



Press release

BioArctic's partner Eisai to present update on the development of BAN2401 at Alzheimer's Association International Conference 2020

Stockholm, July 22, 2020 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) announced today that the company's partner Eisai will present the study design of the Phase 3 program AHEAD 3-45 at the Alzheimer's Association International Conference 2020 (AAIC®) on July 27–31. In the study, the therapeutic effect of drug candidate BAN2401 (an anti-amyloid beta protofibril antibody) on the progression of preclinical, asymptomatic, Alzheimer's disease will be investigated. Additionally, Eisai will present interim results from the open label extension study of the Phase 2b study with BAN2401 in early Alzheimer's disease.

AHEAD 3-45 is a groundbreaking Phase III clinical study, conducted as a public-private partnership between the Alzheimer's Clinical Trial Consortium (ACTC), which is funded by the National Institute on Aging (NIA), part of the US National Institutes of Health, and Eisai. The Phase 3 program consists of two NIA-funded clinical trials, A3 and A45, and will evaluate the therapeutic effects of BAN2401 on the progression of preclinical, asymptomatic, Alzheimer's disease. The same drug candidate is also being studied in a pivotal Phase 3 clinical study in symptomatic early Alzheimer's disease (Clarity AD).

Eisai will also present interim results from an ongoing open label extension study of the Phase 2b trial of BAN2401 in early Alzheimer's disease. The presentations will include preliminary results concerning the effect of BAN2401 on amyloid levels in the brain as well as the frequency of ARIA-E (brain edema) in the patient group.

	Presentation	Date
Oral Presentation Oral #44511 Session O2-09 Presentation O2-09-05	AHEAD 3-45 Study Design: A Global Study to Evaluate Efficacy and Safety of Treatment with BAN2401 for 216 Weeks in Preclinical Alzheimer's Disease with Intermediate Amyloid (A3 Trial) and Elevated Amyloid (A45 Trial)	Wednesday, July 29
Poster #46059 Session P3-01	A Preliminary Account of ARIA-E in the Ongoing Open Label Extension Phase of BAN2401-G000-201 in Subjects with Early Alzheimer's Disease	Wednesday, July 29
Poster #46209 Session P4-01	A Preliminary Assessment of Longitudinal Amyloid Status in the Ongoing Open-Label Extension Phase in Subjects with Early Alzheimer's Disease	Wednesday, July 29



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

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About BAN2401

BAN2401 is a humanized monoclonal antibody that is the result of a strategic research alliance between BioArctic and Eisai. BAN2401 has a unique binding profile and selectively binds to and eliminates soluble, toxic amyloid-beta aggregates (protofibrils) 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. Currently, a global confirmatory Phase 3 clinical study (Clarity AD) of BAN2401 in patients with early Alzheimer's disease is underway. According to Eisai, the final readout of the primary endpoint of the study is targeted for 2022.

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. BioArctic has no development costs for BAN2401 in 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. 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). For more information about BioArctic, please visit www.bioarctic.com.



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>.