Press release

Latest data on lecanemab presented at Alzheimer's Association International Conference (AAIC)

Stockholm, August 5, 2022 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai presented new data for lecanemab (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, at the Alzheimer's Association International Conference (AAIC) held in San Diego, California and virtually July 31 through August 4, 2022.

Eisai presented lecanemab data and research in one oral and eight poster presentations at the meeting. Highlights included new data on a subcutaneous formulation of lecanemab. The new data has been used to define the appropriate subcutaneous dosing now being further evaluated in the Phase 3 Clarity AD open label extension study. A further highlight was the presentation of a modeling simulation of the impact of ApoE4 genotype on the incidence of amyloid-related imaging abnormalities – edema/effusion (ARIA-E) – in subjects treated with lecanemab. The modeling predicted incidence on ARIA-E in ApoE4 carriers (homo- and heterozygotes) and non-carriers, and corresponds well with what has been observed in the Phase 2b core and open label extension studies.

"Eisai's broad clinical program for lecanemab continues to deliver data regarding how lecanemab could be used as a potential disease-modifying treatment for patients with Alzheimer's disease. The subcutaneous dosing currently being evaluated in the Clarity AD open-label extension study can potentially be of further benefit for patients. There is a great enthusiasm in the Alzheimer field for lecanemab and the other late-stage second generation anti-amyloid antibodies with Phase 3 readouts in the coming months. We are eagerly looking forward to the topline data of the Clarity AD Phase 3 study this fall and the possibility of helping the Alzheimer community battle the disease," said BioArctic's CEO Gunilla Osswald.

In July 2022, the U.S. Food and Drug Administration (FDA) accepted the Biologics License Application (BLA) for lecanemab under the accelerated approval pathway and was granted priority review, with a Prescription Drug User Fee Act (PDUFA) action date of January 6, 2023. The readout of the primary endpoint data of Clarity AD 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.

All Eisai's presentation and posters from the AAIC congress regarding lecanemab are available on www.bioarctic.com.

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.

For further information, please contact:
Gunilla Osswald, CEO
E-mail: gunilla.osswald@bioarctic.se
Phone: +46 8 695 69 30

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

The information was released for public disclosure, through the agency of the contact persons above, on August 5, 2022, at 08:00 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.