Press release

FDA accepts filing of Leqembi® (lecanemab-irmb) sBLA for IV maintenance dosing for the treatment of early Alzheimer's Disease

Stockholm, Sweden, June 10, 2024 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that that the U.S. Food and Drug Administration (FDA) has accepted Eisai's Supplemental Biologics License Application (sBLA) for less frequent monthly lecanemab-irmb (U.S. brand name: Leqembi) intravenous (IV) maintenance dosing. A Prescription Drug User Fee Act (PDUFA) action date is set for January 25, 2025. In the US, Leqembi is indicated for the treatment of Alzheimer's disease (AD) in patients with mild cognitive impairment or mild dementia stage of disease (collectively referred to as early AD).

As part of the monthly IV maintenance regimen, the patients who have completed the biweekly IV initiation phase, exact period under discussion with the FDA, would receive a less frequent monthly IV dose that maintains effective drug concentration to sustain the clearance of highly toxic amyloid beta (Aβ) protofibrils[i] which can continue to cause neuronal injury. The sBLA is based on modeling of observed data from the Phase 2 study (Study 201) and its open-label extension (OLE) as well as the Clarity AD study (Study 301) and its OLE study.

Alzheimer's disease is a progressive disease caused by toxic amyloid proteins. Once established, this pathophysiological process continues through the patient's life and therefore sustained treatment is necessary. The treatment should be initiated as early as possible to maximize patient outcomes. Data from Studies 201, 301 and their OLEs show that continued treatment with LEQEMBI beyond the 18-month core phase prolongs the benefit as highly toxic protofibrils are continuously removed. If approved, the clinical and biomarker benefits may be maintained through the once-monthly dosing regimen that is less burdensome and easier for patients and care partners to continue long-term.

Additionally, Eisai initiated the rolling submission of a BLA to the FDA for the Leqembi subcutaneous autoinjector for weekly maintenance dosing after it was granted Fast Track designation by the FDA in May 2024.

Leqembi is now approved in the U.S., Japan, China and South Korea, and applications have been submitted for review in several countries including the European Union, Australia, Brazil, Canada, Hong Kong, Great Britain, India, Israel, Russia, Saudi Arabia, Taiwan, Singapore and Switzerland.

Eisai is responsible for the clinical development, applications for market approval and commercialization of Lecanemab for Alzheimer's disease. BioArctic has no development costs for lecanemab in Alzheimer's disease and is entitled to payments in connection with certain regulatory approvals, and sales milestones as well as royalties on global sales. In addition, BioArctic has the right

to commercialize lecanemab 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 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 persons below, on June 10, 2024, at 01.30 a.m. CET.

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About lecanemab (generic name, U.S., Japan and China brand name: 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). Lecanemab is approved in the U.S., Japan, China, and South Korea with the following indications:

- U.S.: For the treatment of Alzheimer's disease (AD). It should be initiated in patients with mild cognitive impairment or mild dementia stage of disease. See full US prescribing information including boxed waring.
- Japan: For slowing progression of mild cognitive impairment (MCI) and mild dementia due to AD.
- China: For the treatment of MCI due to AD and mild AD dementia.
- South Korea: For treatment in adult patients with mild cognitive impairment due to Alzheimer's disease (AD) or mild AD (early AD)

Lecanemab approvals were based on the large global Phase 3 Clarity AD study. In the Clarity AD study, lecanemab met its primary endpoint and all key secondary endpoints with statistically significant results. In November 2022, the results of the Clarity AD study were presented at the 2022 Clinical Trials on Alzheimer's Disease (CTAD) conference, and simultaneously published in the New England Journal of Medicine, a peer-reviewed medical journal.

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 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. 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.