Press release

New lecanemab-data to be presented at the AD/PD™ 2023 conference

Stockholm, March 23, 2023 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) and its partner Eisai announced today that the latest findings on lecanemab (generic name, U.S. brand name: LEQEMBI™), an anti-amyloid beta (Aβ) protofibril[1] antibody for the treatment of Alzheimer's disease (AD), will be presented at the 2023 International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders (AD/PD™) from March 28-April 1 in Gothenburg, Sweden and virtually. AD/PD is a key scientific event with a focus on improving the treatment of Alzheimer's, Parkinson's, and other related neurodegenerative diseases.

The lecanemab data will be featured in five oral presentations. BioArctic's founder Professor Lars Lannfelt, will be presenting on the topic of the science of the amyloid-beta cascade as well as the distinct mechanisms of action of lecanemab and characterization of the targeted protofibrils in Alzheimer's disease brain. Eisai will present new findings from the large, global Phase III confirmatory study of lecanemab, Clarity AD, including research into the management and monitoring of amyloid-related imaging abnormalities (ARIA) and health-related quality of life (HRQoL) measures. Eisai will also host a symposium, titled "Patient Clinical Care Pathway in Alzheimer's disease: Dialogue Amongst Experts," which will address the evolving landscape in AD.

Key lecanemab presentations

- Two presentations related to ARIA in the Clarity AD trial will be presented during an oral session on Thursday, March 30:
  - An analysis evaluating the use of antiplatelet and anticoagulant drugs in patients who experienced ARIA.
  - An analysis of isolated ARIA-H events in the Clarity AD trial.
- Research evaluating caregiver burden and HRQoL across multiple scales using Clarity AD data will be presented during an oral session on Thursday, March 30.
- Research studying the characterization of Aβ protofibrils and the unique binding properties and mechanisms of Aβ clearance of lecanemab will be presented during an oral session on Friday, March 31.

[1] Protofibrils are large Aβ aggregated soluble species of 75-500 Kd.

Eisai Symposium – Patient Clinical Care Pathway in AD: Dialogue Amongst Experts
Eisai is sponsoring a symposium featuring three prominent clinical experts in the field of AD, Dr. Alireza Atri, Dr. Sharon Cohen and Dr. Lutz Frölich, who will provide insights on the AD landscape, evolving diagnostic workflow, identifying appropriate patients, and addressing patient needs. The session aims to provide guidance on the clinical management of patients and drive effective communication between physicians and patients.

AD/PD 2023 presentations relating to lecanemab

Oral Presentations

Asset in Development, Session, Time (CEST)	Presentation Title
Lecanemab On-site Symposium: Aβ Targeting Therapies in AD 01 Thu, Mar 30 Session Time: 13:50 - 15:50 Lecture Time: 14:50 - 15:05	Lecanemab Phase 3 Clarity AD Trial: ARIA with the Use of Antiplatelets or Anticoagulants in Early Alzheimer's Disease
Lecanemab On-site Symposium: Aβ Targeting Therapies in AD 01 Thu, Mar 30 Session Time: 13:50 - 15:50 Lecture Time: 15:05 - 15:20	Isolated ARIA-H in Patients Treated with Lecanemab in the Phase 3 Clarity AD Study in Early Alzheimer's Disease
Lecanemab On-site Symposium: Aβ and Tau Targeting Therapies in AD Thu, Mar 30 Session Time: 18:35 - 19:35 Lecture Time: 19:05 - 19:20	Lecanemab Clarity AD: Quality-of-Life Results from a Randomized, Double-blind, Phase 3 Trial in Early Alzheimer's Disease
Lecanemab On-site Symposium: Aβ Targeting Therapies in AD 02 Fri, Mar 31 Session Time: 13:50 - 15:50 Lecture Time: 14:35 - 14:50	Lecanemab, an Amyloid-beta Protofibril Selective Antibody, Its Mechanism of Action and Characterization of the Targeted Protofibrils in Alzheimer's Disease Brain
Lecanemab On-site Symposium: Clinical Trial Designs Fri, Mar 31 Session Time: 16:20 - 18:20 Lecture Time: 17:35 - 17:50	Amyloid, Tau and Cognitive Decline During the Preclinical Stages of Alzheimer's Disease

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. 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.

The information was released for public disclosure, through the agency of the contact person below, on March 23, 2023, at 08:00 a.m. CET.

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About lecanemab
Lecanemab (Brand Name in the U.S.: LEQEMBI™) is the result of a strategic research alliance between BioArctic and Eisai. Lecanemab is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid-beta (Aβ). In the U.S., LEQEMBI was granted accelerated approval by the U.S. Food and Drug Administration (FDA) on January 6, 2023. LEQEMBI is indicated for the treatment of Alzheimer's disease (AD) in the U.S. 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. This indication is approved under accelerated approval based on reduction in Aβ plaques observed in patients treated with LEQEMBI. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial.

Please see LEQEMBI US Prescribing Information.

In the U.S., Eisai submitted a supplemental Biologics License Application (sBLA) to the FDA for approval under the traditional pathway on January 6, 2023. On March 3, 2023, the FDA accepted Eisai's sBLA based on the Clarity AD clinical data, and the LEQEMBI application has been granted Priority Review, with a Prescription Drug User Fee Act (PDUFA) action date of July 6, 2023. The Clarity AD study of lecanemab met its primary endpoint and all key secondary endpoints with highly statistically significant results. Eisai submitted an application for manufacturing and marketing approval to the Pharmaceuticals and Medical Devices Agency (PMDA) on January 16, 2023, in Japan. The Priority Review was granted by the Ministry of Health, Labour and Welfare (MHLW) on January 26, 2023. Eisai utilized the prior assessment consultation system of PMDA, with the aim of shortening the review period for lecanemab. In Europe, Eisai submitted a marketing authorization application (MAA) to the European Medicines Agency (EMA) on January 9, 2023, which was accepted on January 26, 2023. In China,

Eisai initiated submission of data for a BLA to the National Medical Products Administration (NMPA) of China in December 2022 and priority review was granted February 27, 2023.

Eisai has completed a LEQEMBI subcutaneous bioavailability study and subcutaneous dosing is currently being evaluated in the Clarity AD open label extension study.

Since July 2020 Eisai's 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 and Eisai.

Since January 2022, the Tau NexGen clinical study for Dominantly Inherited AD (DIAD) is ongoing, where lecanemab is given as a background anti-amyloid treatment when exploring combination therapies with anti-tau treatments. The study is conducted by Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU), led by Washington University School of Medicine in St. Louis.

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 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. In March 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.