



## Press release

# BioArctic's partner Eisai initiates the confirmatory Phase 3 study of BAN2401 in early Alzheimer's Disease

**Stockholm, Sweden, March 22, 2019** – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) announced today that its partner Eisai has initiated the global Phase 3 confirmatory study of BAN2401 in patients with early Alzheimer's disease.

The Phase 3 study (named Clarity AD/Study 301) that is now initiated is a global placebo-controlled, double-blind, parallel-group, randomized study in 1566 patients with early Alzheimer's disease i.e. mild cognitive impairment (MCI) due to Alzheimer's disease or mild Alzheimer's disease with confirmed amyloid pathology in the brain. Patients are allocated in a 1:1 ratio to receive either placebo or treatment. In the treatment group, BAN2401 will be administered at a dosage of 10 mg/kg twice a month. 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 is targeted for 2022.

The confirmatory Phase 3 study follows the results from the Phase 2b study of BAN2401 in 856 patients with early Alzheimer's disease that robustly demonstrated slowing of clinical decline with good tolerability after 18 months treatment. The results also showed a very strong reduction of aggregated amyloid-beta in the brain and effect on CSF biomarkers of neurodegeneration. Data from the Phase 2b study were presented at international congresses in 2018.

BAN2401 is a humanized monoclonal antibody selectively targeting toxic aggregated forms of amyloid-beta in the brain. BioArctic's partner Eisai is responsible for the clinical development of BAN2401 in Alzheimer's disease. After discussion with regulatory agencies based on the results of the Phase 2b clinical study, Eisai has initiated the single Phase 3 clinical study in early Alzheimer's disease to support a regulatory filing for BAN2401.

Eisai acquired the global rights to develop and market BAN2401 for the treatment of Alzheimer's disease in 2007. BioArctic has no development costs for BAN2401 in Alzheimer's disease. The value of the total deals amounts to MEUR 218 plus royalties of which MEUR 47 has already been received. BioArctic is entitled to a milestone payment when the first patient has been dosed in the confirmatory Phase 3 study with BAN2401 in early Alzheimer's disease.



“We are very pleased to see that the confirmatory Phase 3 study with BAN2401 in early Alzheimer’s disease is now initiated. There is a plan for fast recruitment and Eisai is targeting a final readout already in 2022. The Phase 3 study is designed to confirm the previously observed positive Phase 2b results in early Alzheimer’s disease patients. The intention with BAN2401 is to slow down the progression of the disease and improve the quality of life for Alzheimer’s patients,” comments Gunilla Osswald, Ph.D., CEO, BioArctic.

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 March 22, 2019, at 00.40 a.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 selectively binds to neutralize and eliminate soluble, toxic amyloid-beta aggregates 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. Eisai is responsible for the Phase 2b and Phase 3 studies of BAN2401 for Alzheimer’s disease. In March 2014, Eisai and Biogen entered into a joint development and commercialization agreement for BAN2401. Currently, the



open label extension phase of a Phase 2b clinical study targeting patients who were enrolled in the study is ongoing.

#### **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.

#### **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. The company also develops a potential treatment for Complete Spinal Cord Injury. 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 our 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](http://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 our strategic areas of Neurology and Oncology.

Leveraging the experience gained from the development and marketing of Aricept<sup>®</sup>, 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](http://www.eisai.com).