Press release

BioArctic and Eisai presented latest data regarding lecanemab at the AD/PD™ 2022 conference

Stockholm, March 21, 2022 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) today announced data on the drug candidate lecanemab (BAN2401) – an investigational anti-amyloid-beta (Aβ) protofibril antibody being developed for the treatment of early Alzheimer's disease (AD) – which were presented by the company and its partner Eisai at the 16th International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders, AD/PD. New data on blood biomarkers of amyloid and p-tau from the Phase 2b study in early Alzheimer's disease was presented, as well as preliminary results from its ongoing open-label extension study. All data continue to support the effect of lecanemab with a continued low incidence of the side effect ARIA-E. The presentations also included an update on the development of a subcutaneous formulation, and data describing the unique binding profile of the drug candidate.

The International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders is a key scientific event with a focus on improving the treatment of Alzheimer's, Parkinson's and other related neurodegenerative diseases. The 2022 edition was held 15-20 March in Barcelona and online and both BioArctic and its partner Eisai presented updated data on the drug candidate lecanemab.

"During AD/PD 2022 our partner Eisai as well as BioArctic held several well received presentations on lecanemab. Together, we continue to generate consistent data in support both for the science behind lecanemab and its biomarker and clinical effects in early AD, with continued low frequency of the side effect ARIA. It is truly encouraging to see how our partner Eisai wholeheartedly continues the development of lecanemab and now moves on with the subcutaneous formulation. Overall, the AD/PD conference 2022 showcases the great achievements being done within the field and we are looking forward to the key results coming later this year", says Gunilla Osswald, CEO, BioArctic.

Highlights from the data on lecanemab presented at AD/PD 2022 include:

Data on the mechanism of action of lecanemab
BioArctic's founder Professor Lars Lannfelt presented data highlighting the distinct binding profile of lecanemab and two other late stage anti-Aβ antibodies. The three antibodies have different binding profiles to Aβ species. All three antibodies bind to fibrils, but with different selectivity. Lecanemab prefers protofibrils, which are believed to be the most toxic forms of Aβ, while the other agents prefer insoluble fibrils. These differences in binding profiles may result in differences in clinical outcomes and safety profiles.

Data from the Phase 2b study, including the open-label extension (OLE)
Dr Sabbagh from Barrow Neurological Institute in Phoenix, Arizona, reviewed the Phase 2b data, including the ongoing open-label extension emphasising the dose- and time-dependant response of the observed clinical benefits and lower ARIA-E and H incidence for lecanemab compared to other late stage anti-Aβ antibodies.

Dr McDade, from Washington University School of Medicine in St. Louis, Missouri, presented new biomarker data from the Phase 2b study of lecanemab in early Alzheimer's disease. Lecanemab treatment results in a dose- and time-dependent change of central and blood amyloid and p-tau biomarkers. The robust changes in blood biomarkers (Aβ 42/40 and p-tau181) due to lecanemab treatment begin to return towards pre- treatment levels following discontinuation of dosing, while brain amyloid PET remain at low levels. Blood biomarkers are thus positioned to provide information on initial response to lecanemab and may also guide decisions on maintenance dosing and long-term use. These data indicate the importance of continued treatment.

Update regarding the development of lecanemab
Dr Irizarry from Eisai gave an update on the broad lecanemab clinical program. He also shared Eisai's plans to evaluate reduced frequency for maintenance dosing up to quarterly intervals. Ongoing studies with sustained periods of effective amyloid suppression are key to further understanding the association of blood amyloid and p-tau biomarkers with clinical outcomes. An update was also provided on the development of a new formulation of lecanemab, with the aim at offering a substitute to the biweekly infusion with weekly subcutaneous administration. This new formulation, which will be explored as part of the Clarity AD open label extension study, has potential to provide improved convenience and a further reduced incidence of ARIA-E.

Lecanemab was granted Breakthrough Therapy and Fast Track designations by the U.S. Food and Drug Administration (FDA) in June and December 2021, respectively. Eisai anticipates completing lecanemab's rolling submission of a Biologics License Application for the treatment of early AD to the FDA under the accelerated approval pathway in the second quarter 2022. Additionally, the readout of the Phase 3 confirmatory Clarity AD clinical trial is expected by end of September 2022. Eisai initiated a submission to the Pharmaceuticals and Medical Devices Agency (PMDA) of application data of lecanemab under the prior assessment consultation system in Japan in March 2022.

The six presentations from AD/PD 2022 relating to lecanemab can be found on https://www.bioarctic.se/en/section/investors/presentations/.

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 further information, please contact:
Gunilla Osswald, CEO

E-mail: gunilla.osswald@bioarctic.se
Phone: +46 8 695 69 30

Oskar Bosson, VP Communications and IR
E-mail: oskar.bosson@bioarctic.se
Phone: +46 70 410 71 80

The information was released for public disclosure, through the agency of the contact persons above, on March 21, 2022, at 08:00 a.m. CET.

About lecanemab (BAN2401)
Lecanemab is an investigational humanized monoclonal antibody for Alzheimer's disease (AD) that is the result of a strategic research alliance between Eisai and BioArctic. Lecanemab selectively binds to, neutralize and eliminate soluble toxic Aβ aggregates (protofibrils) that are thought to contribute to the neurodegenerative process in AD. As such, lecanemab 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 lecanemab 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 lecanemab. Currently, lecanemab 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 addition, 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 brain amyloid, is ongoing. 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, and Eisai. In 2021, DIAN-TU selected lecanemab for a clinical trial for dominantly inherited Alzheimer's disease as a background anti-amyloid treatment when exploring combination therapies with anti tau treatments in dominantly inherited Alzheimer's disease subjects. In June 2021, FDA granted lecanemab Breakthrough Therapy designation and in September 2021, Eisai initiated a rolling submission for the US FDA Biologics license application of lecanemab for early Alzheimer's disease under the accelerated approval pathway. In December 2021, FDA granted lecanemab Fast track designation and the second part of the rolling application was submitted. Eisai expects the rolling submission to be completed during the second quarter 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 for the lecanemab antibody, which was signed in December 2007, and the Development and Commercialization agreement for 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 lecanemab in Alzheimer's disease and is entitled to payments in connection with regulatory filings, approvals, and sales milestones.

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.