Press release

Leqembi approved for the treatment of Alzheimer's disease in Hong Kong

Stockholm, Sweden, July 11, 2024 – BioArctic AB's (publ) (Nasdaq Stockholm: BIOA B) partner Eisai announced today that the Department of Health in Hong Kong has approved Leqembi® (brand name in Hong Kong: "樂意保®", generic name: lecanemab) for treatment of Alzheimer's disease (AD). 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. Hong Kong is the fifth approval following the US, Japan, China and South Korea.

Leqembi's approval in Hong Kong is based on the large global Phase 3 Clarity AD study. In the Clarity AD study, Leqembi met its primary endpoint and all key secondary endpoints with statistically significant results.[1] In Hong Kong, 9.3% of people aged 70 years and older are living with dementia, and 32% of those aged 85 years and older, of whom 73.5% are reported to have Alzheimer's disease.[2, 3]

Leqembi selectively binds to soluble amyloid-beta (Aβ) aggregates (protofibrils[4]), as well as insoluble Aβ aggregates (fibrils) which are a major component of Aβ plaques in AD, thereby reducing both Aβ protofibrils and Aβ plaques in the brain. Leqembi is the first approved treatment shown to reduce the rate of disease progression and to slow cognitive and functional decline through this mechanism.

Leqembi is the result of a long-standing collaboration between BioArctic and Eisai, and the 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. Eisai is responsible for the clinical development, applications for market approval and commercialization of Lecanemab for Alzheimer's disease. BioArctic has no development costs for Leqembi in Alzheimer's disease and is entitled to payments in connection with certain regulatory approvals, and sales milestones as well as royalty of 9 percent on

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[1] van Dyck, H., et al. Lecanemab in Early Alzheimer's Disease. New England Journal of Medicine. 2023;388:9-21. https://www.nejm.org/doi/full/10.1056/NEJMoa2212948

[2] Department of Health - Press Release "Dementia Care Seminar cum Kick-off Ceremony for Dementia Care Campaign. Available at: https://www.dh.gov.hk/english/press/2006/061013.html

[3] Ruby Yu , et al. Trends in Prevalence and Mortality of Dementia in Elderly Hong Kong Population: Projections, Disease Burden, and Implications for Long-Term Care. Int J Alzheimer's Dis. 2012(7593):406852. doi: 10.1155/2012/406852

[4] Protofibrils are believed to contribute to the brain injury that occurs with AD and are considered to be the most toxic form of Aβ, having a primary role in the cognitive decline associated with this progressive, debilitating condition. Protofibrils cause injury to neurons in the brain, which in turn, can negatively impact cognitive function via multiple mechanisms, not only increasing the development of insoluble Aβ plaques but also increasing direct damage to brain cell membranes and the connections that transmit signals between nerve cells or nerve cells and other cells. It is believed the reduction of protofibrils may prevent the progression of AD by reducing damage to neurons in the brain and cognitive dysfunction.

global sales. In addition, BioArctic has the right to commercialize Leqembi in the Nordic region, pending European approval, and currently Eisai and BioArctic are preparing for a joint commercialization in the region.

The information was released for public disclosure, through the agency of the contact persons below, on July 11, 2024, at 01:30 a.m. CET.

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About lecanemab (generic name, brand name: Leqembi®)
Lecanemab (Leqembi) is the result of a strategic research alliance between BioArctic and Eisai. It is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble (protofibril) and insoluble forms of amyloid-beta (Aβ). Lecanemab is also approved in the U.S., Japan, China, and South Korea with the following indications:

- U.S.: For the treatment of Alzheimer's disease (AD). It should be initiated in patients with mild cognitive impairment or mild dementia stage of disease. See full US prescribing information including boxed waring.
- Japan: For slowing progression of mild cognitive impairment (MCI) and mild dementia due to AD.
- China: For the treatment of MCI due to AD and mild AD dementia.
- South Korea: For treatment in adult patients with mild cognitive impairment due to Alzheimer's disease (AD) or mild AD (early AD)

Lecanemab approvals were based on the large global Phase 3 Clarity AD study. In the Clarity AD study, lecanemab met its primary endpoint and all key secondary endpoints with statistically significant results. In November 2022, the results of the Clarity AD study were presented at the 2022 Clinical Trials on Alzheimer's Disease (CTAD) conference, and simultaneously published in the New England Journal of Medicine, a peer-reviewed medical journal.

Eisai has also submitted applications for approval of lecanemab in 13 countries and regions, including the European Union (EU). A supplemental Biologics License Application (sBLA) for intravenous maintenance dosing was submitted to the U.S. Food and Drug Administration (FDA) in March 2024. The rolling submission of a Biologics License Application (BLA) for maintenance dosing of a subcutaneous injection formulation, which is being developed to enhance convenience for patients, was initiated in the U.S. under Fast Track status in May 2024.

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 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.com.