Press release

Eisai completes rolling BLA submission for subcutaneous maintenance dosing of Leqembi® (lecanemab-irmb) in the US

Stockholm, Sweden November 1, 2024 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that Eisai has completed the rolling submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for lecanemab-irmb (U.S. brand name: Leqembi®) subcutaneous autoinjector for weekly maintenance dosing after it was granted Fast Track designation by the FDA. Leqembi is indicated 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).

The BLA is based on data from the Clarity AD open-label extension (OLE) study and modeling of observed data. If the application is approved by the FDA, the Leqembi autoinjector could be used to administer Leqembi at home or at medical facilities, and the injection process is expected on average to take about 15 seconds. As part of the subcutaneous autoinjector 360 mg weekly maintenance regimen under review, patients who have completed the biweekly intravenous (IV) initiation phase would receive weekly doses that maintain effective drug concentrations to sustain the clearance of highly toxic protofibrils[1,2] which can continue to cause neuronal injury even after the amyloid-beta (Aβ) plaque has been cleared from the brain. If the FDA accepts the BLA, the Prescription Drug User Fee Act (PDUFA) action date (target date for completion of examination) will be set.

AD is an ongoing neurotoxic process that begins before and continues after plaque deposition. Data suggest that early and continuing treatment may prolong the benefit even after plaque is cleared from the brain. This SC autoinjector is expected to be easier for patients and their care partners to use and may reduce the need for hospital visits and nursing care compared to IV administration. In addition to potentially maintaining the clinical and biomarker benefits, subcutaneous maintenance dosing may be more convenient for patients and their care partners to continue the treatment.

Leqembi is approved in the U.S., Japan, China, South Korea, Hong Kong, Israel, UAE and Great Britain. Eisai has also submitted applications for approval of lecanemab in 10 countries and regions, including the European Union (EU). The US FDA accepted Eisai's Supplemental Biologics License Application (sBLA) for monthly Leqembi IV maintenance dosing in June 2024 and set a PDUFA action date for January 25, 2025.

Lecanemab 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

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[1] 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

[2] 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

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 commercialize lecanemab in the Nordic region and pending European approval Eisai and BioArctic 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 November 1, 2024, at 00:30 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, China, South Korea, Hong Kong, Israel, UAE and Great Britain for the treatment of MCI due to AD and mild AD dementia. Lecanemab's approvals in these countries 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.

Please find full US prescribing information here including Boxed WARNING.

Lecanemab marketed in the U.S., Japan and China. Eisai has also submitted applications for approval of lecanemab in 10 countries and regions, including the European Union.

Since July 2020 Eisai's Phase 3 clinical study (AHEAD 3-45) for individuals with preclinical AD, meaning they are clinically normal and have intermediate or elevated levels of amyloid in their brains, is ongoing. AHEAD 3-45 is 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.

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 under certain conditions 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.