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Eisai Co., Ltd.

EISAI PUBLISHES SOCIETAL VALUE OF LECANEMAB USING PHASE 3 CLARITY AD DATA IN PEER-REVIEWED NEUROLOGY AND THERAPY JOURNAL

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) today announced the publication of updated results from an evaluation estimating the societal value of anti-amyloid-beta (A β) protofibril* antibody lecanemab (generic name, U.S. brand name: LEQEMBI™) in people living with mild cognitive impairment (MCI) due to Alzheimer’s disease (AD) and mild AD (collectively known as early AD) using data from the Phase 3 clinical study, Clarity AD by applying a validated disease simulation model, AD Archimedes Condition Event (AD ACE) model^{1,2,3} from the healthcare payer and societal perspectives in the United States, in the peer-reviewed journal [Neurology and Therapy](#). While the healthcare payer perspective focuses on direct care costs (e.g., outpatient and inpatient services, medications, intervention costs, nursing home and home healthcare services), the societal perspective further considers societal costs (e.g., productivity loss and informal care costs).

The findings of this academic paper about the societal value of lecanemab in the U.S. was used to inform the development of “Eisai’s Approach to Pricing for LEQEMBI™ (lecanemab), a Treatment for Early Alzheimer’s disease, Sets forth Our Concept of “Societal Value of Medicine” in Relation to “Price of Medicine” that was described in [our press release](#) issued on January 7, 2023 (Japan Standard Time).

This model-based simulation was conducted using the results of the Phase 3 Clarity AD study evaluating the efficacy and safety of lecanemab for early AD with confirmed amyloid pathology as well as published literature.

Lecanemab+SoC (standard of care**) was predicted to result in a gain of 0.61 quality-adjusted life-years*** (QALY)s and a decrease in total non-treatment costs of \$6,263 per person from the healthcare payer perspective (Societal perspective: 0.64 QALYs gain and \$7,451 decrease) compared to the SoC for patients with early AD who have confirmed presence of amyloid pathology. The mean duration of lecanemab treatment in this simulation was 3.91 years. The model estimated that the annual value of lecanemab for the U.S. payer perspective was \$18,709 to \$35,678 (\$19,710 to \$37,351 for societal perspective) at the willingness-to-pay (WTP) threshold of \$100,000 to \$200,000 per QALY gained, respectively. A modified societal perspective at \$200,000 WTP threshold per QALY gained is used in the U.S. when the societal cost of the disease is large with substantial impacts on caregivers, such as AD. The paper concluded that lecanemab treatment would improve health and humanistic (quality of life) outcomes and reduce economic burden for patients and caregivers in early AD.

“The outcomes of this simulation quantitatively demonstrate the societal value of lecanemab, showing that lecanemab provides significant impact not only to people living with early AD and their caregivers, but also to society as a whole. While a broader range of values was considered, the severity-adjusted WTP threshold of \$200,000 per QALY gained accurately reflects the societal value of lecanemab,” said Ivan Cheung, Senior Vice President, and Global Alzheimer’s Disease Officer, Eisai Co., Ltd., Chairman and CEO, Eisai Inc. “Eisai will continue to transparently and expeditiously publish data and information about lecanemab in order to

transparently discuss its societal value for people and countries around the globe.”

Lecanemab was approved under the accelerated approval pathway in the U.S. and was launched in the U.S. on January 18, 2023. The accelerated approval was based on Phase 2 data that demonstrated that lecanemab reduced the accumulation of A β plaque in the brain, a defining feature of AD, and its continued approval may be contingent upon verification of lecanemab’s clinical benefit in a confirmatory trial. The U.S. Food and Drug Administration (FDA) determined that the results of Clarity AD can serve as the confirmatory study to verify the clinical benefit of lecanemab.

In the U.S., Eisai submitted a supplemental Biologics License Application (sBLA) to the FDA for approval under the traditional pathway on January 6, 2023. On March 3, 2023, the FDA accepted Eisai’s sBLA based on the Clarity AD clinical data, and the lecanemab application has been granted Priority Review, with a Prescription Drug User Fee Act (PDUFA) action date of July 6, 2023. Eisai submitted an application for manufacturing and marketing approval to the Pharmaceuticals and Medical Devices Agency (PMDA) on January 16, 2023, in Japan. The Priority Review was granted by the Ministry of Health, Labour and Welfare (MHLW) on January 26, 2023. Eisai utilized the prior assessment consultation system of PMDA, with the aim of shortening the review period for lecanemab. In Europe, Eisai submitted a marketing authorization application (MAA) to the European Medicines Agency (EMA) on January 9, 2023, which was accepted on January 26, 2023. In China, Eisai initiated submission of data for a BLA to the National Medical Products Administration (NMPA) of China in December 2022, and the Priority Review was granted on February 27, 2023.

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

* Protofibrils are large A β aggregated soluble species of 75-5000 Kd.⁴

** Standard of Care (SoC) for AD currently consists of lifestyle modifications and pharmacologic treatment of symptoms.

*** The quality-adjusted life year (QALY) is a measure of the value of health outcomes. Since health is a function of length of life (i.e., quantity) and quality of life (QOL), the QALY was developed as an attempt to combine the value of these attributes into a single index number. One QALY equates to one year in perfect health. QOL scores range from 1 (full health) to 0 (dead). For example, a new intervention may increase length of life by 3 years and improve quality of life by 70% (QALY score of 2.1) compared to an existing intervention that may increase length of life by 3 years and only improve QOL by 50% (QALY score of 1.5), the incremental QALY for this new intervention will be 0.6 QALYs.

¹ Kansal AR, Tafazzoli A, Ishak KJ, Krotneva S. Alzheimer’s disease Archimedes condition-event simulator: Development and validation. *Alzheimers Dement* (NY). 2018;4:76-88. Published 2018 Feb 16. doi:10.1016/j.trci.2018.01.001.

² Tafazzoli A and Kansal A. Disease simulation in drug development, External validation confirms benefit in decision making. The Evidence Forum. 2018.

https://www.evidera.com/wp-content/uploads/2018/10/07-Disease-Simulation-in-Drug-Development_Fall2018.pdf

³ Tafazzoli A, Weng J, Sutton K, et al. Validating simulated cognition trajectories based on ADNI against 436 trajectories from the National Alzheimer’s Coordinating Center (NACC) dataset. 11th edition of Clinical Trials on 437 Alzheimer’s Disease (CTAD); Barcelona, Spain: 2018. https://www.evidera.com/wp-content/uploads/2018/10/07-Disease-Simulation-in-Drug-Development_Fall2018.pdf

⁴ Söderberg, L., Johannesson, M., Nygren, P. et al. Lecanemab, Aducanumab, and Gantenerumab — Binding Profiles to Different Forms of Amyloid-Beta Might Explain Efficacy and Side Effects in Clinical Trials for Alzheimer’s Disease. *Neurotherapeutics* (2022). <https://doi.org/10.1007/s13311-022-01308-6>. Accessed February 9, 2023

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[Notes to editors]

1. About Lecanemab

Lecanemab (Brand Name in the U.S.: LEQEMBI™) is the result of a strategic research alliance between Eisai and BioArctic. Lecanemab is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble (protofibril) and insoluble forms of amyloid-beta (Aβ). In the U.S., LEQEMBI was granted accelerated approval by the U.S. Food and Drug Administration (FDA) on January 6, 2023. LEQEMBI is indicated for the treatment of Alzheimer's disease (AD) 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. This indication is approved under accelerated approval based on reduction in Aβ plaques observed in patients treated with LEQEMBI. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial.

Please see full [Prescribing Information](#).

Eisai has completed lecanemab subcutaneous bioavailability study, and subcutaneous dosing is currently being evaluated in the Clarity AD (Study 301) OLE.

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.

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.