BioArctic announces that Eisai will initiate Phase 3 confirmatory study with BAN2401 in early Alzheimer's Disease

Stockholm, Sweden, February 4, 2019 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) announced today that Eisai stated at their Q3 FY2018 Financial Results Meeting on February 4, 2019 that a single Phase 3 confirmatory study of BAN2401 in early Alzheimer´s disease patients is under preparation and planned to be initiated within Eisai's FY2018 i.e. the first quarter 2019.

BAN2401 is the result of a strategic research alliance between BioArctic and Eisai to identify a potential immunotherapy for Alzheimer's Disease. Eisai is responsible for the clinical development of BAN2401.

Eisai also provided further information regarding BAN2401 at today's meeting. An open-label extension study for patients previously enrolled in the Phase 2b clinical study has been initiated with the highest dose of BAN2401, 10 mg/kg twice a month. This enables prior enrolled patients in the Phase 2b study access to and benefit of treatment with BAN2401. This open-label extension study will provide further important information on tolerability and effect on disease progression of longer term treatment with BAN2401.

Today Eisai reported feed-back and current status from meetings with major health authorities (US, EU and Japan). Eisai reported that authorities have acknowledged that the BAN2401 Phase 2b study showed robust data demonstrating dose dependent reduction of amyloid plaque in the brain and slowing of clinical decline. According to Eisai, they have confirmed with health authorities that a single Phase 3 study would meet the requirements for the approval as a confirmatory study. A global confirmatory study with BAN2401 will be initiated in patients with early Alzheimer´s disease in Eisai's FY 2018, that is first quarter 2019. Eisai also reported that they continue to seek opportunities for potential earlier approval for BAN2401.

BAN2401 is a humanized monoclonal antibody selectively targeting the toxic aggregated forms of amyloid-beta in the brain. In the Phase2b study in 856 patients with early Alzheimer´s disease, BAN2401 demonstrated strong reduction of aggregated amyloid-beta in the brain and slowing of clinical decline with good tolerability. The potential disease-modifying effect of BAN2401 was further supported by effect on neurodegenerative biomarkers in CSF (cerebrospinal fluid) such as neurogranin, total-tau, phospho-tau, and Neurofilament light. These data were presented at international congresses in 2018 (AAIC and CTAD).

"Today's news announced by Eisai is encouraging and I am pleased to notice the progress in the clinical development of BAN2401. The Phase 3 confirmatory study is a key step in advancing BAN2401. Our aim is that the drug candidate BAN2401 will address the unmet medical need for an effective disease-modifying treatement that improves the quality of life for Alzheimer patients," said Gunilla Osswald, Ph.D., CEO, BioArctic.

Eisai's presentation material referred to in this press release is available at the Investors section of Eisai's website www.eisai.com/ir/index.html**.**

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 February 4, 2019, 10.00 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 study and the development of BAN2401 for Alzheimer's disease. In March 2014, Eisai and Biogen entered into a joint development and commercialization agreement for BAN2401.

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.

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**.**