



“LEQEMBI®” (Lecanemab) Approved for the Treatment of Alzheimer’s Disease in South Korea

May 26, 2024

TOKYO and CAMBRIDGE, Mass., May 27, 2024 – Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) and Biogen Inc. (Nasdaq: BILB, Corporate headquarters: Cambridge, Massachusetts, CEO: Christopher A. Viehbacher, “Biogen”) announced today that the Ministry of Food and Drug Safety (MFDS) in South Korea has approved humanized anti-soluble aggregated amyloid-beta (Aβ) monoclonal antibody “LEQEMBI®” (lecanemab) for treatment in adult patients with mild cognitive impairment due to Alzheimer’s disease (AD) or mild AD (early AD).

LEQEMBI selectively binds to soluble Aβ aggregates (protofibrils*), 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 and only approved treatment shown to reduce the rate of disease progression and to slow cognitive and functional decline through this mechanism. South Korea is the fourth country to grant approval, following approvals in the U.S., Japan, and China.

It is estimated there were approximately 900,000 dementia patients in South Korea in 2021,¹ with one in ten people over the age of 65 suffering from dementia,¹ and one in five from mild cognitive impairment (MCI).² The average annual nursing care and medical costs per dementia patient is estimated to be 21.1 million KRW, while the cost for patients with severe dementia reaches 33.1 million KRW.¹

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. In South Korea, Eisai Korea Inc. will distribute the product and conduct information provision activities. Eisai is committed to working together with healthcare professionals and other stakeholders to realize the early diagnosis and treatment of AD.

* 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.³ 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.⁴

MEDIA CONTACTS

Eisai Co., Ltd.

Public Relations Department

TEL: +81 (0)3-3817-5120

Eisai Inc. (U.S.)

Julie Edelman

+1-201-753-1945

Julie_Edelman@eisai.com

Biogen Inc.

Jack Cox

+ 1-781-464-3260

public.affairs@biogen.com

INVESTOR CONTACTS

Eisai Co., Ltd.

Investor Relations Department

TEL: +81 (0) 3-3817-5122

Biogen Inc.

Chuck Triano

+ 1-781-464-2442

IR@biogen.com

Notes to Editors

1. About lecanemab (LEQEMBI®)

Lecanemab is the result of a strategic research alliance between Eisai and BioArctic. It is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble (protofibril) and insoluble forms of amyloid-beta (Aβ).⁵ Lecanemab is approved in the U.S.,⁶ Japan,⁷ and

China.⁸ In the U.S., Japan and China, the indications are as follows:

- U.S.: For the treatment of Alzheimer's disease (AD). It should be initiated in patients with mild cognitive impairment (MCI) or mild dementia stage of disease.⁶
- Japan: For slowing progression of MCI and mild dementia due to AD.⁷
- China: For the treatment of MCI due to AD and mild AD dementia.⁸

LEQEMBI's FDA approval was based on Phase 3 data from Eisai's, global Clarity AD clinical trial, in which it met its primary endpoint and all key secondary endpoints with statistically significant results.⁹ The primary endpoint was the global cognitive and functional scale, Clinical Dementia Rating Sum of Boxes (CDR-SB). In the Clarity AD clinical trial, treatment with lecanemab reduced clinical decline on CDR-SB by 27% at 18 months compared to placebo.⁹ The mean CDR-SB score at baseline was approximately 3.2 in both groups. The adjusted least-squares mean change from baseline at 18 months was 1.21 with lecanemab and 1.66 with placebo (difference, -0.45; 95% confidence interval [CI], -0.67 to -0.23; P<0.001).⁹ In addition, the secondary endpoint from the AD Cooperative Study-Activities of Daily Living Scale for Mild Cognitive Impairment (ADCS-MCI-ADL), which measures information provided by people caring for patients with AD, noted a statistically significant benefit of 37% compared to placebo.⁹ The adjusted mean change from baseline at 18 months in the ADCS-MCI-ADL score was -3.5 in the lecanemab group and -5.5 in the placebo group (difference, 2.0; 95% CI, 1.2 to 2.8; P<0.001).⁹ The ADCS MCI-ADL assesses the ability of patients to function independently, including being able to dress, feed themselves and participate in community activities. The most common adverse events (>10%) in the lecanemab group were infusion reactions, ARIA-H (combined cerebral microhemorrhages, cerebral macrohemorrhages, and superficial siderosis), ARIA-E (edema/effusion), headache, and fall.⁹

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.

2. About the Collaboration between Eisai and Biogen for AD

Eisai and Biogen have been collaborating on the joint development and commercialization of AD treatments since 2014. Eisai serves as the lead of lecanemab development and regulatory submissions globally with both companies co-commercializing and co-promoting the product and Eisai having final decision-making authority.

3. About the Collaboration between Eisai and BioArctic for AD

Since 2005, Eisai and BioArctic have had a long-term collaboration regarding the development and commercialization of AD treatments. Eisai obtained the global rights to study, develop, manufacture and market lecanemab for the treatment of AD pursuant to an agreement with BioArctic in December 2007. The development and commercialization agreement on the antibody lecanemab back-up was signed in May 2015.

4. About Eisai Co., Ltd.

Eisai's Corporate Concept is "to give first thought to patients and people in the daily living domain, and to increase the benefits that health care provides." Under this Concept (also known as *human health care (hhc)* Concept), we aim to effectively achieve social good in the form of relieving anxiety over health and reducing health disparities. With a global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to create and deliver innovative products to target diseases with high unmet medical needs, with a particular focus in our strategic areas of Neurology and Oncology.

In addition, we demonstrate our commitment to the elimination of neglected tropical diseases (NTDs), which is a target (3.3) of the United Nations Sustainable Development Goals (SDGs), by working on various activities together with global partners.

For more information about Eisai, please visit www.eisai.com (for global headquarters: Eisai Co., Ltd.), and connect with us on [X](#), [LinkedIn](#) and [Facebook](#).

5. About Biogen

Founded in 1978, Biogen is a leading biotechnology company that pioneers innovative science to deliver new medicines to transform patient's lives and to create value for shareholders and our communities. We apply deep understanding of human biology and leverage different modalities to advance first-in-class treatments or therapies that deliver superior outcomes. Our approach is to take bold risks, balanced with return on investment to deliver long-term growth.

The company routinely posts information that may be important to investors on its website at www.biogen.com. Follow Biogen on social media – [Facebook](#), [LinkedIn](#), [X](#), [YouTube](#).

Biogen Safe Harbor

This news release contains forward-looking statements, about the potential clinical effects of lecanemab; the potential benefits, safety and efficacy of LEQEMBI; potential regulatory discussions, submissions and approvals and the timing thereof; the treatment of Alzheimer's disease; the anticipated benefits and potential of Biogen's collaboration arrangements with Eisai; the potential of Biogen's commercial business and pipeline programs, including LEQEMBI; and risks and uncertainties associated with drug development and commercialization. These statements may be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "possible," "potential," "will," "would" and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical studies may not be indicative of full results or results from later stage or larger scale clinical studies and do not ensure regulatory approval. You should not place undue reliance on these statements.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including without limitation unexpected concerns that may arise from additional data, analysis or results obtained during clinical studies; the occurrence of adverse safety events; risks of unexpected costs or delays; the risk of other unexpected hurdles; regulatory submissions may take longer or be more difficult to complete than expected; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of Biogen's drug candidates, including lecanemab; actual timing and content of submissions to and decisions made by the regulatory

authorities regarding lecanemab; uncertainty of success in the development and potential commercialization of lecanemab; failure to protect and enforce Biogen's data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; product liability claims; and third party collaboration risks, results of operations and financial condition. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement as well as the risk factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission. These statements speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements.

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