Press release

Eisai will seek re-examination of CHMP opinion för lecanemab

Stockholm, Sweden July 26, 2024 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that they will request re-examination of the Committee for Medicinal Products for Human Use (CHMP's) negative opinion posted today on the Marketing Authorization Approval (MAA) for lecanemab as treatment for Alzheimer's disease in the EU.

"We are surprised and very disappointed by the CHMP's opinion posted today. Foremost the negative opinion adopted by the CHMP is sad for all patients, caregivers and healthcare professionals in the EU who will now have to wait longer for a treatment which can effectively change the course of this devastating disease. We know that for these patients, time is what they value the most, and potentially denying them a treatment which has been shown to delay the onset of more severe stages of the diseases is of course not what they or we had hoped for," said Gunilla Osswald, BioArctic's CEO. "This is not the final verdict however, and our partner Eisai will seek re-examination of the CHMP opinion and continue work with authorities to ensure this treatment is available for eligible people living with early Alzheimer's disease in the EU as soon as possible."

A formal request for re-examination allows the applicant a 60-day period to provide the CHMP with the grounds for the re-examination request. The CHMP, led by new rapporteurs, will have 60 days to respond.

Lecanemab is already approved in the United States, Japan, China, South Korea, Hong Kong and Israel, and is being marketed in the U.S., Japan and China.

Alzheimer's disease currently affects 6.9 million people in Europe,[1] and this figure is expected to nearly double by 2050 as aging populations increase.[2]

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

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[1] European Medicines Agency. Involvement of patients in Scientific Advisory Group and Ad Hoc Expert meetings at EMA. Available at: https://www.ema.europa.eu/system/files/documents/other/involvement_of_patients_in_scientific_advisory_group-en.pdf. Last accessed: June 2024.

[2] European Medicines Agency. The Centralised Procedure at the EMA. Available at: https://www.ema.europa.eu/en/documents/presentation/presentation-centralised-procedure-european-medicines-agency_en.pdf. Last accessed: June 2024.

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 July 26, 2024, at 13:15 p.m. CET.

For further information, please contact:
Oskar Bosson, VP Communications and IR
E-mail: oskar.bosson@bioarctic.se
Phone: +46 70 410 71 80

About lecanemab (generic name, brand name: 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, and Israel as treatment for early Alzheimer's disease (mild cognitive impairment and mild dementia due to Alzheimer's disease).

Lecanemab approvals were based on the large global Phase 3 Clarity AD study. In the Clarity AD study, lecanemab met its primary endpoint and all key secondary endpoints with statistically significant results. In November 2022, the results of the Clarity AD study were presented at the 2022 Clinical Trials on Alzheimer's Disease (CTAD) conference, and simultaneously published in the New England Journal of Medicine, a peer-reviewed medical journal.

Eisai has also submitted applications for approval of lecanemab in 11 other countries and regions, including the European Union (EU). A supplemental Biologics License Application (sBLA) for intravenous maintenance dosing was submitted to the U.S. Food and Drug Administration (FDA) in March 2024. The rolling submission of a Biologics License Application (BLA) for maintenance dosing of a subcutaneous injection formulation, which is being developed to enhance convenience for patients, was initiated in the U.S. under Fast Track status in May 2024.

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.