Press release

Full results of lecanemab Phase 3 confirmatory Clarity AD study for early Alzheimer's disease published in the New England Journal of Medicine

Stockholm, November 30, 2022 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that the results from the large global Phase 3 confirmatory Clarity AD clinical study of 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, were published in the New England Journal of Medicine, one of the world's most prestigious peer-reviewed medical journals. For the details of the paper, please refer to here.

Eisai serves as the lead of lecanemab development and regulatory submissions globally and remain committed to disclosing data and information on lecanemab. If approved, Eisai will work to bring the drug expeditiously to people living with early AD and their families.

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 such an investigational agent will successfully gain health authority approval.

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 November 30, 2022, at 01:50 a.m. CET.

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About the published article in the New England Journal of Medicine
Eleven experts from leading medical institutions and eight experts form Eisai: Christopher H. van Dyck1), Chad J. Swanson2), Paul Aisen3), Randall J. Bateman4), Christopher Chen5), Michelle Gee6), Michio Kanekiyo2), David Li2), Larisa Reyderman2), Sharon Cohen7), Lutz Froelich8), Sadao Katayama9), Marwan Sabbagh11), Bruno Vellas12), David Watson13), Shobha Dhadda2), Michael Irizarry2), Lynn D. Kramer2), and Takeshi Iwatsubo10). Trial of Lecanemab in Early Alzheimer's Disease. N Engl J Med 2022.

The authors' affiliations are as follows: 1)The Alzheimer's Disease Research Unit, Yale School of Medicine, New Haven, CT; 2)Eisai, Nutley, NJ; 3)The Alzheimer's Therapeutic Research Institute, University of Southern California, San Diego; 4)Washington University School of Medicine in St. Louis, St. Louis; 5)The Memory, Aging, and Cognition Center, Department of Pharmacology, Yong Loo Lin School of Medicine, National University of Singapore, Singapore; 6)Eisai, Hatfield, United Kingdom; 7)Toronto Memory Program, Toronto; 8)Medical Faculty Mannheim, University of Heidelberg, Central Institute of Mental Health, Mannheim, Germany; 9)Katayama Medical Clinic, Okayama, Japan; 10)the Department of Neuropathology, Graduate School of Medicine, University of Tokyo, and the National Center of Neurology and Psychiatry, Tokyo, Japan; 11)Barrow Neurological Institute, Phoenix, AZ; 12)Toulouse Gerontopole University Hospital, Université Paul Sabatier, INSERM Unité 1295, Toulouse, France; and 13)Alzheimer's Research and Treatment Center, Wellington, FL.

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. Currently, lecanemab is being developed as the only late-stage anti-Aβ antibody that can be used for the treatment of early AD without the need for titration, enabling full treatment effect from day one.

The Clarity AD open-label extension is underway with treatment initiated after completion of the Core period to further evaluate the safety and efficacy of lecanemab. In addition, the lecanemab Phase 3 clinical study AHEAD 3-45 is ongoing for individuals with preclinical (asymptomatic) AD, meaning they are clinically normal and have intermediate or elevated levels of brain amyloid. 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, lecanemab was selected for the Tau NexGen clinical study for Dominantly Inherited Alzheimer's disease (DIAD), as a background anti-amyloid treatment when exploring combination therapies with anti-tau treatments. The study, which is ongoing, is conducted by Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU), led by Washington University School of Medicine in St. Louis. 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.

In July 2022, the U.S. Food and Drug Administration (FDA) accepted Eisai's Biologics License Application (BLA) for lecanemab under the Accelerated Approval Pathway and granted Priority Review. The Prescription Drug User Fee Act action date (PDUFA) is set for January 6, 2023. The FDA has agreed that the results of Clarity AD can serve as the confirmatory study to verify the clinical benefit of lecanemab. In an effort to secure traditional FDA approval for lecanemab as soon as possible, Eisai submitted the BLA through the FDA's Accelerated Approval Pathway so that the agency could complete its review of all lecanemab data with the exception of the data from the confirmatory Clarity AD study. In March 2022, Eisai began submitting application data, with the exception of Clarity AD data, to Japan's Pharmaceuticals and Medical Devices Agency (PMDA) under the prior assessment consultation system. Eisai will discuss the results of Clarity AD study with regulatory authorities in the U.S., Japan and Europe with the aim to file for traditional approval in the U.S., and to submit marketing authorization applications in Japan and Europe by the end of the first quarter 2023.

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 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. In March 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 right to commercialize lecanemab in the Nordic 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 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.