## Press release

# LEQEMBI® to be launched in Japan for Alzheimer's disease on December 20

**Stockholm, Sweden, December 13, 2023 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai today announced that LEQEMBI (lecanemab) will be launched in Japan on December 20, following its scheduled inclusion in the price listing on the Japan National Health Insurance (NHI) drug price list.**

LEQEMBI obtained manufacturing and marketing approval for the indication of slowing progression of mild cognitive impairment (MCI) and mild dementia due to Alzheimer's disease (AD) in Japan on September 25, 2023. In addition to inclusion in Japan's NHI drug price list, the products Optimal Clinical Use Guidelines were agreed at a general meeting of the Central Social Insurance Medical Council, an advisory body of the Japanese Ministry of Heath, Labour and Welfare, held today. The launch, planned for December 20, will make Japan the second country to have the product on the market, following the U.S.

"This is a great Christmas present! Alzheimer's disease patients in Japan will now have access to the first disease modifying treatment. This gives hope for the large aging population in Japan with a great need for new treatment options," says Gunilla Osswald, CEO of BioArctic.

LEQEMBI selectively binds to soluble amyloid-beta (Aβ) aggregates (protofibrils[1]), as well as insoluble Aβ aggregates (fibrils) which are a major component of Aβ plaques, 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.

Eisai will conduct a post-marketing special use results survey in all patients who are administered LEQEMBI (all-case surveillance) until data from a certain number of patients are accumulated, in accordance with an approval condition imposed by the Ministry of Health, Labour and Welfare. In addition, the appropriate use of LEQEMBI will be promoted in accordance with the package insert and the Optimal Clinical Use Guidelines, and training materials will be provided for healthcare professionals to assist with the management and monitoring of amyloid-related imaging abnormalities (ARIA).

Eisai serves as the lead of LEQEMBI development and regulatory submissions globally with both Eisai and Biogen co-commercializing and co-promoting the product and Eisai having final decision-making authority. BioArctic has the right to commercialize lecanemab in the Nordic region, pending

[1] Protofibrils are large Aβ aggregated soluble species of 75-5000 Kd

European approval, and currently Eisai and BioArctic are preparing for a joint commercialization in the region.

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*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 December 13, 2023, at 03:05 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

**Product Outline in Japan**
Product name：LEQEMBI® Intravenous Infusion 200mg, LEQEMBI® Intravenous Infusion 500mg
Generic name: Lecanemab (recombinant)
Indication for use: Slowing progression of mild cognitive impairment (MCI) and mild dementia due to Alzheimer's disease.
Dosage and administration：The usual dose of lecanemab (recombinant) is 10mg/kg infused intravenously over approximately 1 hour, once every 2 weeks.
National Health Insurance (NHI) drug price (Scheduled to be listed on December 20):

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| LEQEMBI Intravenous Infusion | 200mg | JPY 45,777 per vial |
| LEQEMBI Intravenous Infusion | 500mg | JPY 114,443 per vial |

Packaging:

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| LEQEMBI Intravenous Infusion | 200mg | 2mL per vial |
| LEQEMBI Intravenous Infusion | 500mg | 5mL per vial |

Warnings and Contraindications

1. Warning

1.1 Prior to initiating administration of this drug, sufficient information should be provided to patients and their families/caregivers about the occurrence rate of ARIA due to this drug, the risk of ARIA, tests necessary for risk management, and measures to be taken when ARIA occurs. This drug should be administered after being informed and obtaining their consent. Also, patients should be instructed to immediately contact their attending physician if any abnormalities are observed.

1.2 Prior to initiating administration of this drug, sufficient information should be provided to patients and their families/caregivers about the occurrence rate of ARIA due to this drug, the risk of ARIA, tests necessary for risk management, and measures to be taken when ARIA occurs. This drug should be administered after being informed and obtaining their consent. Also, patients should be instructed to immediately contact their attending physician if any abnormalities are observed.

2. Contraindications (This drug is contraindicated to the following patients.)

2.1 Patients with a history of serious hypersensitivity to the ingredients of this drug.

2.2 Patients with cerebral vasogenic edema confirmed before the start of administration of this drug. [Due to the possible increased risk of ARIA
2.3 Patients with 5 or more cerebral microhemorrhages, focal cerebral surface hemosiderosis or cerebral hemorrhage >1 cm in size confirmed before the start of administration of this drug. [Due to the possible increased risk of ARIA]

**About lecanemab (generic name, U.S. and Japan brand name: LEQEMBI®)**
Lecanemab is the result of a strategic research alliance between BioArctic and Eisai. Lecanemab is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble (protofibril) and insoluble forms of amyloid-beta (Aβ). In the U.S., LEQEMBI was granted traditional approval by the US Food and Drug Administration (FDA) on July 6, 2023. LEQEMBI is an amyloid beta-directed antibody indicated as a disease-modifying treatment for Alzheimer's disease (AD) in the US. 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. 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.

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

Eisai has also submitted applications for approval of lecanemab in EU, China, Canada, Great Britain, Australia, Switzerland, South Korea, Israel, Singapore, Taiwan, Brazil and Hong Kong. In China and Israel, the applications have been designated for priority review, and in Great Britain, lecanemab has been designated for the Innovative Licensing and Access Pathway (ILAP), which aims to reduce the time to market for innovative medicines.

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 disease-modifying treatments for neurodegenerative diseases, such as Alzheimer's disease, Parkinson's disease and ALS. BioArctic focuses on innovative treatments in areas with high unmet medical needs. The company was founded in 2003 based on innovative research from Uppsala University, Sweden. Collaborations with universities are of great importance to the company together with its strategically important global partner Eisai in Alzheimer disease. The project portfolio is a combination of fully funded projects run in partnership with global pharmaceutical companies and innovative in-house projects with significant market and out-licensing potential. BioArctic's Class B share is listed on Nasdaq Stockholm Large Cap (ticker: BIOA B). For more information about BioArctic, please visit www.bioarctic.com.