



## Press release

### **BioArctic announces that the Phase 2b study of BAN2401 in early Alzheimer's Disease continues toward 18 month endpoint**

*Criteria for success at 12 month interim analysis of ADCOMS not met*

*Study to remain blinded per protocol until final readout of comprehensive 18 month data*

**Stockholm, Sweden, December 21, 2017** – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) announced today that an Independent Data Monitoring Committee has determined that BAN2401, an anti-amyloid beta protofibril selective antibody, did not meet the criteria for success based on a Bayesian analysis at 12 months as the primary endpoint in an 856-patient Phase 2b clinical study (Study 201).

Following the predefined study protocol, the blinded study will continue and a comprehensive final analysis of safety, tolerability and efficacy will be conducted at 18 months with the objective of demonstrating clinical efficacy of BAN2401. The results of the final analysis are expected to be obtained during the second half of 2018.

Study 201 (ClinicalTrials.gov identifier NCT01767311) is a placebo-controlled, double-blind, parallel-group, randomized study in patients with prodromal or mild Alzheimer's Disease (collectively known as early Alzheimer's Disease) and with positive biomarkers for brain amyloid pathology.

The study design included 16 interim analyses that assessed potential for futility or stopping for safety. The study has passed all interim analyses since it met the criteria for continuation and the study continues to a full analysis at 18 months.

The efficacy of five dose groups of BAN2401 was evaluated at 12 months based on Eisai's in-house developed novel endpoint Alzheimer's Disease Composite Score (ADCOMS). According to the Bayesian analysis at 12 months, success was judged as an 80% or higher probability of having efficacy expected to correspond to a 25% or greater reduction in the rate of decline of ADCOMS by BAN2401 compared to placebo.

In the final analysis at 18 months, safety, tolerability and a comprehensive evaluation of efficacy measured by ADCOMS and Clinical Dementia Rating Sum of Boxes (CDR-SB), as well as changes in



biomarkers such as brain amyloid levels as measured by amyloid PET and total hippocampal volume using vMRI, will be assessed.

BioArctic develops completely new types of drugs for Alzheimer patients with the aim of slowing down the progression of the disease, unlike today's symptomatic drugs. Since 2005, BioArctic has long-term collaboration with Eisai regarding the development and commercialization of drugs including BAN2401 for the treatment of Alzheimer's Disease. Since March 2014, Eisai and Biogen have been jointly developing BAN2401.

“The 12 month interim analysis of this study utilizes an innovative Bayesian design with a high hurdle for crossing the success boundary. It is considered that 18 month treatment is a more appropriate assessment time to demonstrate efficacy of a disease modifying therapy for Alzheimer's Disease. We look forward to the final results after completion of the study following 18 months of treatment,” said Gunilla Osswald, CEO of BioArctic.

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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 21, 2017, at 01.00 p.m. CET.*

**Notes to editors**

**About BAN2401**

BAN2401 is a humanized monoclonal antibody for Alzheimer's Disease that is the result of a strategic research alliance between BioArctic and Eisai. BAN2401 selectively binds, neutralizes and eliminates soluble, toxic A $\beta$  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 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.

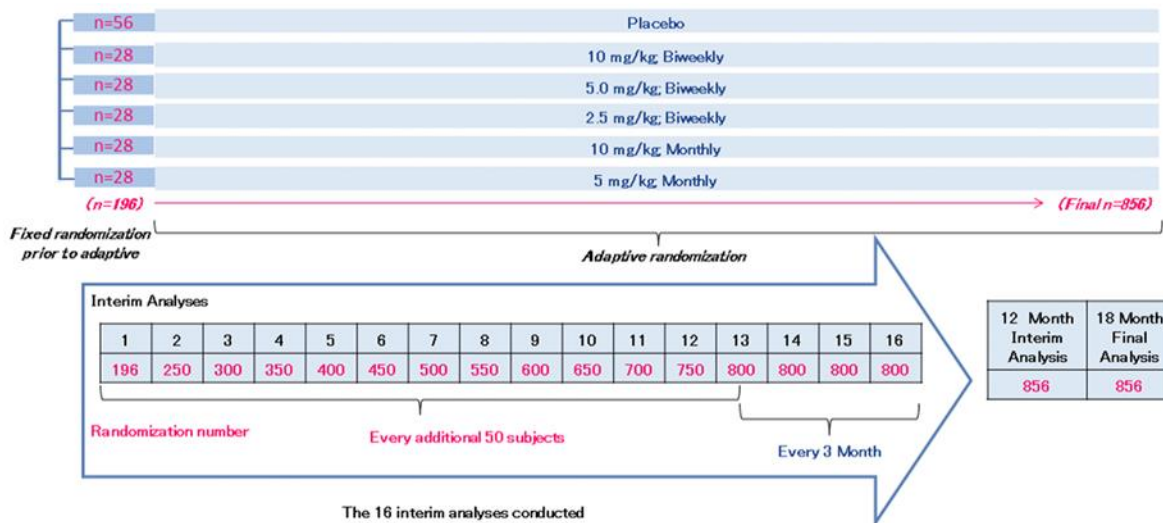
**About Study 201 (ClinicalTrials.gov identifier NCT01767311)**

Study 201 is a placebo-controlled, double-blind, parallel-group study to evaluate safety, tolerability and efficacy of BAN2401 in patients with prodromal or mild Alzheimer’s Disease (collectively known as early Alzheimer’s Disease) and with positive biomarkers for brain amyloid pathology. Bayesian Adaptive Randomization Design is used which allows for adaptively changing the subject allocation ratio to treatment arms with higher probabilities based on the results of interim analyses in order to more efficiently identify the effectiveness and optimal dose regimen of BAN2401.

The patients are treated with BAN2401 or placebo for 18 months with a 3 months follow-up period. The study will explore efficacy and the dose response of BAN2401 with 16 interim analyses, a 12 month interim based on ADCOMS and an 18 months comprehensive assessment of treatment with placebo or 5 active arms. The 5 treatment arms consist of 3 dose levels (2.5 mg/kg, 5 mg/kg, 10 mg/kg) given biweekly and 2 dose levels (5 mg/kg, 10 mg/kg) given monthly.

After 12 months of treatment, change from baseline in the ADCOMS is evaluated at the analysis. In the final analysis at 18 months, comprehensive evaluation including changes from baseline in ADCOMS and Clinical Dementia Rating Sum of Boxes (CDR-SB), as well as changes in brain amyloid levels as measured by amyloid PET and in total hippocampal volume using vMRI, will be conducted.

**Bayesian Adaptive Randomization Design:**





### **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.

### **About BioArctic AB**

BioArctic AB 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. 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 (STO:BIOA B). For more information about BioArctic AB, 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 the strategic areas of Oncology and Neurology.

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).