Press release

The European Commission to make final decision on EU Marketing Authorisation for lecanemab

Stockholm, Sweden, April 14, 2025 – The European Commission (EC) has today disclosed information that on the ongoing process regarding the Marketing Authorisation Application (MAA) for lecanemab in the EU, the Appeal Committee completed its deliberations without reaching a decision. In accordance with the established process, the final decision regarding the MAA is now entrusted to the EC.

The final process for the EC decision on lecanemab's Marketing Authorisation Application (MAA) is underway, following the reconfirmation of the positive opinion for lecanemab's approval by the Committee for Medicinal Products for Human Use (CHMP) in February 2025. Following the EC deliberations on the MAA in its Standing Committee in March 2025, the issue was referred to the Appeal Committee. The Appeal Committee has conducted its deliberations but was unable to reach a decision.

In accordance with the established process, the final decision regarding this MAA is now entrusted to the EC. BioArctic and Eisai will promptly disclose the final decision by the EC as soon as it is announced.

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 April 14, 2025, at 13:00 CET.

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

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

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, United Kingdom, 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 in November 2024, 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 lecanemab 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.se.