Press release

Leqembi® Iqlik™ (lecanemab-irmb) maintenance treatment launched in the U.S.

Stockholm, October 6, 2025 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that lecanemab-irmb subcutaneous injection (U.S. brand name: Leqembi Iqlik) is now available in the U.S. as a maintenance dosing regimen 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). 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 start the new weekly 360 mg subcutaneous injection using the Leqembi Iqlik autoinjector. It is the first and only anti-amyloid treatment to offer an at-home injection after initial treatment of 18 months

Eisai and their partner Biogen have also launched the Leqembi Companion™ program which aims to provide expanded resources that support patients throughout their Leqembi treatment journey, from initiation through maintenance therapy. The program offers resources such as help with understanding insurance coverage and potential out-of-pocket costs and identifying financial support programs, injection education through Nurse Educators either in-person or virtually to provide patients with training on injecting their maintenance dose using the Leqembi Iqlik, an injection tracking tool and more. There is also a Leqembi Companion app to help support patients and care partners along their treatment journey.

Alzheimer's disease is a progressive, relentless disease with amyloid beta (Aβ) and tau as hallmarks that is caused by a continuous underlying neurotoxic process that begins before amyloid plaque accumulation and continues after removal. [1,2,3] The data show that amyloid-beta protofibrils and tau tangles play roles in the neurodegeneration process,[4,5,6] and Leqembi is the only approved treatment that fights Alzheimer's disease in two ways – targeting both amyloid plaque and protofibrils[i], which can impact tau downstream.

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[1] Leqembi (lecanemab-irmb) injection, for intravenous use [package insert]. Nutley, NJ: Eisai Inc.
[2] Iwatsubo T, Irizarry M, van Dyck C, Sabbagh M, Bateman RJ, Cohen S. Clarity AD: a phase 3 placebo-controlled, double-blind, parallel-group, 18-month study evaluating lecanemab in early Alzheimer's disease. Presented at: CTAD Conference; November 29-December 2, 2022; San Francisco, CA.
[3] Hampel H, Hardy J, Blennow K, et al. The amyloid-? pathway in Alzheimer's disease. Mol Psychiatry. 2021;26(10):5481-5503.
[4] 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.
[5] 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.
[6] Morris JC. Neurology. 1993;43(11):2412-4.

Due to the reaccumulation of AD biomarkers and return to placebo rate of decline after therapy is stopped,[4,5,6] continuing maintenance treatment after the initial 18-month therapy is essential to slow the progression of AD and extend the therapeutic benefits, helping patients maintain who they are for longer.

The availability of Leqembi Iqlik in the U.S. offers patients and care partners the ability to use the device at home, shortening treatment time, and providing an option to continue treatment without having to worry about visiting an infusion center. The Leqembi Iqlik 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.

Please see full Prescribing Information for Leqembi in the US, including Boxed WARNING.

The information was released for public disclosure, through the agency of the contact person below, on October 6, 2025, at 10:35 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 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 8 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 9 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 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.[1] 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.[2]