



Press release

BioArctic's partner Eisai presents data from the ongoing BAN2401 Phase 2b extension study in early Alzheimer's disease

Stockholm, Sweden, December 5, 2019 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) announced today that data from the ongoing BAN2401 Phase 2b open-label extension study in early Alzheimer's disease patients was presented by Eisai at the Clinical Trials in Alzheimer's Disease (CTAD) conference in San Diego, US. A subset of patients from the core Phase 2b study enrolled in the open label extension study. The analysis compared baseline assessments from the open-label extension phase with results at the end of the core Phase 2b study. Patients were off treatment between the end of the core Phase 2b study until the start of the Phase 2b extension phase. The analysis showed that amyloid reductions in the brain that occurred as a result of treatment with BAN2401 persisted after treatment was stopped. Differences in benefits on clinical outcomes were maintained after stopping treatment in patients who received BAN2401 at the two highest doses as compared with patients receiving placebo. The full presentation from the CTAD conference can be viewed on BioArctic's website at www.bioarctic.com.

"This baseline open label extension study data is encouraging and supports the consistent benefits seen in the core Phase 2b study. We are pleased with Eisai's commitment to the program and look forward to the potential for BAN2401 to be a disease modifying treatment for Alzheimer's disease patients," said Gunilla Osswald, CEO of BioArctic.

The design of the ongoing Phase 3 Clarity AD trial will be presented by Eisai on Friday, December 6 in a poster session at the CTAD conference. For more information on CLARITY AD (ClinicalTrials.gov Identifier: NCT03887455) please visit <https://clinicaltrials.gov/ct2/show/NCT03887455>.

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 December 5, 2019, at 8.15 p.m. CET.

Notes to editors

About BAN2401

BAN2401 is a humanized monoclonal antibody that is the result of a strategic research alliance between BioArctic and Eisai. BAN2401 has a unique binding profile and selectively binds to and eliminates soluble, toxic amyloid beta aggregates (protofibrils and oligomers) that are thought to contribute to the neurodegenerative process in Alzheimer's disease. As such, BAN2401 has the potential to have an effect on the disease pathology and to slow down the progression of the disease. Eisai obtained the global rights to study, develop, manufacture and market BAN2401 for the treatment of Alzheimer's disease 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 BAN2401.

About the Clarity AD Phase 3 study

BAN2401 is being studied by BioArctic's partner Eisai in a global Phase 3 study (named Clarity AD) to confirm the efficacy and safety of BAN2401 in patients with early Alzheimer's disease. The confirmatory Phase 3 study is a global placebo-controlled, double-blind, parallel-group, randomized study in 1,566 patients between 50 and 90 years of age with early Alzheimer's disease (i.e. mild cognitive impairment (MCI) due to Alzheimer's disease or mild Alzheimer's disease dementia with confirmed amyloid pathology in the brain). Amyloid pathology will be confirmed by positron emission tomography (PET) or cerebrospinal fluid (CSF) assessment. Patients will be allocated in a 1:1 ratio to receive either placebo or BAN2401 treatment. In the treatment group, BAN2401 will be administered at a dosage of 10 mg/kg every other week. The primary endpoint is the change from baseline in the cognition and function scale Clinical Dementia Rating-Sum of Boxes (CDR-SB) at 18 months of treatment. Changes in the clinical scales AD composite score (ADCOMS) and AD Assessment Scale-Cognitive Subscale (ADAS-Cog) will be key secondary endpoints together with brain amyloid levels as measured by amyloid PET. According to Eisai, the final readout of the primary endpoint of the study is targeted for 2022.

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 on the BAN2401 antibody, which was signed in December 2007, and the development and commercialization agreement on 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 BAN2401 in Alzheimer's disease.

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 partners in the Alzheimer (Eisai) and Parkinson (AbbVie) projects. 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 B-share is listed on Nasdaq Stockholm Mid Cap (ticker: BIOA B). For more information about BioArctic, please visit www.bioarctic.com.

About Eisai Co., Ltd.

Eisai Co., Ltd. is a leading global research and development-based pharmaceutical company headquartered in Japan. Eisai defines their corporate mission as "giving first thought to patients and their families and to increasing the benefits health care provides," which Eisai calls their *human health care (hhc)* philosophy. With approximately 10,000 employees working across the global network of R&D facilities, manufacturing sites and marketing subsidiaries, Eisai strives to realize their *hhc* philosophy by delivering innovative products to address unmet medical needs, with a particular focus in the strategic areas of Neurology and Oncology.

Leveraging the experience gained from the development and marketing of Aricept[®], a treatment for Alzheimer's disease and dementia with Lewy bodies, Eisai has been working to establish a social environment that involves patients in each community in cooperation with various stakeholders including the government, healthcare professionals and care workers, and is estimated to have held over ten thousand dementia awareness events worldwide. As a pioneer in the field of dementia treatment, Eisai is striving to not only develop next generation treatments but also to develop diagnosis methods and provide solutions. For more information about Eisai Co., Ltd., please visit www.eisai.com.