Press release

Leqembi® approved for the treatment of Alzheimer's disease in China

Stockholm, Sweden, January 9, 2024 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that Leqembi® (brand name in China: "乐意保", generic name: lecanemab-irmb) has been approved in China as a treatment for mild cognitive impairment (MCI) due to Alzheimer's disease (AD) and mild AD dementia. China is the third country to grant marketing approval, following the traditional approval in the United States in July 2023 and Japanese approval in September 2023. Eisai's preparations for the Chinese launch in the of the third quarter 2024 are underway.

Amyloid-beta (Aβ) is a protein that forms and breaks down naturally in the brain. In Alzheimer's disease, there is an imbalance between the production and elimination of Aβ, which then causes the protein to aggregate, first in smaller, soluble forms, oligomers and protofibrils, and eventually insoluble fibrils and plaques. These aggregates interfere with normal brain functions and cause gradual loss of nerve cells and memory. Leqembi selectively binds to soluble (protofibrils), as well as insoluble Aβ aggregates (fibrils), thereby reducing both Aβ protofibrils and Aβ plaques in the brain. Leqembi is the first and only approved treatment shown to reduce the rate of disease progression and to slow cognitive and functional decline through this mechanism.

Leqembi's approval in China is based on the large global Phase 3 Clarity AD study. In the Clarity AD study, Leqembi 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.

Eisai estimates that there are 17 million patients with MCI or mild dementia due to AD in China today, which is expected to increase with the aging of the population. Eisai will distribute the product in China and will conduct information provision activities through specialized Medical Representatives. Moving forward, Eisai will focus on AD awareness via omnichannel systems and collaborate with specialists to improve the diagnostic environment, including blood-based biomarkers. In addition, by utilizing online health platform for the elderly "Yin Fa Tong"[1], which is already being accessed by a certain number of users and helping provide treatments, Eisai is providing a one-stop service that promotes early consultation by referring patients to medical specialists and follow-up after treatment. Eisai will work to improve access environments including

[1] An online business (Chinese name:銀髪通) of Jingyi Weixiang (Shanghai) Health Industry Development Limited Company, a joint venture company with JD Health.

the development of insurance programs for AD in collaboration with insurance companies. Through these efforts, Eisai will accelerate the construction of a simple patient journey in China.

BioArctic has a long-term collaboration with Eisai regarding the development and commercialization for Leqembi. Eisai is responsible for the clinical development, applications for market approval and commercialization of the drug. BioArctic has no development costs for Leqembi 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 January 9, 2024, at 09.30 a.m. CET.

For further information, please contact:
Oskar Bosson, VP Communications and IR
E-mail: oskar.bosson@bioarctic.se
Phone: +46 70 410 71 80

Jiang Millington, Director Corporate Communication and Social Media
E-mail: jiang.millington@bioarctic.se
Phone: +46 79 33 99 166

"乐意保®" (LEQEMBI®) Product Outline
Chinese Trade name: "乐意保" (LEQEMBI)
Chinese generic name: 仑卡奈单抗注射液 (lecanemab injection)
Indication for use: Treatment of mild cognitive impairment (MCI) due to Alzheimer's disease (AD) and mild AD dementia
Dosage and administration: The usual dose of lecanemab (recombinant) is 10mg/kg infused intravenously over approximately 1 hour, once every 2 weeks.
Active ingredients and strength: 200mg (2mL)/1 vial and 500mg (5mL)/1 vial

About Leqembi® (lecanemab)
Leqembi (lecanemab) is the result of a strategic research alliance between BioArctic and Eisai. Leqembi is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble (protofibril) and insoluble forms of amyloid-beta (Aβ). Leqembi is an amyloid beta-directed antibody indicated as a disease-modifying treatment for Alzheimer's disease (AD) in the US. Leqembi was granted traditional approval by the US Food and Drug Administration (FDA) on July 6, 2023. Treatment with Leqembi should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied.

Please see full U.S. Prescribing Information, including Boxed WARNING.

In Japan, Eisai received approval from the Ministry of Health, Labour and Welfare (MHLW) on September 25, 2023, to manufacture and market lecanemab as a treatment for slowing progression of MCI and mild dementia due to AD.

Eisai has also submitted applications for approval of lecanemab in 11 countries and regions, including EU, Canada and Great Britain.

Eisai has completed a lecanemab subcutaneous bioavailability study, and subcutaneous dosing is currently being evaluated in the Clarity AD (Study 301) open-label extension (OLE) study. A maintenance dosing regimen has been evaluated as part of the Phase 2b study (Study 201).

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.se.