Press release

BioArctic announces positive topline results of BAN2401 Phase 2b at 18 months in early Alzheimer's Disease

- *The full 18 month analysis of the 856 patient BAN2401 Phase 2b clinical study in early Alzheimer's disease demonstrated statistically significant and dose-dependent slowing in clinical decline and reduction of amyloid beta accumulated in the brain.*
- *First late-stage study successfully demonstrating potential disease-modifying effects on both clinical function and amyloid beta accumulation in the brain.*

Stockholm, Sweden, July 6, 2018 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) today announced positive topline results from the Phase 2b study with BAN2401, an anti-amyloid beta protofibril antibody, in 856 patients with early Alzheimer's disease. The study achieved statistical significance on key efficacy endpoints at 18 months on slowing progression in Alzheimer's Disease Composite Score (ADCOMS) and on reduction of amyloid accumulated in the brain as measured by using amyloid-PET (Positron Emission Tomography).

The Phase 2b study with BAN2401 (ClinicalTrials.gov identifier NCT01767311) is a placebo-controlled, double-blind, parallel-group, randomized study in 856 patients with mild cognitive impairment (MCI) due to Alzheimer's disease (AD) or mild Alzheimer's dementia (collectively known as early Alzheimer's disease) with confirmed amyloid pathology in the brain at the start of the study. The study used an innovative Bayesian adaptive design allowing several doses to be evaluated. Efficacy was analyzed up to 18 months based on ADCOMS which combines items from the Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-Cog), the Clinical Dementia Rating Sum of Boxes (CDR-SB) scale and the Mini-Mental State Examination (MMSE) to enable sensitive detection of changes in early AD symptoms. Patients were randomized to placebo and five dose regimens, 2.5 mg/kg twice a month, 5 mg/kg monthly, 5 mg/kg twice a month, 10 mg/kg monthly and 10 mg/kg twice a month.

Topline results of the final analysis of the study demonstrated a statistically significant slowing of disease progression on the key clinical endpoint (ADCOMS) after 18 months of treatment in patients receiving the highest treatment dose (10 mg/kg twice a month) as compared to placebo. Results of amyloid PET analyses at 18 months, including reduction in amyloid PET standardized uptake value ratio (SUVR) and amyloid PET image visual read of subjects converting from positive to negative for amyloid in the brain, were also statistically significant at this dose. Dose-dependent changes from baseline were observed across the PET results and the clinical endpoints. Further,

the highest treatment dose of BAN2401 began to show statistically significant clinical benefit as measured by ADCOMS as early as 6 months including at 12 months.

BAN2401 was well tolerated through 18 months of study drug administration. The most common treatment emergent adverse events were infusion-related reactions and Amyloid Related Imaging Abnormalities (ARIA). Infusion related reactions were mostly mild to moderate in severity. Incidence of ARIA-E (edema) was not more than 10% in any of the treatment arms, and less than 15% in patients with APOE4 at the highest dose per the study protocol safety and reporting procedures.

As reported in December 2017, the study did not achieve its primary outcome measure which was designed to enable a potentially more rapid entry into Phase 3 development based on Bayesian analysis at 12 months of treatment. Following the predefined study protocol, the blinded study continued with a comprehensive final analysis on treatment conducted at 18 months. Upon the final analysis at 18 months using predefined conventional statistical method, the study did demonstrate a statistically significant slowing of disease progression on the key clinical endpoint (ADCOMS) after 12 months of treatment in patients receiving the highest treatment dose (10 mg/kg twice a month) as compared to placebo. The study is ongoing with a further follow-up assessment at 21 months.

BioArctic's partner Eisai is responsible for the Phase 2b study and the development of BAN2401 for Alzheimer's disease. Detailed results of the study will be presented at future scientific conferences.

"BAN2401 has a unique target which lead to a clinically meaningful benefit with good tolerability in the Phase 2b study. The antibody was developed to selectively target soluble, toxic aggregated amyloid-beta, i. e. protofibrils, in the brain of Alzheimer patients. We made a clinical observation in the late 1990's of elevated protofibrils in patients with the Arctic mutation. This led to the hypothesis that soluble protofibrils of amyloid-beta was a good target for treatment. The current study results confirm that it is possible to generalize this to the common Alzheimer population," said Lars Lannfelt, Professor, M.D., and co-founder of BioArctic.

"This is the first late stage anti-amyloid antibody study to successfully achieve statistically significant results at 18 months, further validating the amyloid hypothesis," said Lynn Kramer, M.D., Chief Clinical Officer and Chief Medical Officer, Neurology Business Group, Eisai. "We will discuss these very encouraging results with regulatory authorities to determine the best path forward. We continue to work towards the goal of delivering BAN2401 to patients and healthcare professionals as early as possible."

"BioArctic's ambition is to apply breakthrough scientific discoveries to improve the quality of life for patients with Alzheimer's disease and other neurodegenerative disorders. The BAN2401 Phase 2b results are the strongest evidence to date of realizing this ambition, based on our strong collaborations and partnerships with universities and pharmaceutical companies," said Gunilla Osswald, CEO of 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
Telephone: + 46 8 695 69 30

Christina Astrén, IR & Communications Director, BioArctic AB
E-mail: christina.astren@bioarctic.se
Telephone: + 46 70 835 43 36

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 July 6, 2018, at 01.30 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. In March 2014, Eisai and Biogen entered into a joint development and commercialization agreement for BAN2401, and the parties amended that agreement in October 2017.

About ADCOMS
Developed by Eisai, ADCOMS (AD Composite Score) combines items from the ADAS-Cog (Alzheimer's Disease Assessment Scale-cognitive subscale), CDR-SB (Clinical Dementia Rating Sum of Boxes) and the MMSE (Mini-Mental State Examination) scales to enable a sensitive detection of changes in clinical functions of early AD symptoms and changes in memory. The Phase 2b study with BAN2401 utilizes ADCOMS as its key endpoint for assessing clinical symptoms.

About Amyloid PET Imaging
Amyloid PET (Positron Emission Tomography) imaging is a diagnostic method that enables the visualization of amyloid plaque present in the brain as well as the quantitative evaluation of amyloid plaque distribution and accumulation in the brain via administration of a minute amount of PET tracer, which specifically binds to amyloid plaque. Amyloid PET imaging enables the assessment of pathology change and assistance of diagnosis of patients with Alzheimer's disease including MCI, and estimates the clinical effect of disease modifiers based on the amyloid hypothesis.

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 (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 (STO: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 our 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**.