Press release

CHMP issues positive recommendation for approval of lecanemab in the EU

Stockholm, November 14, 2024 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) today announces that EMA's Committee for Medicinal Products for Human Use (CHMP) has issued a positive recommendation regarding BioArctic's partner Eisai's marketing authorization application (MAA) for lecanemab as treatment of Alzheimer's disease. The recommendation applies to the treatment of early Alzheimer's disease in adult patients that are apolipoprotein E ε4 (ApoE ε4) heterozygotes or non-carriers.

The CHMP recommendation for the European Commission to approve lecanemab follows Eisai's request for a re-examination of the CHMP's earlier negative recommendation. A decision from the European Commission is expected within 67 days.

The CHMP recommends approval of lecanemab for the treatment of mild cognitive impairment (MCI) and mild dementia caused by Alzheimer's disease, in adult patients who are heterozygotes (carry one copy) or are non-carriers of the Apolipoprotein E ε4 (ApoE ε4) gene.

"We are very happy and grateful that the CHMP, during their re-examination of lecanemab, has recognized that for the patients in this population, the benefit of the treatment is greater than the risk. We now look forward to the European Commission's decision that is the next step towards providing access to this new treatment for patients in Europe with Alzheimer's disease," said Gunilla Osswald, CEO at BioArctic.

Lecanemab is already approved in the US, Japan, China, South Korea, Hong Kong, Israel, the United Arab Emirates, and the Great Britain.

Eisai is responsible for the clinical development, applications for market approval and commercialization of lecanemab for Alzheimer's disease. BioArctic has the rights to commercialize lecanemab in the Nordic region. Currently, BioArctic and Eisai are preparing for joint commercialization in these countries, pending approval from the European Commission.

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 (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, United Arab Emirates and Great Britain for the treatment of MCI due to AD and mild AD dementia. Lecanemab's approvals in these countries, as well as the CHMP's 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. 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). Of the total number of patients randomized 31% were non-carriers, 53% were heterozygotes and 16% were homozygotes. 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.

The primary endpoint was the global cognitive and functional scale, CDR-SB. In the Clarity AD clinical trial, treatment with lecanemab, in the recommended indicated population (ApoE ε4 heterozygotes or non-carriers), reduced clinical decline on CDR-SB by 33% at 18 months compared to placebo. The mean CDR-SB score at baseline was approximately 3.2 in both groups. The adjusted least-squares mean change from baseline at 18 months was 1.15 with lecanemab and 1.73 with placebo (difference, −0.58; 95% confidence interval [CI], −0.81 to −0.35; P<0.00001). 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 39% less decline compared to placebo at 18 months. The adjusted mean change from baseline at 18 months in the ADCS-MCI-ADL score was −3.5 in the lecanemab group and −5.7 in the placebo group (difference, 2.2; 95% CI, 1.3 to 3.1; P<0.00001). 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 recommended indicated population (ApoE ε4 heterozygotes or non-carriers), the most common adverse reactions were infusion-related reaction (26%), ARIA-H (13%), fall (11%), headache (11%) and ARIA-E (9%).

Eisai has also submitted applications for regulatory approval of lecanemab in 17 other countries and regions, including the European Union. A supplemental Biologics License Application (sBLA) for less frequent intravenous maintenance dosing was submitted to the U.S. Food and Drug Administration (FDA) in March 2024, which was accepted in June 2024. In October 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 completed in the U.S. under Fast Track status.

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 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.