Press release

New global Phase 3 program of BAN2401 initiated in preclinical (asymptomatic) Alzheimer's disease

Stockholm, July 14, 2020 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) announced today that its business partner Eisai, in collaboration with Alzheimer's Clinical Trials Consortium (ACTC) and Biogen, has initiated a new global Phase 3 clinical study (AHEAD 3-45) with BAN2401, an anti-amyloid beta (Aβ) protofibril antibody. The study will evaluate the therapeutic effect of BAN2401 on the progression of Alzheimer's disease in individuals in preclinical (asymptomatic) stages of the disease. They are clinically normal and have intermediate or elevated levels of amyloid in their brains. BAN2401 is currently being studied in a pivotal Phase 3 clinical study in symptomatic early Alzheimer's disease (Clarity AD), following the favorable outcome of the Phase 2b clinical study. The AHEAD 3-45 study will be conducted in the US, Canada, Japan, Australia, Singapore and Europe.

The AHEAD 3-45 program consists of two trials, A3 and A45, which aim to evaluate the potential of BAN2401 to reduce accumulation of harmful amyloid beta aggregates in the brain and prevent cognitive decline due to Alzheimer's disease. After a common screening process in AHEAD 3-45, participants can be enrolled into one of the two randomized, double-blind, placebo-controlled trials based on the level of amyloid in the brain. A total of 1400 participants will be enrolled in the study.

The A3 trial will enroll participants who have an intermediate amount of amyloid in the brain, and who are at high risk for further amyloid beta accumulation, and thus at risk for developing clinical symptoms of Alzheimer's disease. The aim of the trial is to evaluate the potential of BAN2401 to stop or reduce aggregation of harmful amyloid beta in the brain before any clinical symptoms develop.

The A45 trial will enroll participants with elevated levels of amyloid beta in the brain. The aim of the trial is to measure the effect of BAN2401 in preventing cognitive decline and suppressing progression of Alzheimer's disease pathology in the brain.

"We welcome the initiative to perform this new and extensive Phase 3 program with BAN2401. In contrast to the Clarity AD study, AHEAD 3-45 will investigate BAN2401 as a potential preventive treatment in the pre-symptomatic stages of the disease continuum. A successful outcome would provide opportunities to treat patients at a very early stage, or even preventing the disease, thereby substantially reducing patients' suffering and providing substantial cost savings for society at large," said Gunilla Osswald, CEO, BioArctic AB.

For further information, please contact:
Gunilla Osswald, CEO, BioArctic AB
E-mail: gunilla.osswald@bioarctic.se
Phone: +46 8 695 69 30

Oskar Bosson, Vice President Communications and Investor Relations, BioArctic AB
E-mail: oskar.bosson@bioarctic.se
Phone: +46 70 410 71 80

This information was submitted for publication at 08:00 a.m. CET on July 14, 2020.

About AHEAD 3-45
AHEAD 3-45 is a groundbreaking Phase 3 clinical study that consists of both the A45 and the A3 trials. AHEAD 3-45 is conducted as a public-private partnership between the ACTC, funded by the National Institute on Aging and Eisai. After a common screening segment in AHEAD 3-45, participants can be enrolled into one of the two randomized, double-blind, placebo-controlled trials based on the level of amyloid in the brain. A total of 1400 participants will be enrolled in the study.

The A45 trial will enroll participants who have elevated levels of amyloid in the brain and aims to prevent cognitive decline and suppress the progression of brain AD pathology by BAN2401 administration. The primary endpoint is the change from baseline in the Preclinical AD Cognitive Composite 5 (PACC5) at 216 weeks of treatment. Secondary endpoints include changes from baseline in brain amyloid levels as measured by amyloid positron emission tomography (PET), in brain tau levels as measured by tau PET and in the Cognitive Function Index.

The A3 trial will enroll participants who have an intermediate amount of amyloid in the brain and who are at high risk for further Aβ accumulation. The primary endpoint is the change from baseline in brain amyloid levels as measured by amyloid PET. Secondary endpoints include changes from baseline in brain tau levels as measured by tau PET.

Both trials include various clinical assessment scales and changes in imaging, cerebrospinal fluid and blood biomarkers comprising a biomarker panel as exploratory endpoints.

About CLARITY AD
The confirmatory 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 out-licensing 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 pharmaceutical company headquartered in Japan. Eisai's corporate philosophy is based on the human health care (hhc) concept, which is to give first thought to patients and their families, and to increase the benefits that health care provides to them. With a global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to realize our hhc philosophy by delivering innovative products to target diseases with high 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 aims to establish the "Eisai Dementia Platform." Through this platform, Eisai plans to deliver novel benefits to those living with dementia and their families through constructing a "Dementia Ecosystem," by collaborating with partners such as medical organizations, diagnostic development companies, research organizations, and bio-ventures in addition to private insurance agencies, finance, fitness clubs, automobile makers, retailers, and care facilities. For more information about Eisai Co., Ltd., please visit https://www.eisai.com.