



Press release

New data on lecanemab to be presented at the 14th Clinical Trials on Alzheimer's Disease (CTAD) conference

Stockholm, November 4, 2021 - BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) and partner Eisai today announced that they will hold several oral presentations revealing new data on lecanemab, at the 14th Clinical Trials on Alzheimer's Disease (CTAD) conference, November 9-12, 2021, in Boston, Massachusetts and virtually. The presentations will provide deeper insights into lecanemab's potential as a treatment for early Alzheimer's disease.

Eisai recently initiated a rolling submission of a Biologics License Application (BLA) for lecanemab, an investigational anti-amyloid beta (A β) protofibril antibody, for the treatment of early AD, to the U.S. Food and Drug Administration (FDA) under the accelerated approval pathway. Eisai expects the rolling application to be completed during the first half of 2022.

"CTAD is one of the three key Alzheimer's disease congresses yearly, and it's encouraging to see the great progress in both blood biomarkers and therapeutics of potential benefit to patients. I'm looking forward to presenting new data on lecanemab in comparison with other anti-amyloid antibodies," said Lars Lannfelt, co-founder of BioArctic.

CTAD 2021 presentations relating to lecanemab

Lecanemab, Session, Time (Eastern Standard Time)	Title, Presenter/Author
Oral communication (onsite), Roundtable 5 Wednesday, November 10; 2:00 – 2:30 p.m.	Assessment of the Clinical Effects of Lecanemab, the Correlation of Plasma A β 42/40 Ratio with Changes in Brain Amyloid PET SUVr, and Safety from the Core and Open Label Extension of the Phase 2 Proof-of-Concept Study, BAN2401-G000-201, in Subjects with Early Alzheimer's Disease Presenters: Chad J. Swanson, Dr. Jeffrey Cummings, Dr. Randall Bateman and Dr. Christopher van Dyck
Oral presentation (onsite), OC9 Wednesday, November 10; 2:45 – 3:00 p.m.	Binding profiles to different amyloid-beta species of lecanemab, aducanumab and gantenerumab, the three most developed antibodies for Alzheimer's disease Presenter: Dr. Lars Lannfelt
Oral communication (onsite), LB9 Thursday, November 11; 11:20 – 11:35 a.m.	Consistency of Efficacy Assessments Across Various Statistical Methods from the Lecanemab Phase 2 Proof-of-Concept Study, BAN2401-



	G000-201, in Subjects with Early Alzheimer's Disease Presenter: DA Berry
Oral communication (onsite), LB4 Thursday, November 11; 9:35 – 9:50 a.m.	Introduction of Plasma Biomarker Screening for the AHEAD 3-45 Study Presenter: R. Sperling
Oral communication (virtual), ROC22 Friday, November 12; On-demand from 8:00 a.m.	Baseline Characteristics for CLARITY-AD: A Phase 3 Placebo-Controlled, Double-Blind, Parallel-Group, 18-Month Study Evaluating Lecanemab (BAN2401) in Early Alzheimer's Disease Presenter: C. Swanson
Oral communication (virtual), ROC23 Friday, November 12; On-demand from 8 a.m.	A Stepwise Tier-Based Approach for Determining Patient Eligibility in CLARITY AD: A Phase 3 Placebo-Controlled, Double-Blind Study to Confirm the Safety and Efficacy of Lecanemab (BAN2401) 10 mg/kg Biweekly in Patients with Early Alzheimer's Disease Presenter: M. Gee

Since 2005, BioArctic has a long-term collaboration with Eisai regarding the development and commercialization of drugs for the treatment of Alzheimer's disease. Eisai is responsible for the clinical development, application for market approval and commercialization of lecanemab 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.

"We are very impressed with our partner Eisai's progression of lecanemab including the rolling BLA under the accelerated approval pathway to the FDA, the confirmatory Phase 3 Clarity AD clinical trial, initiation of a lecanemab subcutaneous dosing Phase 1 study and the ongoing Phase 3 AHEAD 3-45 study in people with pre-symptomatic Alzheimer's disease. We are looking forward to the congress and deeper insights into lecanemab's potential to help patients with early Alzheimer's disease," said BioArctic's CEO Gunilla Osswald.

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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This information is information that BioArctic AB (publ) is obliged to disclose pursuant to the EU Market Abuse Regulation. The information was released for public disclosure, through the agency of the contact persons above, on November 4, 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 A β 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 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 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.

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.