



## Press release

# **BioArctic: Alzheimer’s Clinical Trials Consortium and Eisai announce BAN2401 to be evaluated in clinical study for prevention of Alzheimer’s disease**

**Stockholm, Sweden, May 10, 2019** – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) informed today that the Alzheimer’s Clinical Trials Consortium (ACTC) and BioArctic’s partner Eisai have announced the selection of BAN2401 to be evaluated in an upcoming clinical study targeting secondary prevention of Alzheimer’s disease (the A45 study). This study will be conducted with funding from various sources including the United States National Institute on Aging (NIA), part of the National Institutes of Health (NIH), and Eisai.

The ACTC, which is an NIA-funded clinical trial network with 35 primary clinical study sites across the United States, aims to accelerate and expand studies for therapies in Alzheimer’s disease and related dementias across the spectrum from pre-symptomatic to more severe stages of disease. The network was established with grant funding from the NIA in December 2017. The A45 Study is led by three academic principal investigators: Dr. Paul Aisen from University of Southern California, and Drs. Reisa Sperling and Keith Johnson from Brigham and Women’s Hospital and Massachusetts General Hospital, Harvard Medical School.

The A45 study will target the preclinical (pre-symptomatic) stage of Alzheimer’s disease. The study will enroll clinically normal participants (no/minor cognitive impairment) who have elevated levels of amyloid in the brain and are at high risk for progression to mild cognitive impairment and Alzheimer’s disease dementia. The A45 study will be a global, multicenter, double-blinded, placebo-controlled, randomized trial of a treatment regimen consisting of an anti-Abeta antibody and a BACE inhibitor to prevent cognitive decline and delay biomarkers of pathological progression versus placebo. In the active arm, individuals will be provided first with BAN2401 (the anti-Abeta antibody) with the goal to clear amyloid deposits and Abeta protofibrils from the brain, after which they will be maintained on elenbecestat (the BACE inhibitor) with the aim of decreasing the production of Abeta and preventing the reaccumulation of amyloid plaques and protofibrils. Elenbecestat is Eisai’s investigational candidate for the treatment of Alzheimer’s disease that inhibits beta amyloid cleaving enzyme (BACE inhibitor). The trial will be starting in early 2020.

“We are pleased that Eisai and the ACTC consortium are partnering to evaluate BAN2401 as a potential treatment for even earlier stages of Alzheimer’s disease. The ACTC planned clinical study



will include individuals that are at risk for, or at a very early stages of, Alzheimer's disease," comments Gunilla Osswald, 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.

**For more information, please contact:**

Gunilla Osswald, PhD, CEO, BioArctic AB

E-mail: [gunilla.osswald@bioarctic.se](mailto:gunilla.osswald@bioarctic.se)

Telephone: + 46 8 695 69 30

Jan Mattsson, CFO, BioArctic AB

Telephone: +46 70 352 27 72

E-mail: [jan.mattsson@bioarctic.se](mailto:jan.mattsson@bioarctic.se)

*This information was submitted for publication at 09:30 a.m. CET on May 10, 2019.*

**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 neutralize and eliminate soluble, toxic amyloid-beta aggregates (protofibrils) 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. Currently, a global confirmatory Phase 3 clinical study (Clarity AD) of BAN2401 in patients with early Alzheimer's disease is underway. 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. 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 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](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).