Press release

FDA approves IV maintenance dosing of Leqembi® (lecanemab-irmb) for the treatment of early Alzheimer's Disease in the US

Stockholm, January 27, 2025 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) today announced that the U.S. Food and Drug Administration (FDA) has approved BioArctic's partner Eisai's Supplemental Biologics License Application (sBLA) for Leqembi as a once every four weeks intravenous (IV) maintenance dosing. Leqembi is indicated for the treatment of Alzheimer's disease in patients with mild cognitive impairment (MCI) or mild dementia stage of disease in the U.S. (early Alzheimer's disease). This approval means that patients who have completed the biweekly initiation phase of 18 months have the option to transition to a once every four weeks 10 mg/kg dosing regimen.

Eisai has previously published data supporting the importance of continued ongoing treatment. Data from the off-treatment period between the Phase 2 core study and its long-term extension (LTE) showed that discontinuation of treatment is associated with reaccumulation of brain amyloid, and plasma and CSF biomarkers, and reversion to placebo rate of clinical decline.[1] In addition, recent data of three years of bi-weekly treatment across the Phase 3 Clarity AD core study and LTE, showed that Leqembi reduced cognitive decline on the CDR-SB by -0.95 relative to a matched natural history cohort – more than double the mean change from baseline relative to placebo on the CDR-SB at 18 months (-0.45) – showing expanded clinical and personally meaningful benefit for early AD patients.[2]

Alzheimer's disease is caused by a continuous underlying neurotoxic process that begins before and continues after plaque removal. Continuous administration of Leqembi is of great value to patients as Leqembi works to fight Alzheimer's Disease in two ways: not only rapidly clearing the amyloid-beta (Aβ) plaque, but it also works to fight the progressive nature of Alzheimer's disease by continuously clearing the highly toxic protofibrils that otherwise continue to cause neuronal injury.

The sBLA for the once every 4-week dosing regimen is based on modeling of observed data from the Phase 2 study and its long-term extension (LTE) as well as the Clarity AD study and its LTE study. Modeling simulations predict that transitioning to once every 4 weeks maintenance dosing after 18 months of biweekly treatment will maintain clinical and biomarker benefits of therapy.

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[1] 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

[2] A change from 0.5 to 1 on the CDR score domains of Memory, Community Affairs and Home/Hobbies is the difference between slight impairment and loss of independence, such as people's ability to be left alone, remember recent events, participate in daily activities, complete household chores, function independently and engage in hobbies and intellectual interests.

Leqembi is already approved in the US, Japan, China, Great Britain and several other markets. In November 2024, the treatment received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending approval. Eisai has submitted applications for approval of lecanemab in 17 countries and regions. Furthermore, the FDA accepted Eisai's Supplemental Biologics License (BLA) for the Leqembi subcutaneous autoinjector for weekly maintenance dosing in January 2025 and set a PDUFA action date for August 31, 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 Lecanemab for Alzheimer's disease. BioArctic has the right to jointly commercialize Leqembi in the Nordic region, pending European approval, and currently Eisai and BioArctic are preparing for a joint commercialization in the region.

This information is information that BioArctic is obliged to make public pursuant to the Financial Instruments Trading Act. The information was released for public disclosure, through the agency of the contact persons below, on January 27, 2025, at 00:30 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, Great Britain, China, 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 CHMP's positive opinion, were primarily based on Phase 3 data from Eisai's global Clarity AD clinical trial, in which it met its primary endpoint and all key secondary endpoints with statistically significant results. The most common adverse events (>10%) in the lecanemab group were infusion reactions, ARIA-H (combined cerebral microhemorrhages, cerebral macrohemorrhages, and superficial siderosis), ARIA-E (edema/effusion), headache, and fall.

Eisai has also submitted applications for regulatory approval of lecanemab in several other countries and regions, including the European Union. In November 2024, the treatment received positive opinion from the Committee for Medicinal Products for Human Use (CHMP) recommending approval. In January 2025, the rolling submission of a Biologics License Application (BLA) for maintenance dosing of a subcutaneous auto injection formulation, which is being developed to enhance convenience for patients, was accepted in the U.S., with PDUFA date August 31, 2025.

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 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 Institute on Aging, part of the National Institutes of Health and Eisai. 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.

Please find full US prescribing information here including Boxed WARNING.

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.