



Press release

BioArctic announces:

Alzheimer patients at Swedish clinics to be included in Phase 3 study of drug candidate BAN2401

Stockholm, March 3, 2020 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) announced today that the company’s partner Eisai will include Swedish clinics in the confirmatory Phase 3 study of the drug candidate BAN2401. The enrollment of patients with early Alzheimer’s disease will be carried out at memory clinics at four Swedish university hospitals. The global study was initiated in spring 2019 and, according to Eisai, results from the study are expected in 2022.

BAN2401 is an antibody that helps the body to eliminate accumulations of misfolded amyloid beta protein. BAN2401 attacks harmful oligomers and protofibrils, which lead to Alzheimer’s disease. BAN2401 was developed by BioArctic and outlicensed to Eisai. The results from a global Phase 2b study of 856 patients with early Alzheimer’s disease showed a reduced clinical deterioration and good tolerability after 18 months of treatment. It was also observed that there was a significant reduction in amyloid beta plaque in the brain and a favorable effect on the levels of certain substances in the spinal cord fluid that reflect a reduced degree of nerve cell damage.

The confirmatory Phase 3 study of BAN2401 was initiated in spring 2019 in the US and has now expanded to include Canada, Japan, South Korea and a number of European countries, including Sweden. BioArctic’s partner, Eisai, is responsible for the clinical development of BAN2401 and results from the Phase 3 study are expected to be available in 2022.

“We are delighted that Swedish clinics are now being included in the global confirmatory Phase 3 study of BAN2401 in patients with early Alzheimer’s disease, not least because the groundbreaking research on which the drug candidate is based comes from Sweden itself,” says Tomas Odergren, Chief Medical Officer, BioArctic AB.

Patients with early Alzheimer’s disease at the memory clinics at Uppsala University Hospital, Karolinska University Hospital in Huddinge, Sahlgrenska University Hospital in Gothenburg and Skåne University Hospital in Malmö will have the opportunity to be included in the study.

“It feels inspiring to be able to contribute to the implementation of this important clinical study of BAN2401. A confirmation of the positive results from the earlier Phase 2b study could lead to a major step forward in the treatment of Alzheimer’s disease,” says Dr. Anne



Börjesson-Hanson, Chief Physician, Aging Theme at Karolinska University Hospital in Huddinge and primary investigator for the study in Sweden.

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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About the Phase 3 study of BAN2401

The Phase 3 study (Clarity AD/Study 301) is a global, placebo-controlled, double-blind, randomized, parallel-group study expected to encompass 1,566 patients with early Alzheimer's disease with confirmed amyloid pathology in the brain. These patients have mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease. Amyloid pathology will be confirmed by positron emission tomography (PET) or cerebrospinal fluid (CSF) assessment. Patients are allocated equally in the groups that receive either placebo or active substance. The group that receives active substance will be dosed every other week with 10 mg/kg of BAN2401. The primary endpoint is the change from baseline in the cognition and function scale Clinical Dementia Rating-Sum of Boxes (CDR-SB) after 18 months of treatment. Changes in the clinical scales AD composite score (ADCOMS) and AD Assessment Scale-Cognitive Subscale (ADAS-cog) are key secondary endpoints together with brain amyloid levels measured by amyloid PET.

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. 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 outlicensing potential. BioArctic's Class B share is listed on Nasdaq Stockholm Mid Cap (ticker: BIOA B). www.bioarctic.se



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 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.