Press release

US FDA approves Leqembi® IQKLIK ™ (lecanemab-irmb) subcutaneous injection for maintenance dosing for the treatment of early Alzheimer's disease

Stockholm, August 29, 2025 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today the U.S. Food and Drug Administration (FDA) has approved the Biologics License Application (BLA) for once weekly lecanemab subcutaneous injection for maintenance dosing. LEQEMBI IQLIK autoinjector is indicated for maintenance dosing to treat Alzheimer's disease (AD) in patients with mild cognitive impairment (MCI) or mild dementia stage of disease, collectively referred to as early AD, in the U.S. LEQEMBI IQLIK will be launched on October 6, 2025.

The U.S. brand name for the subcutaneous autoinjector is LEQEMBI IQLIK (pronounced "I Click"). After 18 months of Leqembi intravenous (IV) treatment at 10 mg/kg every two weeks, patients may either continue IV infusions at 10 mg/kg once every four weeks or the new weekly 360 mg subcutaneous injection using the LEQEMBI IQLIK autoinjector.

Alzheimer's disease is a progressive, relentless disease with Aβ and tau as hallmarks. It progresses in stages that increase in severity over time, and each stage of the disease presents different challenges for those living with the disease and their care partners. There is a significant unmet need for new treatment options that slow the progression of Alzheimer's disease from its early stage and reduce the overall burden on people affected by Alzheimer's disease and society. Only Leqembi fights Alzheimer's disease (AD) in two ways - targeting both amyloid plaque and protofibrils[1], which can impact tau accumulation downstream.[2,3] Due to the re-accumulation of AD biomarkers and a return to a placebo rate of decline after therapy is stopped, maintenance treatment offers patients options to slow the disease progression and prolong the benefit of therapy, with the goal of helping patients maintain who they are for longer.

"Eisai's continued work to support and simplify patient and healthcare administration and treatment is an important work to help remove potential bottlenecks in healthcare and broaden patient

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[1] 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.[i] 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.[ii]

[2] Eisai presents long-term administration data of lecanemab at the Alzheimer's Association International Conference (AAIC) 2024. Available at: https://www.eisai.co.jp/ir/library/presentations/pdf/4523_240731_1.pdf

[3] McDade et al. Lecanemab in patients with early Alzheimer's disease: detailed results on biomarker, cognitive, and clinical effects from the randomized and open-label extension of the phase 2 proof-of-concept study. Alzheimers Res Ther. 2022 Dec 21;14(1):191. doi: 10.1186/s13195-022-01124-2.

population while supporting a sustainable long-term cost of treatment," says Gunilla Osswald, CEO at BioArctic.

From the perspective of patients and care partners, this can provide the ability to use the device at home, a shortening of treatment time and continued treatment without having to visit an infusion centre. The subcutaneous formulation also has the potential to reduce healthcare resources associated with IV maintenance dosing, such as preparation for infusion and nurse monitoring, while increasing infusion capacity for new eligible patients to begin initiation treatment and streamlining the overall AD treatment pathway.

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 August 29, 2025, at 11:55 p.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 48 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

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 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 Morris JC. Neurology. 1993;43(11):2412-4.
ii 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.