



## Press release

### **Eisai updates Leqembi® outlook for fiscal year 2024 (April 2024 – March 2025). Sales now expected to reach JPY 42.5 billion**

**Stockholm, Sweden, November 8, 2024 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai today updated their revenue outlook for Leqembi for their 2024 fiscal year (FY), which runs from April 2024 through March 2025. Eisai now expects Leqembi sales to total JPY 42.5 billion (approximately SEK 3 billion) for the period, down from JPY 56.5 billion announced in May. This would generate approximately SEK 300 M in royalty to BioArctic in the same period. Leqembi sales for the first half of Eisai's FY2024 amounted to JPY 16.3 billion, resulting in SEK 112.4 M in royalty to BioArctic.**

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

BioArctic's report for the third quarter 2024 will be published on November 14 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 November 8, 2024, at 05.00 a.m. CET.*

**For further information, please contact:**

Oskar Bosson, VP Communications and IR

E-mail: [oskar.bosson@bioarctic.se](mailto:oskar.bosson@bioarctic.se)

Phone: +46 70 410 71 80

**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).

Lecanemab is approved in the U.S., Japan, China, South Korea, Hong Kong, Israel, UAE and Great Britain for the treatment of MCI due to AD and mild AD dementia. Lecanemab's approvals in these countries 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. The most common adverse events (>10%) in the lecanemab group were infusion reactions, ARIA-H (combined cerebral microhemorrhages, cerebral macrohemorrhages, and superficial siderosis), ARIA-E (edema/effusion), headache, and fall.

Please find full US prescribing information [here](#) including Boxed WARNING.



Lecanemab marketed in the U.S., Japan and China. Eisai has also submitted applications for approval of lecanemab in several other countries and regions, including the European Union.

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 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](http://www.bioarctic.com).