BIOARCTIC

Press release

New data on lecanemab presented at the CTAD Alzheimer conference

Stockholm, November 15, 2021 - BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) and partner Eisai held several oral presentations at the 14th Clinical Trials on Alzheimer's Disease (CTAD) conference, November 9-12, 2021, revealing new data on lecanemab (BAN2401), an investigational anti-amyloid beta protofibril antibody. The presentations provided further support for the encouraging data regarding lecanemab's potential as a treatment for early Alzheimer's disease previously seen in the Phase 2b as well as open label extension study. In addition, data presented showed the potential to use blood tests with p-tau181 and Aβ42/40 to monitor treatment effect of lecanemab. Data presented also clarified similarities and differences in the binding profiles of lecanemab compared to other late-stage anti-amyloid antibodies for Alzheimer's disease.

In a presentation by Professor Lars Lannfelt, co-founder of BioArctic, the binding profiles to different amyloid-beta species of lecanemab, aducanumab and gantenerumab, the three most developed antibodies for Alzheimer's disease were compared. All three investigated antibodies were found to mainly bind aggregated forms of amyloid beta, with low binding strength to monomers. The data further identified lecanemab as a strong amyloid-beta binder with the highest selectivity for the aggregated soluble forms of amyloid-beta, called oligomers and protofibrils, believed to be the most neurotoxic.

In a late-breaking roundtable presentation by Eisai, new data from the open label extension study (OLE) of the Phase 2b study of lecanemab, in patients with early Alzheimer's disease, gave further support to the encouraging results seen in the Phase 2b study as well as previous OLE data. The presentation highlighted the rapid reduction of brain amyloid seen in PET scans as early as after three months of treatment and the profound amyloid clearance with more than 80% of patients being amyloid negative after 12 months treatment in the OLE. Clinical treatment difference between the highest dose of lecanemab and placebo was maintained after discontinued dosing over an average 24-month period between the core and OLE study, suggesting potential disease modifying effect. No titration is required for lecanemab, and the treatment was well tolerated. Lecanemab remains associated with a low incidence of the side-effect ARIA-E, below 10%, and with a symptomatic ARIA-E rate of less than 2% in both the Core and OLE study. In addition, data presented showed the potential to use blood tests with p-tau181 and the Aβ42/40 ratio to monitor treatment effect of lecanemab. Amyloid reduction measured by PET and blood Aβ42/40 data suggested a correlation with slower decline the clinical endpoint ADCOMS at population as well as individual levels in the core phase. Eisai stated that monitoring treatment effect using such blood tests may be used for simple dose modification (e.g. less frequent and/or lower dose).

Eisai also presented a new analysis of the robustness of the lecanemab efficacy results from the Phase 2b study in 856 early Alzheimer patients, showing that the clinical efficacy results are consistent across endpoints and multiple statistical methods. Consistent treatment effect was observed after 18 months

treatment with lecanemab 10mg/kg biweekly for all three clinical scales; ADCOMS, CDR-SB, and ADAS-Cog, with separation from placebo observed by six months for the top dose (10mg/kg biweekly) across all analyses.

Baseline characteristics from the pivotal Clarity AD study in 1,795 patients with early Alzheimer's disease, building on the encouraging findings from the lecanemab Phase 2b study, were presented showing that they are consistent with the Phase 2b study and representative of an early Alzheimer's disease population. Clarity AD study is designed to confirm clinical efficacy, safety, and pharmacodynamic properties of lecanemab 10 mg/kg biweekly versus placebo in subjects with early Alzheimer's disease and Eisai expects that the topline data will be available by end of September 2022.

Also on the Clarity AD study, a presentation outlining the stepwise tier-based approach in the screening process for the study showed how this approach could reduce trial burden on clinical sites, patients and study partners. This could allow for sites to focus their resources and attention on potentially qualified patients for the trials.

The blood test with Aβ42/40 ratio was also the focus in another talk outlining how this blood biomarker is now being used in screening of subjects for the Phase 3 AHEAD 3-45 study. 1,400 subjects at risk for developing Alzheimer's disease will be included in the study with the aim to evaluate the efficacy of lecanemab in pre-symptomatic subjects with elevated levels of amyloid in the brain. The plasma Aβ42/40 ratio demonstrated very good ability to predict amyloid PET levels and determine eligibility for the AHEAD 3-45 study. Plasma screening could thus have a potential to substantially reduce the number of PET scans needed to fully enroll the study saving both time and money. Also, if ongoing trials aiming to prevent cognitive decline in pre-symptomatic Alzheimer's disease are successful, plasma screening measures may be critical to identify individuals most likely to benefit from early intervention.

"The great presentations by Lars Lannfelt and our partner Eisai on lecanemab and the progress in the broad ongoing clinical trial program, gives deeper insight into the uniqueness of lecanemab and its potential to help patients with early Alzheimer's disease. We are looking forward to the continued development of this potentially disease-modifying treatment," said BioArctic's CEO Gunilla Osswald.

BioArctic and Eisai's presentations on lecanemab from the CTAD congress are available on www.bioarctic.com.

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.

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The information was released for public disclosure, through the agency of the contact persons above, on November 15, 2021, at 08:00 a.m. CET.

Note to editors

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 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 brain amyloid, was initiated. AHEAD 3-45 will evaluate the efficacy of lecanemab in pre-symptomatic individuals and is conducted as a public-private partnership between the Alzheimer's Clinical Trial Consortium, funded by the National Institute on Aging, the National Institutes of Health and Eisai. DIAN-TU has selected lecanemab as the background anti-amyloid agent to be included in the Tau NexGen study in dominantly inherited Alzheimer's disease. 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. Eisai expects the rolling submission to be completed during the first half of 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.