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

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

TOKYO and CAMBRIDGE, Mass., June 27, 2024 (GLOBE NEWSWIRE) -- 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 the humanized anti-soluble aggregated amyloid-beta (Aβ) monoclonal antibody “LEQEMBI®” (brand name in China: “乐意保®”, generic name: lecanemab) has been launched in China. LEQEMBI received approval in January 2024 as a treatment of mild cognitive impairment (MCI) due to Alzheimer’s disease (AD) and mild AD dementia. China is the third country to launch LEQEMBI following the United States and Japan.

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 world’s first and only approved treatment shown to reduce the rate of disease progression and to slow cognitive and functional decline through this mechanism.

Eisai estimates there will be 17 million patients with MCI or mild dementia due to AD (collectively referred to as early AD) in China in 2024, which is expected to increase as the population ages. Eisai is distributing the product in China and conducting information provision activities through specialized Medical Representatives, while also working to build a unique early AD diagnosis and treatment pathway that combines online and offline services. In collaboration with commercial health insurance companies, private health checkups, and nursing homes, Eisai will widely provide disease awareness and pre-screening opportunities and encourage high-risk individuals to visit specialized hospitals early or refer them to "Yin Fa Tong,"** an online health platform for the elderly that is focused on dementia, developed in a joint venture with JD Health. “Yin Fa Tong” currently has approximately 300,000 registered users and 6,000 registered physicians, and introduces information on nearby hospitals and specialists, as well as online medical consultations, and follow-up after LEQEMBI treatment. Eisai is also working to build evidence for the implementation of definitive diagnosis of early AD using blood biomarkers.

In China, LEQEMBI will first be launched in the private market. In collaboration with Eisai, a major Chinese medical insurance company has developed and launched a healthcare insurance plan specifically for AD including partial coverage of the drug cost.
Through these efforts, Eisai is committed to promoting the early detection, diagnosis, and treatment of AD in China, building the dementia ecosystem, and supporting people with early AD to “live their fullest lives”.

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.

* 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.[1] 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.[2]

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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
Drug price: Lecanemab injection 200mg 2,508 CNY per vial

2. 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).[3] Lecanemab is approved in the U.S.,[4] Japan,[5] China,[6] and South Korea.[7] In the U.S., Japan, China and South Korea, 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.[4]
- Japan: For slowing progression of MCI and mild dementia due to AD.[5]
- China: For the treatment of MCI due to AD and mild AD dementia.[6]
- South Korea: For treatment in adult patients with MCI due to AD or mild AD (early AD).[7]

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.[8] 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.[8] 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).[8] 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.[8] 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).[8] 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.[8]

Eisai has also submitted applications for approval of lecanemab in 14 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, which was accepted in June 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 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 Ying Fa Tong

Yin Fa Tong is an online business (Chinese name: 銀髮通) of Jingyi Weixiang (Shanghai) Health Industry Development Limited Company, a joint venture company with Eisai's Chinese subsidiary Eisai China Holdings Ltd. and JD Health. Yin Fa Tong is a platform that provides community services such as self-checks for cognitive function, and counseling, as well as medical services such as referrals to medical institutions and online consultations, reservations, and medical examinations. For Leqembi, Yin Fa Tong has a dedicated dementia module that allows patients to receive online consultations before a face-to-face appointment, as well as referrals to hospitals where diagnostic tests can be performed before Leqembi administration, notifications regarding the timing of MRI scans, and online consultations during treatment.

4. 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.

5. 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.

6. 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.

7. 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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