BIOARCTIC

Press release

Latest data on lecanemab to be presented at Alzheimer's Association International Conference (AAIC) 2023

Stockholm, July 12, 2023 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai will present the latest findings on lecanemab, an anti-amyloid beta (Aβ) protofibril antibody for the treatment of Alzheimer's disease, at the Alzheimer's Association International Conference (AAIC). The conference will be held in Amsterdam, the Netherlands and virtually from July 16 to 20, 2023.

Key Eisai lecanemab AAIC presentations

- **Amyloid Reduction and Evidence of Downstream Biomarker Modification**
  Presentation of results of Aβ, tau, neurodegeneration, gliosis, and imaging biomarkers in the Phase III, Clarity AD study of lecanemab (#80907)
- **Drug Development in the Era of Anti-Amyloid Therapies**
  Discussion of considerations in the development of new drugs for AD and rational drug combinations based on pathophysiology (#70444)
- **Subcutaneous Lecanemab is Predicted to Achieve Comparable Efficacy and Improved Safety Compared to Lecanemab IV in Early Alzheimer's Disease**
  Presentation and discussion of results from studies to date on a subcutaneous formulation of lecanemab under development to potentially improve convenience and safety profile for patients (#82852)

Asset, session, presentation time (Central European Summer Time)	Presentation number and title
Lecanemab Plenary Panel Wednesday, July 19, 2023 Session Time: 11:15 - 12:30 AAIC ASK Session (Q&A): 13:00	#80907 Amyloid Reduction and Evidence of Downstream Biomarker Modification
Lecanemab Perspectives Session Monday, July 17, 2023 Session Time: 14:15 - 15:30	#70444 Drug Development in the Era of Anti-Amyloid Therapies
Lecanemab Monday, July 17, 2023 Session Time: 8:00 - 8:45	#82852 Subcutaneous Lecanemab is Predicted to Achieve Comparable Efficacy and Improved Safety Compared to Lecanemab IV in Early Alzheimer's Disease
Lecanemab Monday, July 17, 2023 Session Time: 8:00 - 8:45	#83020 Racial and Ethnic Differences in Plasma Biomarker Eligibility in a Preclinical Alzheimer's Disease Trial
Lecanemab Thursday, July 20, 2023 Session Time: 8:00 - 9:15	#80393 Exposure-Response Modeling to Describe Change in Brain Amyloid Following Lecanemab Administration in Patients with Early Alzheimer's Disease

Asset, session, poster presentation Time (Central European Summer Time)	Poster Number, Title
Lecanemab Sunday, July 16, 2023 Poster Session Time: 8:45 - 16:15	Poster P1-746 PK/PD Analysis of ARIA-E and Isolated ARIA-H in Lecanemab Clarity AD Study

Eisai serves as the lead of lecanemab development and regulatory submissions globally with both Eisai and Biogen co-commercializing and co-promoting the product and Eisai having final decision-making authority. BioArctic has the right to commercialize lecanemab in the Nordic region and currently Eisai and BioArctic are preparing for a joint commercialization in the region.

This release discusses investigational uses of agents in development and is not intended to convey conclusions about efficacy or safety. There is no guarantee that such investigational agents will successfully complete clinical development or gain health authority approval.

The information was released for public disclosure, through the agency of the contact person below, on July 12, 2023, at 01.30 a.m. CET.

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About lecanemab (generic name, U.S. brand name: LEQEMBI®)
Lecanemab is the result of a strategic research alliance between Eisai and BioArctic. Lecanemab is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble (protofibril) and insoluble forms of amyloid-beta (Aβ). In the U.S., LEQEMBI was granted traditional approval by the U.S. Food and Drug Administration (FDA) on July 6, 2023. Treatment with Leqembi should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied.

Please see full Prescribing Information, including Boxed WARNING in the United States.

Eisai has also submitted applications for approval of lecanemab in Japan, EU, China, Canada, Great Britain and South Korea. In Japan and China, the applications have been designated for priority review, and in Great Britain, lecanemab has been designated for the Innovative Licensing and Access Pathway (ILAP), which aims to reduce the time to market for innovative medicines.

Eisai has completed lecanemab subcutaneous bioavailability study, and subcutaneous dosing is currently being evaluated in the Clarity AD (Study 301) OLE. A maintenance dosing regimen has been evaluated as part of Study 201 as well as the Clarity AD (Study 301) OLE. Separate supplemental Biologics License Applications for subcutaneous dosing and a maintenance dosing regimen will be submitted to the FDA at the end of Q1 2024.

Since July 2020 the lecanemab Phase 3 clinical study (AHEAD 3-45) for individuals with preclinical AD, meaning they are clinically normal and have intermediate or elevated levels of amyloid in their brains, is ongoing. AHEAD 3-45 is conducted as a public-private partnership between the Alzheimer's Clinical Trial Consortium that provides the infrastructure for academic clinical trials in AD and related dementias in the U.S, funded by the National Institute on Aging, part of the National Institutes of Health, Eisai and Biogen.

Since January 2022, the Tau NexGen clinical study for Dominantly Inherited AD (DIAD), including lecanemab and an anti-tau treatment, that is conducted by Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU), led by Washington University School of Medicine in St. Louis, is ongoing.

About the collaboration between BioArctic and Eisai
Since 2005, BioArctic has a 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 2007, and the Development and Commercialization agreement for the antibody BAN2401 back-up for Alzheimer's disease, which was signed 2015. In 2014, Eisai and Biogen entered into a joint development and commercialization agreement for lecanemab. Eisai is responsible for the clinical development, application for market approval and commercialization of the products for Alzheimer's disease. BioArctic has right to commercialize lecanemab in the Nordic under certain conditions and is currently preparing for commercialization in the Nordics together with Eisai. BioArctic has no development costs for lecanemab in Alzheimer's disease and is entitled to payments in connection with regulatory approvals, and sales milestones as well as royalties on global sales.

About BioArctic AB
BioArctic AB (publ) is a Swedish research-based biopharma company focusing on disease-modifying treatments for neurodegenerative diseases, such as Alzheimer's disease, Parkinson's disease and ALS. 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 partner Eisai in Alzheimer disease. 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 Large Cap (ticker: BIOA B). For more information about BioArctic, please visit www.bioarctic.com.