



## Press release

### **BioArctic and Eisai present new data regarding BAN2401 at the Alzheimer's Association International Conference 2019**

**Stockholm, Sweden, July 18, 2019** – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) announces that new data related to BAN2401 were presented on July 17. The presentations were held by BioArctic and its partner, Eisai, at the Alzheimer's Association International Conference® 2019 (AAIC®) in Los Angeles, USA. BAN2401 was designed and generated to selectively target toxic protofibrils and oligomers, soluble aggregated forms of amyloid beta. The new data included details of the binding profile of BAN2401 and additional analyses from the earlier presented Phase 2b study in 856 patients with early Alzheimer's disease. All data were consistent with previously presented outcomes from the Phase 2b study.

BioArctic presented new data around BAN2401's binding profile. The new data confirmed BAN2401's strong binding and high selectivity for protofibrils and oligomers. The poster presentation can be found on BioArctic's website at [www.bioarctic.com](http://www.bioarctic.com).

Eisai presented data on biomarkers of neurodegeneration (cerebral spinal fluid, or CSF, biomarkers), which suggested that treatment with BAN2401 in patients with early Alzheimer's disease was associated with reduced neurodegeneration at both 12- and 18-months timepoints. CSF biomarker data shows the impact downstream of the amyloid cascade, including a reduction of tau pathology (p-tau) and synaptic function (neurogranin), and a reduction in the increase of axonal degeneration (neurofilament light chain or NfL). These analyses were conducted with a subset of patients from the Phase 2b study where cerebral spinal fluid samples were collected. The findings are consistent with the previously presented positive effects on cognition and on reduction of amyloid beta in the brain with PET imaging.

Further, it was observed that the positive impact on neurodegenerative biomarkers was more pronounced in patients who are ApoE4 carriers. This finding is also consistent with the previously announced results for ApoE4 carriers on cognition and reduction of amyloid beta in the brain with BAN2401.

Eisai also presented new data that showed a positive correlation between clinical cognition endpoints and reduction of amyloid beta in the brain after both 12- and 18-months treatment. The analysis was conducted comparing the clinical endpoints ADCOMS, ADAS-Cog and CDR-SB with two approaches to analyze the reduction of amyloid beta in the brain with PET imaging. The subset of patients included in



this analysis had assessments from both from the clinical endpoints and PET imaging in the Phase 2b study in early Alzheimer's disease.

Further, increased BAN2401 exposure measured by serum concentrations correlated with larger reductions of amyloid beta in the brain measured by PET.

"The data presented today further demonstrate the uniqueness of BAN2401 and the robustness of the positive Phase 2b data previously presented. We look forward to Eisai's progression of the confirmatory Phase 3 study in patients with early Alzheimer's disease," said Gunilla Osswald, CEO of BioArctic.

BAN2401 is being studied by BioArctic's partner Eisai in a Phase 3 study in patients with early Alzheimer's disease to confirm the previously announced Phase 2b study results.

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.

**For more information, please contact:**

Gunilla Osswald, PhD, CEO, BioArctic AB

E-mail: [gunilla.osswald@bioarctic.se](mailto:gunilla.osswald@bioarctic.se)

Telephone: + 46 8 695 69 30

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**Notes to editors**

**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 and oligomers) 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. The company also develops a potential treatment for Complete Spinal Cord Injury. 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 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).

### **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.

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](http://www.eisai.com).