Press release

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

Stockholm, April 3, 2023 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) and its partner Eisai has presented new findings on lecanemab (generic name, U.S. brand name: LEQEMBI™), an anti-amyloid beta (Aβ) protofibril antibody for the treatment of Alzheimer's disease (AD), at the 2023 International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders (AD/PD™). The presentations included analyses of amyloid-related imaging abnormalities (ARIAs) with antiplatelet and anticoagulant therapy, the incidence of isolated ARIA-H, and health-related quality of life (QOL), from the results of the lecanemab Phase 3 Clarity AD study, as well as a presentation by BioArctic's founder Professor Lars Lannfelt on the distinct mechanism of action profile of lecanemab.

Clarity AD was a global confirmatory Phase 3 placebo-controlled, double-blind, parallel-group, randomized study in 1,795 people with early Alzheimer's disease (AD) (lecanemab group: 10 mg/kg bi-weekly IV treatment: 898, placebo group: 897). Lecanemab met the primary endpoint and all key secondary endpoints with highly statistically significant results. In November 2022, results of the Clarity AD study were presented at the Clinical Trials on Alzheimer's Disease (CTAD) conference and simultaneously published in the peer-reviewed medical journal, *The New England Journal of Medicine*.

1. Lecanemab, an Aβ protofibril selective antibody, its mechanism of action and characterization of protofibrils in Alzheimer's disease brain

Professor Lannfelt presented 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. His presentation concluded that lecanemab has a unique binding profile, with strong selectivity for protofibrils over monomers and fibrils of Aβ.

2. Lecanemab Phase 3 Clarity AD Trial: ARIA With the Use of Antiplatelets or Anticoagulants in Early Alzheimer's Disease

In the Clarity AD study, ARIA rates were higher for patients receiving lecanemab compared to those on placebo. The objective of this analysis was to evaluate participants on treatment with either antiplatelet or anticoagulant medication who experienced either ARIA-E (edema) or ARIA-H (combined cerebral microhemorrhages, superficial siderosis, and intracerebral hemorrhages >1 cm in diameter).

The analysis showed that, in Clarity AD, ARIA occurred at similar frequency in lecanemab-treated participants irrespective of antiplatelet or anticoagulant drug use.

3. Isolated ARIA-H in Patients Treated with Lecanemab in the Phase 3 Clarity AD Study in Early Alzheimer's Disease
The objective of this analysis was to describe the occurrences and timing of isolated ARIA-H events (i.e., those events not occurring temporally concurrent with ARIA-E). The analysis showed that, in Clarity AD, the frequency, temporal pattern and association with ApoE genotype of isolated ARIA-H in lecanemab group was similar to that in the placebo group.

4. Lecanemab Clarity AD: Quality-of-Life Results from a Randomized, Double-Blind Phase 3 Trial in Early Alzheimer's Disease
The objective of this analysis was to describe the health-related quality-of-life (HRQoL) pre-specified exploratory results from Clarity AD. HRQoL by subject was measured using the European Quality of Life–5 Dimensions (EQ-5D-5L[1]) and Quality of Life in AD (QOL-AD[2]) scales at baseline and every 6 months post-baseline. QOL-AD was also assessed for the subject by the care partner. Additionally, care partners were administered the Zarit Burden Interview[3] every 6 months to assess care partner burden associated with dementia. The results of the Clarity AD Health-related QoL measures presented further robust evidence for meaningful benefits of lecanemab treatment as experienced by patients and care partners, with scores showing 23-56% less impact of disease progression compared to placebo.

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's and Eisai's presentations from the AD/PD congress regarding lecanemab are available on www.bioarctic.com.

To learn more, visit www.LEQEMBI.com.

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[1] The European Quality of Life-5 Dimensions (EQ-5D-5L) is used as a patient-reported measure of quality of life and consists of five domains (degree of mobility, personal care, daily living, pain/discomfort and anxiety/blushing).
[2] Quality of Life in AD (QOL-AD) is a quality-of-life index specific to dementia.
[3] The Zarit Burden Interview is a scale to measure caregiver burden.

The information was released for public disclosure, through the agency of the contact person below, on April 3, 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). Lecanemab selectively binds and eliminates Aβ protofibrils that are thought to contribute to the neurotoxicity 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. LEQEMBI is indicated for the treatment of Alzheimer's disease (AD) in the U.S. under an accelerated approval by the U.S. Food and Drug Administration (FDA). 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. The Clarity AD study of lecanemab met its primary endpoint and all key secondary endpoints with highly statistically significant results.

Please see LEQEMBI US Prescribing Information.

Lecanemab-irmb was approved under the accelerated approval pathway in the U.S. and was launched in the U.S. on January 18, 2023. The accelerated approval was based on phase 2b data that demonstrated that lecanemab reduced the accumulation of Aβ plaque in the brain, a defining feature of AD, and its continued approval may be contingent upon verification of lecanemab's clinical benefit in a confirmatory trial. The FDA determined that the results of the Phase 3 Clarity AD study can serve as the confirmatory study to verify the clinical benefit of lecanemab. In November 2022, the results of Clarity AD study were presented at the Clinical Trials on Alzheimer's Disease (CTAD) conference and simultaneously published in the peer-reviewed medical journal, *The New England Journal of Medicine*.

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 lecanemab application has been granted Priority Review, with a Prescription Drug User Fee Act (PDUFA) action date of July 6, 2023. 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 the Priority Review was granted on February 27, 2023.
Eisai has completed a lecanemab 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 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.

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.