The U.S. FDA Accepts and Grants Priority Review for EISAI's Biologics License Application of Lecanemab for Early Alzheimer's Disease Under the Accelerated Approval Pathway

July 5, 2022

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 today that the U.S. Food and Drug Administration (FDA) has accepted the Biologics License Application (BLA) under the accelerated approval pathway for 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. Eisai's application, which was completed in early May 2022, has been granted Priority Review, with a Prescription Drug User Fee Act (PDUFA) action date of January 6, 2023.

"Alzheimer's disease is a serious disease that causes significant disability and burden to the people living with Alzheimer's disease and their families. Treatment options for Alzheimer's disease are limited and creation of new treatment options is strongly encouraged. Eisai employees have spent time with people living with Alzheimer's disease to truly understand their feelings and challenges and have been working to create new treatments for many years," said Haruo Naito, Chief Executive Officer at Eisai. "The acceptance of lecanemab's BLA with priority review is an important milestone in serving people living with Alzheimer's disease who have been waiting for new treatment options to address an underlying pathology of Alzheimer's disease. We will continue to actively cooperate with the FDA's review in an effort to bring this new treatment option to people living with Alzheimer's disease and their families as soon as possible."

"We believe in a future where people living with Alzheimer's disease will have different treatment options to address this complex disease, and today's BLA acceptance with priority review by FDA is an important step towards this vision," said Michel Vounatsos, Chief Executive Officer at Biogen. "Together with Eisai, we are committed to continuing our work to address the tremendous unmet need for these patients and their families."

The Clarity AD Phase 3 clinical study for lecanemab in early AD is ongoing and Eisai completed enrollment in March 2021 with 1,795 patients. The readout of the primary endpoint data of Clarity AD will occur in the Fall of 2022. The FDA has agreed that the results of Clarity AD, when completed, can serve as the confirmatory study to verify the clinical benefit of lecanemab. Eisai utilized the FDA's Accelerated Approval Pathway in an effort to streamline the submission process for the potential traditional approval of lecanemab in order to expedite patients' access to lecanemab. Dependent upon the results of the Clarity AD clinical trial, Eisai will submit for traditional approval of lecanemab to the FDA during Eisai's fiscal year 2022, which ends on March 31, 2023.

In Japan, in March 2022, Eisai initiated the submission of application data to the Pharmaceuticals and Medical Devices Agency (PMDA) under the prior assessment consultation system with the aim of obtaining early approval for lecanemab. Eisai aims to file for the manufacturing and marketing approval based on the results of Clarity AD during Eisai's fiscal year 2022. Also, in Europe, based on the results of the Clarity AD study, Eisai plans to submit a new drug application in fiscal year 2022.

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.

Contacts

MEDIA CONTACT:

Eisai Co., Ltd.

Public Relations Department

TEL: +81-(0)3-3817-5120

Eisai Inc. (U.S.)

Libby Holman

+ 1-201-753-1945

Libby_Holman@eisai.com

INVESTOR CONTACT:

Eisai Co., Ltd.

Investor Relations Department

TEL: +81-(0)70-8688-9685

MEDIA CONTACT:

Biogen Inc.

Ashleigh Koss

+ 1-908-205-2572

public.affairs@biogen.com

INVESTOR CONTACT:

Biogen Inc.

Mike Hencke

+ 1-781-464-2442

IR@biogen.com

[Notes to editors]

1. About Lecanemab (BAN2401)

Lecanemab is an investigational humanized monoclonal antibody for Alzheimer's disease (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 with lecanemab 10 mg/kg IV biweekly, 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 patients. 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.

Currently, lecanemab is being studied in a confirmatory Phase 3 clinical study in symptomatic early AD (Clarity-AD), following the outcome of the Phase 2 clinical study (Study 201). 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 Alzheimer's disease (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 in combination with E2814 MTBR-tau antibody or placebo. Furthermore, Eisai has initiated a lecanemab subcutaneous dosing Phase 1 study.

* Developed by Eisai, ADCOMS (AD Composite Score) combines items from the ADAS-Cog (Alzheimer's Disease Assessment Scale-cognitive subscale), CDR (Clinical Dementia Rating) and the MMSE (Mini-Mental State Examination) scales to enable a sensitive detection of changes in clinical functions of early AD symptoms and changes in memory. The ADCOMS scale ranges from a score of 0.00 to 1.97, with higher score indicating greater impairment.

** 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.

2. About the Collaboration between Eisai and Biogen for Alzheimer's Disease

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 under Eisai's final decision-making authority.

3. About the Collaboration between Eisai and BioArctic for Alzheimer's Disease

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 concluded with BioArctic in December 2007. The development and commercialization agreement on the antibody lecanemab back-up was signed in May 2015.

4. About Eisai Co., Ltd.

The Eisai's Corporate Philosophy 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 Philosophy (also known as human health care (*hhc*) philosophy), 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.

Under the medium-term business plan "EWAY Future & Beyond", which began in April 2021, Eisai is expanding its main role in healthcare, that is, we should contribute not only to people in the medical domain but also to people in the daily living domain. We aim to evolve into an *hhc*eco (*hhc* philosophy + eco-system) company that empowers people "to realize their fullest life" by creating solutions based on science and data through building an ecosystem in collaboration with other industries.

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

5. 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. 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 is providing the first and only approved treatment to address a defining pathology of Alzheimer's disease. Biogen is also commercializing biosimilars and focusing on advancing the industry's most diversified pipeline 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 our 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 expected data readout for the Clarity AD study; 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.

###