BIOARCTIC

Press release

Eisai completes rolling submission to the FDA of lecanemab for early Alzheimer's disease under the accelerated approval pathway

Stockholm, May 10, 2022 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that they have completed the rolling submission to the U.S. Food and Drug Administration (FDA) of a Biologics License Application (BLA) under the accelerated approval pathway for the investigational anti-amyloid beta (Aβ) protofibril antibody lecanemab (BAN2401), for the treatment of mild cognitive impairment (MCI) due to Alzheimer's disease (AD) and mild AD (collectively known as early AD) with confirmed presence of amyloid pathology in the brain. In conjunction with the completed regulatory filing to the FDA announced today, and the subsequent acceptance by the FDA of the file, BioArctic is entitled to a milestone of MEUR 15.

As part of the completed rolling submission, Eisai has requested Priority Review. If the FDA accepts the BLA, the Prescription Drug User Fee Act (PDUFA) action date (target date for completion of examination) will be set. While Eisai is currently submitting lecanemab under the accelerated approval pathway, the lecanemab Phase 3 confirmatory Clarity AD clinical trial conducted with 1,795 patients will report out in the Fall of 2022. The FDA has agreed that the results of Clarity AD, when completed, can serve as the confirmatory study to verify the clinical benefit of lecanemab. Dependent upon the results of the Clarity AD clinical trial, Eisai may submit for full approval of lecanemab to the FDA before the end of the first quarter 2023.

The BLA submission for lecanemab is based on clinical, biomarker and safety data from the Phase 2b study in 856 people with early AD with confirmed presence of amyloid pathology, biomarker and safety data from the Phase 2b open-label extension study (180 subjects), and blinded safety data from the confirmatory Clarity AD Phase 3 study (1,795 subjects). The large number of participants across these studies provides the FDA with extensive safety data.

The Phase 2b study explored the impact of treatment with lecanemab on reducing amyloid plaque in the brain and clinical decline. At 18 months of treatment, lecanemab reduced brain amyloid to the extent that over 80% of subjects became amyloid negative by visual read. Furthermore, the extent of reduction in amyloid was correlated with slower clinical decline on ADCOMS (Alzheimer's Disease Composite Score), CDR-SB (Clinical Dementia Rating-Sum-of-Boxes), and ADAS-cog (Alzheimer Disease Assessment Scale-Cognitive Subscale) at the treatment group and patient level. In the Core study, the overall rate of amyloid-related imaging abnormalities-edema/effusion (ARIA-E), an adverse event associated with anti-amyloid beta antibodies therapies was 9.9% (16/161) of patients treated with lecanemab 10 mg/kg biweekly compared with 0.8% (2/245) of placebo patients. The results from the Phase 2b study were published in a peer-reviewed journal Alzheimer's Research and Therapy in April 2021.

"I am impressed by our colleagues at Eisai and their diligent work to help patients and caregivers living with Alzheimer's disease. The completion of the rolling submission is an important milestone to potentially providing new treatment options, and I am proud of the BioArctic coworkers who made their contribution to making this possible," said Gunilla Osswald, BioArctic's CEO.

Lecanemab was granted Breakthrough Therapy and Fast Track designations by the FDA in June and December 2021, respectively. In March 2022, Eisai initiated submission of application data to the Pharmaceuticals and Medical Devices Agency (PMDA) under the prior assessment consultation system in Japan with the aim of obtaining early approval for lecanemab. Eisai aims to file for manufacturing and marketing approval based on the results of Clarity AD in the US, Japan and in EU before the end of the first quarter 2023.

This release discusses investigational uses of an agent in development and is not intended to convey conclusions about efficacy or safety. There is no guarantee that any investigational uses of such product will successfully complete clinical development or gain health authority approval.

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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 above, on May 10, 2022, at 01:35 a.m. CET.

About lecanemab (BAN2401)
Lecanemab is an investigational humanized monoclonal antibody for Alzheimer's disease (AD) that is the result of a strategic research alliance between Eisai and BioArctic. Lecanemab selectively binds to, neutralize and eliminate soluble toxic Aβ aggregates (protofibrils) that are thought to contribute to the neurodegenerative process in AD. As such, lecanemab may have the potential to have an effect on disease pathology and to slow down the progression of the disease. Eisai obtained the global rights to study, develop, manufacture, and market lecanemab for the treatment of AD pursuant to an agreement concluded with BioArctic in December 2007. In March 2014, Eisai and Biogen entered into a joint development and commercialization agreement for lecanemab. Currently, lecanemab is being studied in a pivotal Phase 3 clinical study in symptomatic early AD (Clarity AD), following the outcome of the Phase 2b clinical study (Study 201). In addition, the Phase 3 clinical study, AHEAD 3-45, for individuals with preclinical (asymptomatic) AD, meaning they are clinically normal and have intermediate or elevated levels of brain amyloid, is ongoing. AHEAD 3-45 is conducted as a public-private partnership between the Alzheimer's Clinical Trial Consortium, funded by the National Institute on Aging, part of the National Institutes of Health, and Eisai. In 2021, DIAN-TU selected lecanemab for a clinical trial for dominantly inherited Alzheimer's disease as a background anti-amyloid treatment when exploring combination

therapies with anti tau treatments in dominantly inherited Alzheimer's disease subjects. In June 2021, FDA granted lecanemab Breakthrough Therapy designation and in December 2021, FDA granted lecanemab Fast track designation. Furthermore, Eisai has performed a lecanemab subcutaneous dosing Phase 1 study and the subcutaneous formulation is currently being evaluated in the Clarity AD open label extension study.

About the collaboration between BioArctic and Eisai
Since 2005, BioArctic has 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 in December 2007, and the Development and Commercialization agreement for the antibody BAN2401 back-up for Alzheimer's disease, which was signed in May 2015. Eisai is responsible for the clinical development, application for market approval and commercialization of the products for Alzheimer's disease. BioArctic has no development costs for lecanemab in Alzheimer's disease and is entitled to payments in connection with regulatory filings, 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 disease-modifying treatments and reliable biomarkers and diagnostics for neurodegenerative diseases, such as Alzheimer's disease and Parkinson's disease. BioArctic focuses on innovative treatments in areas with high unmet medical needs. The company was founded in 2003 based on innovative research from Uppsala University, Sweden. Collaborations with universities are of great importance to the company together with its strategically important global partner Eisai in Alzheimer disease. The project portfolio is a combination of fully funded projects run in partnership with global pharmaceutical companies and innovative in-house projects with significant market and out-licensing potential. BioArctic's Class B share is listed on Nasdaq Stockholm Mid Cap (ticker: BIOA B). For more information about BioArctic, please visit www.bioarctic.com.