Press release

Update relating to LEQEMBI® from Eisai's investor presentation of their quarterly report published today

Stockholm, Sweden, November 7, 2023 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai today held a presentation on the second quarter of Eisai's fiscal year, ending March 2024. In addition to presenting sales numbers of 0.4 billion yen for LEQEMBI for the period, Eisai also stated the following;

- The launch of LEQEMBI in the U.S. is progressing as planned and the company reiterated their expectation that 10,000 patients will be on LEQEMBI by the end of March 2024
- The number of neurologists or other Alzheimer disease (AD) specialists who are ready to diagnose, treat and monitor patients on LEQEMBI has increased from approximately 1,400 in June to 2,500 in October
- 60% of the top 100 Integrated Delivery Networks (IDN[1]) in the U.S. have now approved LEQEMBI, which means the treatment is available within their health system
- Eisai aims to achieve 10 billion yen (M 700 SEK in today's currency) level revenue from LEQEMBI in their fiscal year 2023, ending March 2024 (not to be seen as guidance). BioArctic has the right to high single digit royalty on global sales of LEQEMBI.

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

BioArctic's complete interim report for the third quarter 2023 will be published on November 8 at 08:00 CET.

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 November 7, 2023, at 09:15 a.m. CET.

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[1] An integrated delivery network (IDN), sometimes referred to as a health system, is an organization that owns and operates a network of one or more healthcare facilities. Because IDNs are designed to provide a wide variety of care services, they often contain many different types of inpatient and outpatient care facilities including hospitals, physician groups, health clinics, ambulatory surgery centers and imaging centers.

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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 U.S. 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 right to commercialize lecanemab in the Nordic 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.