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

January 9, 2024

China is the Third Country to Approve LEQEMBI Following the United States and Japan

TOKYO and CAMBRIDGE, Mass., January 9, 2024 – Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) and Biogen Inc. (Nasdaq: BIIB, Corporate headquarters: Cambridge, Massachusetts, CEO: Christopher A. Viehbacher, “Biogen”) announced today that humanized anti- soluble aggregated amyloid-beta (Aβ) monoclonal antibody “LEQEMBI®” (brand name in China: “ 乐意保®”, generic name: lecanemab-irmb) has been approved in China as a treatment of mild cognitive impairment (MCI) due to Alzheimer’s disease (AD) and mild AD dementia. Preparations for launch within the second quarter of Eisai’s FY 2024 (July 1 – September 30, 2024) are underway.

LEQEMBI selectively binds to soluble Aβ aggregates (protofibrils*), as well as insoluble Aβ aggregates (fibrils) which are a major component of Aβ plaques, 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. China is the third country to grant marketing approval, following the traditional approval in the U.S. in July 2023 and Japanese approval in September 2023.

LEQEMBI’s approval in China is based on the large global Phase III Clarity AD study. In the Clarity AD study, LEQEMBI 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 estimates that there will be 17 million patients with MCI or mild dementia due to AD in China in 2024, which is expected to increase with the aging of the population. Eisai will distribute the product in China and will conduct information provision activities through specialized Medical Representatives. Moving forward, Eisai will focus on AD awareness via omnichannel systems and collaborate with specialists to improve the diagnostic environment, including blood-based biomarkers. In addition, by utilizing online health platform for the elderly “Yin Fa Tong”**, which is already being accessed by a certain number of users and helping provide treatments, Eisai is providing a one-stop service that promotes early consultation by referring patients to medical specialists and follow-up after treatment. In addition, Eisai will work to improve access environments including the development of insurance programs for AD in collaboration with insurance companies. Through these efforts, Eisai will accelerate the construction of a simple patient journey in China.

* Protofibrils are large Aβ aggregated soluble species of 75-5000 Kd.[1,2,3.]
** An online business (Chinese name:銀髮通) of Jingyi Weixiang (Shanghai) Health Industry Development Limited Company, a joint venture company with JD Health.

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Notes to Editors

1. “乐意保®” (LEQEMBI®) Product Outline

Chinese Trade name: “乐意保” (LEQEMBI)
Chinese generic name: 仑卡奈单抗注射液 (lecanemab injection)
Indication for use: Treatment of mild cognitive impairment (MCI) due to Alzheimer’s disease (AD) and mild AD dementia
Dosage and administration: The usual dose of lecanemab (recombinant) is 10mg/kg infused intravenously over approximately 1 hour, once every 2 weeks.
Active ingredients and strength: 200mg (2mL)/1 vial and 500mg (5mL)/1 vial

2. About LEQEMBI

LEQEMBI (lecanemab) is the result of a strategic research alliance between Eisai and BioArctic. LEQEMBI is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble (protofibril) and insoluble forms of amyloid-beta (Aβ). LEQEMBI is an amyloid

beta-directed antibody indicated as a disease-modifying treatment for Alzheimer's disease (AD) in the U.S. The U.S. Food and Drug Administration (FDA) granted traditional approval on July 6, 2023. 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.

Please see full U.S. Prescribing Information for LEQEMBI, including Boxed WARNING.

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 mild cognitive impairment (MCI) and mild dementia due to AD.

LEQEMBI's approval was based on Phase 3 data from Eisai's large, global Clarity AD clinical trial, in which LEQEMBI met its primary endpoint and all key secondary endpoints with statistically significant results and confirmed the clinical benefit of LEQEMBI. 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 LEQEMBI reduced clinical decline on CDR-SB by 27% at 18 months compared to placebo. 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. 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 LEQEMBI group were infusion reactions, ARIA-H (combined cerebral microhemorrhages, cerebral macrohemorrhages, and superficial siderosis), ARIA-E (edema/effusion), headache, and fall. Full results of the Clarity AD study were presented at the Clinical Trials on Alzheimer's Disease (CTAD) 2022 conference and simultaneously published in the peer-reviewed medical journal The New England Journal of Medicine(New Window) on November 29, 2022.

Eisai has also submitted applications for approval of lecanemab in 11 countries and regions, including EU, Canada and Great Britain.

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

Since July 2020 the 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, Eisai and Biogen. 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.

3. 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 LEQEMBI development and regulatory submissions globally with both companies co-commercializing and co-promoting the product and Eisai having final decision-making authority.

4. 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 LEQEMBI for the treatment of AD pursuant to an agreement with BioArctic in December 2007. The development and commercialization agreement on the antibody LEQEMBI back-up was signed in May 2015.

5. 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.

6. About Biogen

Founded in 1978, Biogen is a leading global biotechnology company that has pioneered multiple breakthrough innovations including a broad portfolio of medicines to treat multiple sclerosis, the first approved treatment for spinal muscular atrophy, two co-developed treatments to address a defining pathology of Alzheimer's disease, the first treatment to target a genetic form of ALS, the first oral treatment approved for postpartum depression, and the first approved treatment for Friedreich's ataxia. Biogen is advancing a pipeline of potential novel therapies across neurology, neuropsychiatry, specialized immunology and rare diseases and remains acutely focused on its purpose of serving humanity through science while advancing a healthier, more sustainable and equitable world.

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, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, about the potential clinical effects of LEQEMBI; 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 or the scientific data

presented.

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, including the Clarity AD clinical trial and AHEAD 3-45 study; 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 LEQEMBI; actual timing and content of submissions to and decisions made by the regulatory authorities regarding LEQEMBI; uncertainty of success in the development and potential commercialization of LEQEMBI; 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; third party collaboration risks; and the direct and indirect impacts of the ongoing COVID-19 pandemic on Biogen's business, 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 a speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements.

References

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