Press release

Eisai projects Leqembi® revenue to total JPY 76.5 billion for fiscal year 2025 (April 2025 – March 2026)

Stockholm, Sweden, May 15, 2025 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai today announced that Leqembi sales are expected to total JPY 76.5 billion (approximately SEK 5.1 billion) for their fiscal year (FY) 2025 (April 2025 through March 2026), corresponding to a 73 percent growth compared to the previous year. This would generate approximately SEK 510 M in royalty to BioArctic during the same period.

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 Leqembi in the Nordic region together with Eisai and the two companies are preparing for a joint commercialization in the region.

BioArctic's report for the first quarter 2025 will be published on May 21 at 08.00 a.m. 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 person below, on May 15, 2025, at 06:00 CET.

For further information, please contact:
Charlotte af Klercker, Senior Director Sustainability and Communications
E-mail: charlotte.afklercker@bioarctic.com
Telephone: +46 73 515 09 70

Anders Martin-Löf, CFO
E-mail: anders.martin-lof@bioarctic.com
Telephone: +46 70 683 79 77

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).[1,2]

Lecanemab is approved in the U.S., Japan, EU, China, Great Britain, and several other markets for the treatment of mild cognitive impairment (MCI) due to Alzheimer's disease (AD) and mild AD dementia. Lecanemab's approvals in these countries, as well as the EC's market authorization, 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.[1,2] Clarity AD was a Phase 3 global, placebo-controlled, double-blind, parallel-group, randomized study in 1,795 patients with early AD (MCI or mild dementia due to AD, with confirmed presence of amyloid pathology), of which 1,521 were in the recommended indicated population in

the label in the European Union (ApoE ε4 heterozygotes or non-carriers).[2] The treatment group was administered lecanemab 10 mg/kg bi-weekly, with participants allocated in a 1:1 ratio to receive either placebo or lecanemab for 18 months.[2]

The primary endpoint was the global cognitive and functional scale, CDR-SB (n=764).[2] In the Clarity AD clinical trial, treatment with lecanemab (n=757), in the EU indicated population (ApoE ε4 non-carriers or heterozygotes, measured by control-based multiple imputation), reduced clinical decline on CDR-SB by 31% at 18 months compared to placebo.[1] The mean CDR-SB score at baseline was approximately 3.2 in both groups.[1] The adjusted least-squares mean change from baseline at 18 months was 1.217 with lecanemab and 1.752 with placebo (difference, −0.535; 95% confidence interval [CI], −0.778 to −0.293).[1] CDR-SB is a global cognitive and functional scale that measures six domains of functioning, including memory, orientation, judgement and problem solving, community affairs, home and hobbies, and personal care.

In addition, the secondary endpoint from the AD Cooperative Study-Activities of Daily Living Scale for Mild Cognitive Impairment (ADCS MCI-ADL), which measures information provided by people caring for patients with AD, noted 33% less decline compared to placebo at 18 months.[1] The adjusted mean change from baseline at 18 months in the ADCS MCI-ADL score was −3.873 in the lecanemab group and −5.809 in the placebo group (difference, 1.936; 95% CI, 1.029 to 2.844).[1] The ADCS MCI-ADL assesses the ability of patients to function independently, including being able to dress, feed themselves and participate in community activities.

In the EU indicated population (ApoE ε4 heterozygotes or non-carriers), the most common adverse reactions were infusion-related reaction (26%), ARIA-H (13%), headache (11%) and ARIA-E (9%).[1]

Eisai has also submitted applications for regulatory approval of lecanemab in several other countries and regions. In January 2025, the supplemental Biologics License Application (sBLA) for intravenous (IV) maintenance dosing of the treatment was approved in the U.S. After an 18 months initiation phase with once every two weeks of dosing, a transition to the maintenance dosing regimen of 10 mg/kg once every four weeks or continuing 10 mg/kg once every two weeks may be considered. Additionally, the U.S. Food and Drug Administration (FDA) accepted Eisai's Biologics License Application (BLA) for the Leqembi subcutaneous autoinjector for weekly maintenance dosing in January 2025 and set a PDUFA action date for August 31, 2025.

Since July 2020, Eisai's Phase 3 clinical study (AHEAD 3-45) with lecanemab in individuals with preclinical AD, meaning they are clinically normal and have intermediate or elevated levels of amyloid in their brains, is ongoing. The study was fully recruited in October 2024. AHEAD 3-45 is a four-year study conducted as a public-private partnership between Eisai, Biogen and 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. 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 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.

1. European Medicines Agency Summary of Product Characteristics (SmPC
2. van Dyck, C.H., *et al*. Lecanemab in Early Alzheimer's Disease. *New England Journal of Medicine*. 2023;388:9-21. https://www.nejm.org/doi/full/10.1056/NEJMoa2212948.
3. Johannesson, M., *et al.* Lecanemab demonstrates highly selective binding to Aβ protofibrils isolated from Alzheimer's disease brains. *Molecular and Cellular Neuroscience.* 2024;130:103949. https://doi.org/10.1016/j.mcn.2024.103949.
4. Sehlin, D., *et al*. Large aggregates are the major soluble Aβ species in AD brain fractionated with density gradient ultracentrifugation. *PLoS One*. 2012;7(2):e32014. https://doi.org/10.1371/journal.pone.0032014.
5. Söderberg, L., *et al*. Lecanemab, Aducanumab, and Gantenerumab — Binding Profiles to Different Forms of Amyloid-Beta Might Explain Efficacy and Side Effects in Clinical Trials for Alzheimer's Disease. *Neurotherapeutics.* 2022;20(1):195-206. https://doi.org/10.1007/s13311-022-01308-6.
6. Selkoe, D. Does the Current Evidence for Lecanemab Mechanism Support a Rationale for Continued Lecanemab Dosing? Presented at Alzheimer's Association International Conference, 2024.
7. Amin, L., Harris, D.A. Aβ receptors specifically recognize molecular features displayed by fibril ends and neurotoxic oligomers. Nature Communications. 2021;12:3451. doi:10.1038/s41467-021-23507-z.
8. Ono, K., Tsuji, M. Protofibrils of Amyloid-β are Important Targets of a Disease-Modifying Approach for Alzheimer's Disease. *International Journal of Molecular Sciences.* 2020;21(3):952. https://doi.org/10.3390/ijms21030952
9. Gustavsson, A., et al. Global estimates on the number of persons across the Alzheimer's disease continuum. Alzheimer's & Dementia. 2023;19:658-670. https://alz-journals.onlinelibrary.wiley.com/doi/full/10.1002/alz.12694.