-carriers) of the ApoE ε4 gene are less likely to experience ARIA than people with two ApoE ε4 copies (homozygous). ARIA is a recognized important side effect with lecanemab that involves swelling and potential bleeding in the brain.

[2] 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

[3] van Dyck, H., et al. Lecanemab in Early Alzheimer's Disease. New England Journal of Medicine. 2023;388:9-21. https://www.nejm.org/doi/full/10.1056/NEJMoa2212948.

[4] Alzheimer Society of Canada "What is Alzheimer's disease?". Available at: https://alzheimer.ca/en/about-dementia/what-alzheimers-disease Last accessed: June 2025.

[5] Alzheimer Society of Canada "Dementia numbers in Canada". Available at: https://alzheimer.ca/en/about-dementia/what-dementia/dementia-numbers-canada Last accessed: June 2025.

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.

The information was released for public disclosure, through the agency of the contact person below, on October 27, 2025, at 00:35 a.m. 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 the U.S., Japan, EU, China, Great Britain, and several other markets for the treatment of mild cognitive impairment (MCI) due to Alzheimer's disease (AD) and mild AD dementia. Lecanemab's approvals in these countries, as well as the EC's market authorization, were primarily based on Phase 3 data from Eisai's global Clarity AD clinical trial, a Phase 3 global, placebo-controlled, double-blind, parallel-group, randomized study in 1,795 patients with early AD (MCI or mild dementia due to AD, with confirmed presence of amyloid pathology), in which it met its primary endpoint and all key secondary endpoints with statistically significant results. The treatment group was administered lecanemab 10 mg/kg bi-weekly, with participants allocated in a 1:1 ratio to receive either placebo or lecanemab for 18 months.[6]

Lecanemab is approved in 51 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 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 China, the U.S. and others, and applications have been filed in 9 countries and regions. Leqembi Iqlik™ is approved for subcutaneous injection for maintenance dosing for the treatment of early Alzheimer's disease in the US. In September 2025, a rolling sBLA application for the subcutaneous initiation dosing with Leqembi Iqlik was also initiated to the U.S. FDA.

Since July 2020, Eisai's Phase 3 clinical study (AHEAD 3-45) with lecanemab in individuals with preclinical AD, 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

[6] van Dyck, C.H., et al. Lecanemab in Early Alzheimer's Disease. New England Journal of Medicine. 2023;388:9-21. https://www.nejm.org/doi/full/10.1056/NEJMoa2212948

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 regulatory approvals, and 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.

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[i] Protofibrils are believed to contribute to the brain injury that occurs with AD and are considered to be the most toxic form of Aβ, 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 Aβ 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.