Press release

Update on regulatory review of lecanemab for treatment of early Alzheimer's disease in the European Union

Stockholm, January 31, 2025 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai today announced that the European Commission has asked the Committee for Medicinal Products for Human Use (CHMP) to consider two additional questions. These questions will now be discussed at the CHMP meeting in February 2025, before the Commission can take a final decision on the Marketing Authorization Application for lecanemab as treatment for early Alzheimer's disease in the European Union.

In November 2024, a positive opinion was received from the Committee for Medicinal Products for Human Use (CHMP) recommending approval of lecanemab. As part of its decision-making process, the European Commission (EC) has asked the CHMP to consider information on the safety of lecanemab that became available after the adoption of the CHMP opinion in November 2024 and whether this may require an update of the opinion, and to consider whether the wording of the risk minimization measures in the opinion is clear enough to ensure correct implementation. These will be discussed at the CHMP meeting in February 2025.

The safety profile of lecanemab reported in clinical practice in the United States, Japan and other countries after launch is consistent with that in the approved labels, and no new safety signals are identified. Eisai believes that the existing information is clear and sufficient, allowing the EC's requests to be addressed and evaluated by the CHMP. Eisai will continue to work closely with the authorities toward approval in the EU.

Eisai will continue to make every effort to deliver lecanemab to patients with early AD in EU countries as soon as possible.

Leqembi is the result of a long-standing collaboration between BioArctic and Eisai, and the antibody was originally developed by BioArctic based on the work of Professor Lars Lannfelt and his discovery of the Arctic mutation in Alzheimer's disease. Eisai is responsible for the clinical development, applications for market approval and commercialization of Lecanemab for Alzheimer's disease. BioArctic has the right to commercialize Leqembi in the Nordic region together with Eisai and currently the two companies are preparing for a joint commercialization in the region.

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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, 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 CHMP's positive opinion, 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. Eisai has also submitted applications for regulatory approval of lecanemab in several other countries and regions. A supplemental Biologics License Application (sBLA) for less frequent intravenous maintenance dosing was approved by the U.S. Food and Drug Administration (FDA) in January 2025. In January 2025, the rolling submission of a Biologics License Application (BLA) for maintenance dosing of a subcutaneous auto injection formulation, which is being developed to enhance convenience for patients, was accepted in the U.S., with PDUFA date 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 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 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.