Press release

Canada's Drug Agency issues final positive recommendation supporting public reimbursement of Leqembi®

Stockholm, Sweden, September 1, 2026 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that Canada's Drug Agency (CDA-AMC) has issued a final recommendation supporting public reimbursement of Leqembi (lecanemab) for eligible patients in Canada with mild cognitive impairment (MCI) or mild dementia due to Alzheimer's disease (early AD).

The final recommendation follows a reconsideration by CDA-AMC and represents an important step toward broadening access to Leqembi in Canada. Next steps include negotiations through the pan-Canadian Pharmaceutical Alliance, followed by reimbursement decisions by public drug plans across Canada's provinces and territories.

More than 770,000 people in Canada were estimated to be living with dementia in 2025, and that number is projected to increase to 1.7 million by 2050.[1]

The information was released for public disclosure, through the agency of the contact person below, on September 1, 2026, at am 07:00 CEST.

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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. In January 2026, the Biologics

[1] Alzheimer Society of Canada. "Dementia numbers in Canada". Available at: https://alzheimer.ca/en/about-dementia/what-dementia/dementia-numbers-canada. Last accessed: August 20, 2026.

License Application for subcutaneous formulation of Leqembi was accepted in China and in February, the application was designated for priority review.

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.