Press release

The FDA accepts BLA and grants priority review for lecanemab for treatment of early Alzheimer's disease under the accelerated approval pathway

Stockholm, July 6, 2022 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that the U.S. Food and Drug Administration (FDA) has accepted the Biologics License Application (BLA) under the accelerated approval pathway for lecanemab (development code: BAN2401), an investigational anti-amyloid beta (Aβ) protofibril antibody 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. Eisai's application, which was completed in early May 2022, has been granted Priority Review with a Prescription Drug User Fee Act (PDUFA) action date on January 6, 2023. The acceptance of the BLA by the FDA entitles BioArctic to a milestone payment of MEUR 15 from Eisai.

The Clarity AD Phase 3 confirmatory clinical trial for lecanemab in early AD is ongoing and enrollment of 1,795 patients was completed in March 2021. The readout of the primary endpoint data from the trial will occur 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. Eisai utilized the FDA's Accelerated Approval Pathway in an effort to streamline the submission process for the potential traditional approval of lecanemab in order to expedite patients' access to lecanemab. Dependent upon the results of the Clarity AD clinical trial, Eisai will submit for traditional approval of lecanemab to the FDA before the end of the first quarter 2023.

"For almost 20 years now, BioArctic's vision has been to develop innovative medicines for people with neurological disorders such as Alzheimer's disease, a disease which affects millions of people around the world. FDA's acceptance of the BLA and granting of a priority review for lecanemab brings us one step closer in our quest to meet the huge medical need in this patient population," 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 Japan's Pharmaceuticals and Medical Devices Agency (PMDA) under the prior assessment consultation system, 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 July 6, 2022, at 01:30 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 BioArctic and Eisai. 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 for neurodegenerative diseases, such as Alzheimer's disease, Parkinson's disease and ALS. 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.