



## Press release

### **Eisai presented latest data regarding drug candidate BAN2401 at CTAD 2020**

**Stockholm, November 9, 2020 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) announced today data on the drug candidate BAN2401 (lecanemab), which were presented by the company's partner Eisai at the Clinical Trials on Alzheimer's Disease conference (CTAD), November 4-7. The presentations included study design and initial screening results from the Phase 3 study AHEAD 3-45, the baseline characteristics of currently enrolled Alzheimer's disease patients in the Phase 3 study Clarity AD, and an update on the effect of BAN2401 on amyloid brain levels and the ARIA-E frequency for patients enrolled in the Phase 2b open label extension study.**

A presentation on the clinical study design and initial screening results from the newly initiated Phase 3 study AHEAD 3-45, in individuals with preclinical (asymptomatic) Alzheimer's disease showed that the initial screening results were according to expectations, with more participants joining the A45 trial than the A3 trial. When the study is fully recruited the aim is to have 1000 participants in the A45 trial and 400 in the A3 trial.

A presentation of currently enrolled participants in the ongoing Phase 3 study Clarity AD study in early Alzheimer's disease patients revealed that the baseline characteristics were consistent with those in the Phase 2b study, and representative of an early Alzheimer's disease population. These characteristics were presented from the 1222 subjects enrolled in the study as of the beginning of October.

Two presentations covered different aspects of the Phase 2b core and open-label extension study in early Alzheimer's disease patients. The data showed that patients who received placebo in the Phase 2b core study entered the open-label extension study with high brain amyloid levels. In the open-label extension study, in patients previously on placebo, a rapid decrease in amyloid levels was observed after three months of treatment with BAN2401 10 mg/kg every other week. Further decreases were observed after six- and twelve-months treatment. After twelve months the observed effect was comparable to the results in patients who received this dose of BAN2401 in the Phase 2b core study. For the patients who received BAN2401 10 mg/kg either monthly or every other week in the core study, the amyloid levels in the brain were already low when they entered the open-label extension study and remained low. Also, the incidence of ARIA-E, a form of cerebral edema that occurs in patients treated with anti-amyloid monoclonal antibodies for Alzheimer's disease, remained on a similar level in the open-label extension study as in the core Phase 2b study, at less than 10 percent. These data are consistent with and expands upon the preliminary



results reported at the AAIC (Alzheimer's Association International Conference®) in July 2020.

"It's encouraging to see the continued progress and additional data from Eisai's broad ongoing clinical trial programs for BAN2401 in Alzheimer's disease. The additional data further support the effects of BAN2401 previously reported from the Phase 2b study. 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 four presentations from the CTAD conference, which were presented virtually as a consequence of the COVID-19 pandemic, are available on [www.bioarctic.com](http://www.bioarctic.com).

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*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.*

*This information was submitted for publication at 08:00 a.m. CET on November 9, 2020.*

**Note to editors**

**About BAN2401**

BAN2401 is an investigational humanized monoclonal antibody for Alzheimer's disease that is the result of a strategic research alliance between Eisai and BioArctic. BAN2401 selectively binds to neutralize and eliminate soluble, toxic A $\beta$  aggregates (protofibril) that are thought to contribute to the neurodegenerative process in AD. As such, BAN2401 may have the potential to have an effect on 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 AD 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, BAN2401 is being studied in a pivotal Phase 3 clinical study in symptomatic early AD (Clarity AD), following the outcome of the Phase 2b clinical study (Study 201). In July of 2020, the Phase 3 clinical study (AHEAD 3-45) for individuals with preclinical (asymptomatic) AD, meaning they are clinically normal and have intermediate or elevated levels of amyloid in their brains, was initiated. AHEAD 3-45 is conducted as a public-private partnership between the Alzheimer's Clinical Trial Consortium, funded by the National Institute on



Aging, part of the National Institutes of Health (grant number R01AG061848 and grant number R01AG054029), and Eisai.

**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](http://www.bioarctic.com).