Press release

Latest data on lecanemab to be presented at the 2024 AD/PD™ congress

Stockholm, February 29, 2024 – BioArctic AB (publ) (Nasdaq Stockholm: BIOA B) today announced that the company and its partner Eisai will present new data on lecanemab (brand name: Leqembi®) at the 2024 International Conference on Alzheimer's and Parkinson's Diseases and related neurological disorders (AD/PD™), to be held in Lisbon, Portugal and virtually, March 5-9. In total, lecanemab will be featured in six presentations, including an oral presentation by BioArctic's founder Professor Lars Lannfelt.

Lecanemab is the result of a long-standing collaboration between BioArctic and Eisai, and the anti-amyloid beta (Aβ) protofibril antibody was originally developed by BioArctic based on the work of Professor Lars Lannfelt and his discovery of the Arctic mutation in Alzheimer's disease.

At AD/PD, BioArctic will present one oral presentation and one poster on lecanemab, both focused on the binding properties of lecanemab to various types of Aβ of lecanemab compared to several other Aβ antibodies. The company will also have two other posters related to Alzheimer's disease.

In addition to BioArctic's presentations, Eisai will present four oral presentations on lecanemab results. From the Phase 3 Clarity AD study in early Alzheimer's disease[1] with confirmed brain Aβ accumulation, data will include the effect of lecanemab treatment on tau[2] accumulation in whole brain regions, and outcomes of long-term efficacy of lecanemab. In addition, the differences in the binding properties of multiple anti-amyloid (Aβ) antibodies to various types of Aβ and other data will be presented.

Eisai will also sponsor a symposium featuring three prominent clinical experts in the field of Alzheimer's disease, Dr. Jeffrey Cummings, Dr. Robert Perneczky and Dr. Miia Kivipelto. Dr. Jeffrey Cummings will chair the symposium, and provide an overview of meaningful benefits, including clinical meaningfulness and the evolution of approaches for the clinical study of Alzheimer's disease. Dr. Robert Perneczky will discuss how to assess meaningful benefits of treatments in development for Alzheimer's disease. Dr. Miia Kivipelto's presentation will provide new statistical methods to measure meaningful benefits and address various stakeholder perspectives.

Furthermore, Eisai's Chief Clinical Officer, Lynn Kramer, M.D., will give a plenary presentation titled "Novel approaches to clinical development and the future potential of simulated placebo" on March 7 at the "Aβ TARGETING THERAPIES IN AD 1" session.

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[1] Early Alzheimer's disease includes mild cognitive impairment (MCI) due to Alzheimer's disease and mild Alzheimer's disease

[2] A protein that aggregates intracellularly in nerve cells in Alzheimer's disease, disrupting both the function and survival of the cell. Tau levels can be measured in plasma, cerebrospinal fluid, and with a positron camera (PET).

Eisai serves as the lead of Leqembi 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, pending European approval, and currently Eisai and BioArctic are preparing for a joint commercialization in the region.

Presentations by BioArctic and Eisai

Oral presentations

Asset in Development, Session, Time	Presentation Title
Lecanemab Abeta Targeting Therapies in AD 01 Thursday, March 7, 13:50 - 14:05	Treatment with lecanemab disrupts tau accumulation across brain regions in early Alzheimer's disease
Lecanemab Abeta Targeting Therapies in AD 02 Saturday, March 9, 8:40 – 8:55	Binding characteristics of lecanemab, donanemab and other amyloid-beta antibodies to different forms of amyloid-beta in Alzheimer's disease brains *Presented by BioArctic*
Lecanemab Abeta Targeting Therapies in AD 02 Saturday, March 9, 9:10 - 9:25	Lecanemab for the treatment of early Alzheimer's disease: the extension of efficacy results from Clarity AD
Lecanemab Abeta Targeting Therapies in AD 02 Saturday, March 9, 9:25-9:40	Structural dynamics of amyloid-β protofibrils and action of lecanemab as observed by high-speed atomic force microscopy
Lecanemab Virtual Oral Presentation VO028 / #2922	A neuro-dynamic quantitative systems pharmacology (QSP) model for Alzheimer's disease incorporating amyloid and tau pathophysiology

Poster presentations

Asset in Development, Topic, Poster Number	Presentation Title
Lecanemab P0213 / #1510 March 8 to 9	Characterization of amyloid-beta species in Alzheimer's disease brain and the unique binding properties of lecanemab *Presented by BioArctic*
General AD P0110 / #562 March 8 to 9	Increased level of 12 KDA C-terminal ApoE fragments in AD brain *Presented by BioArctic*
General AD P0111 / #943 March 8 to 9	Functional and morphological effects of 12 KDA C-terminal ApoE fragments in rat cortex cultures *Presented by BioArctic*

Eisai-Sponsored Symposium

Time	Title, Presenter
Thursday, March 7, 11:10 - 12:50	Defining meaningful benefits to patients, caregivers, and healthcare systems in Alzheimer's disease Jeffrey Cummings, Robert Perneczky, Miia Kivipelto,

Plenary presentation

Session, Time	Title
Abeta Targeting Therapies in AD 01 Thursday, March 7, 15:20 - 15:35	Novel approaches to clinical development and the future potential of simulated placebo

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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 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 persons below, on February 29, 2024, at 08.00 a.m. CET.

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About lecanemab (generic name, U.S., Japan and China brand name: Leqembi®)
Lecanemab 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 (protofibril) and insoluble forms of amyloid-beta (Aβ). In the U.S., Leqembi was granted traditional approval by the US Food and Drug Administration (FDA) on July 6, 2023. Leqembi is indicated as a disease-modifying treatment for Alzheimer's disease (AD) in the US. Treatment with Leqembi should be initiated in patients with mild cognitive impairment (MCI) or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. Please see full U.S. Prescribing Information.

In Japan, Eisai received approval from the Ministry of Health, Labour and Welfare (MHLW) on September 25, 2023, to manufacture and market lecanemab as a treatment for slowing progression of MCI and mild dementia due to AD. Furthermore, in China, Leqembi was approved by the National Medical Products Administration (NMPA) as a treatment of MCI due to AD and mild AD dementia in January 2024.

Eisai has also submitted applications for approval of lecanemab in 14 different countries, including EU, Canada and Great Britain.

Eisai has completed a lecanemab subcutaneous bioavailability study, and subcutaneous dosing is currently being evaluated in the Clarity AD (Study 301) open-label extension (OLE) study. A maintenance dosing regimen has been evaluated as part of the Phase 2b study (Study 201).

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), that is conducted by Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU), led by Washington University School of Medicine in St. Louis, is ongoing and includes lecanemab as the backbone anti-amyloid therapy.

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 Leqembi 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 the right to commercialize lecanemab in the Nordic region 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 innovative treatments that can delay or stop the progression of neurodegenerative diseases. The company invented Leqembi® (lecanemab) – the world's first drug proven to slow the progression of the disease and reduce cognitive impairment in early Alzheimer's disease. Leqembi has been developed together with BioArctic's partner Eisai, who are responsible for regulatory interactions and commercialization globally. In addition to Leqembi, BioArctic has a broad research portfolio with antibodies against Parkinson's disease and ALS as well as additional projects against Alzheimer's disease. Several of the projects utilize the company's proprietary BrainTransporter™ technology, which has the potential to actively transport antibodies across the blood-brain barrier to enhance the efficacy of the treatment. BioArctic's B share (BIOA B) is listed on Nasdaq Stockholm Large Cap. For further information, please visit www.bioarctic.se.