



Press release

Eisai presents the latest data from the Phase 2b open-label extension study of BAN2401 at AAIC 2020

Stockholm, July 30, 2020 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) announced today that the company’s partner Eisai presented the latest data from the open-label extension of the Phase 2b study with the investigational BAN2401 in early Alzheimer’s disease. The preliminary results show, among other things, a continuous decrease in amyloid levels in the brain measured at three, six and twelve months with BAN2401 treatment in those patients who had previously received placebo. The frequency of amyloid-related imaging abnormalities-edema (ARIA-E) during BAN2401 treatment to date in the open-label extension study is comparable to the Phase 2b study. The data were presented at the Alzheimer’s Association International Conference® 2020 (AAIC®) on July 29.

The ongoing open-label extension study (OLE) includes 180 of the patients with early Alzheimer’s disease that were originally included in the Phase 2b study. The aim is to evaluate the long-term safety and tolerability of BAN2401 and brain amyloid levels measured by amyloid PET during continued treatment with BAN2401 at the highest dose used in the Phase 2b study.

At AAIC, preliminary results from ARIA-E and amyloid PET were presented. In the patients randomized to placebo in the Phase 2b study, a rapid decrease in amyloid levels was observed after three months of open-label treatment with BAN2401. After twelve months the observed effect was comparable to the results in patients randomized to start with this dose of BAN2401 in the Phase 2b study. The incidence of ARIA-E, a form of cerebral edema that occurs in patients treated for Alzheimer’s disease, remained low during treatment with BAN2401, and on a similar level as in the core Phase 2b study.

“The new data from the ongoing open-label extension study with BAN2401 further support the effects of our drug candidate on amyloid in the brain. We look forward to the continued development of BAN2401 as a potential disease-modifying treatment for patients with Alzheimer’s disease,” said BioArctic’s CEO Gunilla Osswald.

Eisai’s presentations from the AAIC congress, which were presented virtually as a consequence of the COVID-19 pandemic, are available on www.bioarctic.com. The material includes the posters from the Phase 2b OLE study as well as the presentation of the design of the new Phase 3 study AHEAD 3-45.



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About BAN2401

BAN2401 is an investigational humanized monoclonal antibody for Alzheimer's disease 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 may have a potential 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.

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>.