EISAI SUBMITS MARKETING AUTHORIZATION APPLICATION FOR LECANEMAB AS TREATMENT FOR EARLY ALZHEIMER'S DISEASE IN GREAT BRITAIN

May 21, 2023

TOKYO and CAMBRIDGE, Mass., May 21, 2023 – 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 Eisai has submitted a Marketing Authorization Application (MAA) for lecanemab, an investigational anti-amyloid beta (Aβ) protofibril antibody, for the treatment of early Alzheimer's disease (mild cognitive impairment due to Alzheimer's disease (AD) and mild AD dementia) with confirmed amyloid pathology in the brain, to the UK Medicines and Healthcare products Regulatory Agency (MHRA) in Great Britain. Lecanemab has been designated by the MHRA for the Innovative Licensing and Access Pathway (ILAP).

The MAA is based on the results of the confirmatory Phase III Clarity AD study and Phase IIb clinical study (Study 201), which demonstrated that lecanemab treatment showed a reduction of clinical decline in early AD, and is subject to a validation to determine whether it will be accepted by the MHRA. Lecanemab selectively binds and eliminates soluble, toxic Aβ aggregates (protofibrils) that are thought to contribute to the neurotoxicity in AD. As such, lecanemab may have the potential to have an effect on disease pathology and the progression of the disease. The Clarity AD study of lecanemab met its primary endpoint and all key secondary endpoints with highly statistically significant results.

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

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[Notes to editors]

About the Innovative Licensing and Access Pathway (ILAP) in the UK

The ILAP is a program offered by the MHRA (UK) for development programs with the goal of reducing the time to market for innovative medicines that treat life-threatening or seriously debilitating conditions and/or conditions for which there is a significant unmet patient need. The ILAP aims to achieve this goal by enabling enhanced coordination between sponsors, the MHRA and reimbursement bodies such as National Institute for Health and Care Excellence (NICE), leading up to Marketing Authorization Application (MAA) submissions to support accelerated access.

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).

In the U.S., lecanemab was granted accelerated approval for Alzheimer's disease (AD) by the U.S. Food and Drug Administration (FDA) on January 6, 2023. On the same day, Eisai submitted a supplemental Biologics License Application (sBLA) to the FDA for approval under the traditional pathway. This application was accepted, and has been granted Priority Review, with a Prescription Drug User Fee Act (PDUFA) action date of July 6, 2023. In Europe, Eisai submitted a MAA to the European Medicines Agency (EMA) on January 9, 2023, which was accepted on January 26, 2023. In Japan, Eisai submitted a Marketing Authorization Application to the Pharmaceuticals and Medical Devices Agency (PMDA) on January 16, 2023, and Priority Review was designated by the Ministry of Health, Labour and Welfare (MHLW) 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, which was designated for Priority Review on February 27, 2023. In Canada, Eisai submitted a New Drug Submission (NDS) to Health Canada on March 31, 2023, and was accepted on May 15 of the same year.

Lecanemab is indicated for the treatment of AD in the U.S. Treatment with lecanemab 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 lecanemab. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial.

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

Since July 2020 the Phase III 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. 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, has been ongoing since January 2022.

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.

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.

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), with 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 Twitter, LinkedIn and Facebook. For more information about Eisai in the EMEA region please visit www.eisai.eu.

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, and two co-developed treatments to address a defining pathology of Alzheimer's disease. 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. Follow Biogen on social media – Twitter, LinkedIn, Facebook, 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 lecanemab; the potential benefits, safety and efficacy of lecanemab; 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 lecanemab; 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 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; 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 speak only as of the date of this press release. We do not undertake any obligation to publicly update any forward-looking statements.

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