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Eisai Co., Ltd.

Eisai Awarded “The 9th Bioindustry Award” for Drug Discovery Research for Anti- Amyloid β Monoclonal Antibody Lecanemab

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) announced today that the drug discovery research for Lecanemab (product name: "LEQEMBI®"), a humanized anti-human soluble amyloid β (Aβ) protofibril monoclonal antibody indicated for early Alzheimer's disease (early AD*), which was co-developed by Eisai and BioArctic AB (Headquarters: Sweden; hereinafter, BioArctic), has received “The 9th Bioindustry Award” from the Japan Bioindustry Association (JBA).

The Bioindustry Award, now marking its 9th year, recognizes achievements that have significantly contributed to the development of the bioindustry or are expected to contribute to its future growth. This award acknowledges that “based on the amyloid cascade hypothesis proposed in 1992, which is a leading theory for the cause and progression mechanism of Alzheimer's disease (AD), the successful development of lecanemab—designed specifically to target highly neurotoxic Aβ protofibrils, beginning with the Arctic mutation—represents a major breakthrough in drug discovery originating from Japan. It is expected to contribute significantly to the advancement of the biopharmaceutical industry both domestically and internationally.”

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.

Theme of awarded research:

Drug Discovery Research for Anti- Amyloid β Monoclonal Antibody Lecanemab, for the Novel Treatment of Alzheimer's disease

Award recipients:

Teiji Kimura (Senior Group Officer and Head of Global Alzheimer's Disease Office, Eisai Co., Ltd.)

Lars Lannfelt (Professor Emeritus, Uppsala University)

Hiroyuki Kato (Director, Eisai Co., Ltd.)

Akihiko Koyama (Officer and Head of Data Innovation Clinical Research, DHBL, Eisai Co., Ltd.,)

Tomoo Ogawa (Group Officer and Head of Medical HQs, Eisai Co., Ltd.)

[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 (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.[2] It is believed the reduction of protofibrils may prevent the progression of AD by reducing damage to neurons in the brain and cognitive dysfunction.[3]

Lecanemab has been approved in 45 countries and regions, including Japan, the United States, China, the European Union, South Korea, and Taiwan, and been under regulatory review in 11 countries. 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 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.

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

1. Sehlin D, Englund H, Simu B, Karlsson M, Ingelsson M, Nikolajeff F, Lannfelt L, Pettersson FE. Large aggregates are the major soluble Aβ species in AD brain fractionated with density gradient ultracentrifugation. *PLoS One.* 2012;7(2):e32014. doi: 10.1371/journal.pone.0032014. Epub 2012 Feb 15. PMID: 22355408; PMCID: PMC3280222.
2. Amin L, Harris DA. Aβ receptors specifically recognize molecular features displayed by fibril ends and neurotoxic oligomers. *Nat Commun*. 2021;12:3451. doi:10.1038/s41467-021-23507-z
3. Ono K, Tsuji M. Protofibrils of Amyloid-β are Important Targets of a Disease-Modifying Approach for Alzheimer's Disease. *Int J Mol Sci.* 2020;21(3):952. doi: 10.3390/ijms21030952. PMID: 32023927; PMCID: PMC7037706.