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Eisai Co., Ltd.

World's First Early Alzheimer's Disease Treatment Developed in Japan LEQEMBI® Receives Prime Minister's Award at the 12th Technology Management and Innovation Awards

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that humanized anti-soluble aggregated amyloid-beta (Aβ) monoclonal antibody "LEQEMBI®" (lecanemab) for the treatment of early Alzheimer's disease (early AD *) has received the Prime Minister's Award at the 12th Technology Management and Innovation Awards hosted by the Japan Techno-Economics Society (JATES **).

The Technology Management and Innovation Awards was established in 2012 with the aim of recognizing outstanding examples of technology management that have produced world-changing innovations, and widely introduce them to society so that the awardees can serve as models for the next generation of managers and engineers. This year marks the 12th annual awards.
This award recognized LEQEMBI as "a world-first treatment for early AD developed in Japan which selectively binds to and clears neurotoxic substances (abnormal proteins), thereby reducing the rate of disease progression. While companies and researchers around the world gave up on development, LEQEMBI is the result of Eisai's long-term research on dementia. The increase in dementia patients in an aging society is serious, with enormous medical and nursing care costs, and considerable burden on caregivers. The contribution to addressing these challenges is of immense social significance."

AD is a progressive, fatal disease, and a global healthcare issue that greatly impacts not only the people living with the disease, but also their loved ones, care partners and society. Based on its corporate concept of "*human health care* (*hhc*)," Eisai has taken on the challenge of this difficult issue through nearly 40 years of drug discovery in the field of dementia, while spending time with patients and their families, as well as collaborating with various stakeholders including healthcare professionals, academia, patient organizations, care centers, health screening companies, and diagnostic companies to drive the development of a dementia ecosystem that aims to raise awareness and realize early diagnosis and treatment of AD. Eisai will strive to deliver LEQEMBI to more people with early AD who need it, while accelerate the building of a dementia ecosystem and continuing to create positive impact on the various issues surrounding dementia.

Eisai serves as the lead of LEQEMBI development and regulatory submissions globally with both Eisai and Biogen Inc. (U.S.) co-commercializing and co-promoting the product and Eisai having final decision-making authority.

* Collectively referred to mild cognitive impairment due to Alzheimer's disease (AD) or mild AD dementia.

** Institute founded in October 1966 to research technology, management, and economics, facilitate exchange among sectors thereof, and promote industrial activities (Japanese only): http://www.jates.or.jp/

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[Notes to editors]

1. About lecanemab

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). 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]

Lecanemab has been approved in the U.S.,[3] Japan,[4] China,[5] South Korea,[6] Hong Kong,[7] Israel,[8] the United Arab Emirates,[9] the United Kingdom,[10] Mexico,[11] Macau and Oman, and is under regulatory review in 16 countries and regions including the EU. In the EU, in February 2025, the Committee for Medicinal Products for Human Use reaffirmed its positive opinion for lecanemab in early AD, adopted in November 2024, and the European Commission is proceeding with the decision-making process for lecanemab's marketing authorization. In January 2025, the supplemental Biologics License Application (sBLA) for intravenous (IV) maintenance dosing of the treatment was approved in the U.S. After an 18 months initiation phase with once every two weeks of dosing, a transition to the maintenance dosing regimen of 10 mg/kg once every four weeks or continuing 10 mg/kg once every two weeks may be considered. Additionally, the U.S. Food and Drug Administration (FDA) accepted Eisai's Biologics License Application (BLA) for the LEQEMBI subcutaneous autoinjector for weekly maintenance dosing in January 2025 and set a PDUFA action date for August 31, 2025.

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.

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 Eisai and Biogen 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.

References

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