FOR IMMEDIATE RELEASE
September 28, 2022

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LECANEMAB CONFIRMATORY PHASE 3 CLARITY AD STUDY MET PRIMARY ENDPOINT, SHOWING HIGHLY STATISTICALLY SIGNIFICANT REDUCTION OF CLINICAL DECLINE IN LARGE GLOBAL CLINICAL STUDY OF 1,795 PARTICIPANTS WITH EARLY ALZHEIMER'S DISEASE

Eisai Co., Ltd. (Tokyo, Japan) announced the press release of the title at 8:30AM on September 28 as the attached document.

In addition, this event will have a minor impact on the consolidated result forecast for FY2023. There are no changes to the consolidated financial forecast announced on June 8, 2022.

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- *ALL KEY SECONDARY ENDPOINTS ALSO MET, DEMONSTRATING HIGHLY STATISTICALLY SIGNIFICANT RESULTS*
- *PROFILE OF AMYLOID-RELATED IMAGING ABNORMALITIES (ARIA) INCIDENCE WAS WITHIN EXPECTATIONS*
- *EISAI AIMS TO FILE FOR TRADITIONAL APPROVAL IN THE U.S., AND TO SUBMIT MARKETING AUTHORIZATION APPLICATIONS IN JAPAN AND EUROPE BY THE END OF EISAI FY2022, WHICH ENDS ON MARCH 31, 2023*

TOKYO and CAMBRIDGE, Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") and Biogen Inc. (Nasdaq: BIIB, Corporate headquarters: Cambridge, Massachusetts, CEO: Michel Vounatsos, "Biogen") announced positive topline results from Eisai's large global Phase 3 confirmatory Clarity AD clinical trial of lecanemab (development code: BAN2401), an investigational anti-amyloid beta (Aβ) protofibril antibody for the treatment of mild cognitive impairment (MCI) due to Alzheimer's disease (AD) and mild AD (collectively known as early AD) with confirmed presence of amyloid pathology in the brain. Lecanemab met the primary endpoint (CDR-SB: Clinical Dementia Rating-Sum of Boxes*) and all key secondary endpoints with highly statistically significant results. Eisai will discuss this data with regulatory authorities in the U.S., Japan and Europe with the aim to file for traditional approval in the US and for marketing authorization applications in Japan and Europe by the end of Eisai's FY2022, which ends March 31, 2023. Additionally, Eisai will present the Clarity AD study results on November 29, 2022, at the Clinical Trials on Alzheimer's Congress (CTAD), and publish the findings in a peer-reviewed medical journal.

* CDR-SB is a numeric scale used to quantify the various severity of symptoms of dementia. Based on interviews of people living with AD and family/caregivers, qualified healthcare professionals assess cognitive and functional performance in six areas: memory, orientation, judgment and problem solving, community affairs, home and hobbies, and personal care. The total score of the six areas is the score of CDR-SB, and CDR-SB is also used as an appropriate item for evaluating the effectiveness of therapeutic drugs targeting the early stages of AD.

Lecanemab treatment met the primary endpoint and reduced clinical decline on the global cognitive and functional scale, CDR-SB, compared with placebo at 18 months by 27%, which represents a treatment difference in the score change of -0.45 ($p=0.00005$) in the analysis of Intent-to-treat (ITT) population. Starting as early as six months, across all time points, the treatment showed highly statistically significant changes in CDR-SB from baseline compared to placebo (all p-values are less than 0.01). All key secondary endpoints were also met with highly statistically significant results compared with placebo ($p<0.01$). Key

secondary endpoints were the change from baseline at 18 months compared with placebo of treatment in amyloid levels in the brain measured by amyloid positron emission tomography (PET), the AD Assessment Scale-cognitive subscale14 (ADAS-cog14), AD Composite Score (ADCOMS) and the AD Cooperative Study-Activities of Daily Living Scale for Mild Cognitive Impairment (ADCS MCI-ADL).

The incidence of amyloid-related imaging abnormalities-edema/effusion (ARIA-E), an adverse event associated with anti-amyloid antibodies, was 12.5% in the lecanemab group and 1.7% in the placebo group. The incidence of symptomatic ARIA-E was 2.8% in the lecanemab group and 0.0% in the placebo group. The ARIA-H (ARIA cerebral microhemorrhages, cerebral macrohemorrhages, and superficial siderosis) rate was 17.0% in the lecanemab group and 8.7% in the placebo group. The incidence of symptomatic ARIA-H was 0.7% in the lecanemab group and 0.2% in the placebo group. There was no imbalance in isolated ARIA-H (i.e., ARIA-H in patients who did not also experience ARIA-E) between lecanemab (8.8%) and placebo (7.6%). The total incidence of ARIA (ARIA-E and/or ARIA-H) was 21.3% in the lecanemab group and 9.3% in the placebo group. Overall, lecanemab's ARIA incidence profile was within expectations.

Clarity AD was a global confirmatory Phase 3 placebo-controlled, double-blind, parallel-group, randomized study in 1,795 people with early AD. The treatment group was administered a dosage of 10 mg/kg bi-weekly of lecanemab, with participants allocated in a 1:1 ratio to receive either placebo or lecanemab. The baseline characteristics of both placebo and lecanemab groups are similar and well balanced. Eligibility criteria allowed patients with a broad range of comorbidities/comedications: hypertension, diabetes, heart disease, obesity, renal disease and anti-coagulants, etc. Eisai's recruitment strategy for the Clarity AD clinical trial ensured greater inclusion of ethnic and racial populations in the U.S., resulting in approximately 25% of the total U.S. enrollment including Hispanic and African American persons living with early AD. Due to the inclusive eligibility criteria and the successful recruitment of diverse ethnic and racial populations in the U.S., Clarity AD's population is generally comparable to the country's Medicare population.

"Since Eisai launched Aricept in the U.S. and Japan in the late 1990s and obtained its approval in over 100 countries, Eisai has provided the drug to people living with dementia while building empathy for them and their families through disease education efforts and community involvement. The positive result of the lecanemab, an anti-Aβ protofibril antibody, pivotal study after almost 25 years since Aricept's launch is an important milestone for Eisai in fulfilling our mission to meet the expectations of the Alzheimer's disease community. Alzheimer's disease not only presents a great challenge for patients and their families, but it also negatively impacts society, including decreased productivity, increased social costs and disease-related anxiety. We believe that helping to alleviate these burdens will positively impact society as a whole," said Haruo Naito, Chief Executive Officer at Eisai. "Additionally, the lecanemab Clarity AD study results prove the amyloid hypothesis, in which the abnormal accumulation of Aβ in the brain is one of the main causes of Alzheimer's disease, when targeted with a protofibril-binding therapy. Eisai believes these findings will create new horizons in the diagnosis and treatment of Alzheimer's disease as well as further activate innovation for new treatment options. The successful results of the Clarity AD clinical trial would not be possible without the truly inspiring dedication of the study's participants, their families and caregivers and the clinical investigators around the world. We thank all the people involved in the study for their invaluable contributions."

“Today’s announcement gives patients and their families hope that lecanemab, if approved, can potentially slow the progression of Alzheimer’s disease, and provide a clinically meaningful impact on cognition and function,” said Michel Vounatsos, Chief Executive Officer at Biogen. “Importantly, the study shows that removal of aggregated amyloid beta in the brain is associated with a slowing of disease in patients at the early stage of the disease. We want to thank the many patients who participated in this groundbreaking global study and want to acknowledge the clinical investigators who worked tirelessly to increase the enrollment of traditionally underrepresented populations. As pioneers in neuroscience, we believe defeating this disease will require multiple approaches and treatment options, and we look forward to continuing the discussion about the significance of these findings with the patient, scientific, and medical communities.”

In July 2022, the U.S. Food and Drug Administration (FDA) accepted Eisai’s Biologics License Application (BLA) for lecanemab under the accelerated approval pathway and granted Priority Review. The Prescription Drugs User Fee Act action date (PDUFA) is set for January 6, 2023. The FDA has agreed that the results of Clarity AD can serve as the confirmatory study to verify the clinical benefit of lecanemab. In an effort to secure traditional FDA approval for lecanemab as soon as possible, Eisai submitted the BLA through the FDA’s Accelerated Approval Pathway so that the agency could complete its review of all lecanemab data with the exception of the data from the confirmatory Clarity AD study.

In March 2022, Eisai began submitting application data, with the exception of Clarity AD data, to Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) under the prior assessment consultation system with the aim of obtaining early approval for lecanemab so that people living with early AD may have access to the therapy as soon as possible.

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]

1. About Clarity AD

Study title	A Study to Confirm Safety and Efficacy of Lecanemab in Participants With Early AD (Clarity AD)
Study population	1,795 participants of mild cognitive impairment (MCI) due to AD and mild AD (collectively known as early AD) with confirmed presence of amyloid pathology in the brain in the global study, and an additional 111 subjects ongoing in China.
Treatment administered	10 mg/kg bi-weekly of lecanemab
Duration of treatment	18 months
Study locations	Japan, the U.S., Europe and China
Primary endpoint	Change from baseline in the Clinical Dementia Rating-Sum of Boxes (CDR-SB) at 18 months
Key secondary endpoints	Change From Baseline in Amyloid Positron Emission Tomography (PET) using Centiloids, AD Assessment Scale - Cognitive Subscale 14 (ADAS-cog14*), AD Composite Score (ADCOMS**) and AD Cooperative Study-Activities of Daily Living Scale for Mild Cognitive Impairment (ADCS MCI-ADL***) at 18 months

* ADAS-cog is the most common cognitive assessment instrument used in AD clinical trials all over the world. ADAS-cog14 consists of 14 competencies: word recall, commands, constructional praxis, object and finger naming, ideational praxis, orientation, word recognition, remembering word recognition instructions, comprehension of spoken language, word finding difficulty, spoken language ability, delayed word recall, number cancellation, and maze task. ADAS-cog has been used in clinical trials for earlier stages of AD including MCI.

** Developed by Eisai, combines items from the ADAS-cog scale for assessing cognitive functions, MMSE and the CDR scale for evaluating the severity of dementia to enable highly sensitive detection of changes in clinical functions of early AD symptoms and changes in memory

*** ADCS MCI-ADL assesses the competence of patients with MCI in activities of daily living (ADLs), based on 24 questions to the patient's partner about actual recent activities of daily living.

2. About Lecanemab

Lecanemab is an investigational humanized monoclonal antibody for AD that is the result of a strategic research alliance between Eisai and BioArctic. Lecanemab selectively binds to neutralize and eliminate soluble, toxic amyloid-beta (Aβ) aggregates (protofibrils) that are thought to contribute to the neurodegenerative process in AD. As such, lecanemab may have the potential to have an effect on disease pathology and to slow down the progression of the disease. Currently, lecanemab is being developed as the only anti- Aβ antibody that can be used for the treatment of early AD without the need for titration. With regard to the results from pre-specified analysis at 18 months of treatment, Study 201 demonstrated reduction of brain Aβ accumulation ($P<0.0001$) and slowing of disease progression measured by ADCOMS ($P<0.05$) in early AD subjects. The study did not achieve its primary outcome measure* at 12 months of treatment. The Study 201 open-label extension was initiated after completion of the Core period and a Gap period off treatment of 9-59 months (average of 24 months, n=180 from core study enrolled) to evaluate safety and efficacy, and is underway.

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.
Furthermore, Eisai has initiated a lecanemab subcutaneous dosing Phase 1 study.

* An 80% or higher estimated probability of demonstrating 25% or greater slowing in clinical decline at 12 months treatment measured by ADCOMS from baseline compared to placebo.

3. About Amyloid Related Imaging Abnormalities (ARIA)

ARIA is an important adverse event of amyloid-lowering therapies that is critical to monitor and manage during treatment. ARIA is most commonly seen as temporary swelling/effusion (ARIA-E) in areas of the brain that usually resolves over time. Some people may also have small spots of bleeding in or on the surface of the brain (ARIA-H) with the swelling. Although most people with ARIA-E do not have symptoms, some people may have symptoms such as: headache, confusion, dizziness, vision changes and nausea.

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), 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 @Eisai_SDGs.

7. About Biogen

As pioneers in neuroscience, Biogen discovers, develops, and delivers worldwide innovative therapies for people living with serious neurological diseases as well as related therapeutic adjacencies. As one of the world's first global biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Sir Kenneth Murray, and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today, Biogen has a leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, and developed the first and only approved treatment to address a defining pathology of Alzheimer's disease. Biogen is also commercializing biosimilars and focusing on advancing one of the industry's most diversified pipelines in neuroscience that will transform the standard of care for patients in several areas of high unmet need.

In 2020, Biogen launched a bold 20-year, $250 million initiative to address the deeply interrelated issues of climate, health, and equity. Healthy Climate, Healthy Lives™ aims to eliminate fossil fuels across the company's operations, build collaborations with renowned institutions to advance the science to improve human health outcomes, and support underserved communities.

The company routinely posts information that may be important to investors on its website at www.biogen.com. To learn more, please visit www.biogen.com and 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 are based on Biogen's current beliefs and expectations and speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

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