FDA Approves LEQEMBI™ (lecanemab-irmb) Under the Accelerated Approval Pathway for the Treatment of Alzheimer's Disease

January 6, 2023

Accelerated Approval is based on Phase 2 data showing a reduction in amyloid-beta plaques in early AD patients treated with LEQEMBI™

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

TOKYO and CAMBRIDGE, Mass., Jan. 6, 2023 /PRNewswire/ -- 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 under the Accelerated Approval Pathway the U.S. Food and Drug Administration (FDA) has approved lecanemab-irmb (Brand Name in the U.S.: LEQEMBI™) 100 mg/mL injection for intravenous use, a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble ("protofibril")* and insoluble forms of amyloid beta (Aβ) for the treatment of Alzheimer's disease (AD). The approval is based on Phase 2 data that demonstrated that LEQEMBI reduced the accumulation of Aβ plaque in the brain, a defining feature of AD. Using the recently published data from the large global confirmatory Phase 3 clinical trial, Clarity AD, Eisai will work quickly to file a Supplemental Biologics License Application (sBLA) to the FDA for approval under the traditional pathway.

INDICATION
LEQEMBI is indicated for the treatment of Alzheimer's disease. 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 amyloid beta plaques observed in patients treated with LEQEMBI. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial.

DOSAGE AND ADMINISTRATION (Patient Selection, Dosing Instructions, Monitoring and Dosing Interruption for ARIA)
The recommended dosage of LEQEMBI is 10 mg/kg administered intravenously once every two weeks to eligible patients with confirmed presence of Aβ pathology prior to initiating treatment. Enhanced clinical vigilance for amyloid-related imaging abnormalities (ARIA) is recommended during the first 14 weeks of treatment with LEQEMBI. Baseline, recent (within one year) brain MRI prior to initiating treatment with LEQEMBI and periodic monitoring with MRI prior to the 5th, 7th, and 14th infusions should be obtained.

ADVERSE REACTIONS
The safety of LEQEMBI has been evaluated in 763 patients who received at least one dose of LEQEMBI in Study 201. The most common adverse reactions reported in at least 5% of patients treated with LEQEMBI 10 mg/kg biweekly (N=161) and at least 2% higher incidence than patients on placebo (N=245) were infusion-related reactions (LEQEMBI 20%; placebo 3%), headache (LEQEMBI 14%; placebo 10%), ARIA-E (LEQEMBI 10%; placebo 1%), cough (LEQEMBI, 9%; placebo, 5%) and diarrhea (LEQEMBI, 8%; placebo, 5%). The most common adverse reaction leading to discontinuation of LEQEMBI was infusion-related reactions that led to discontinuation in 2% (4/161) of patients treated with LEQEMBI compared to 1% (2/245) of patients on placebo.

CONCOMITANT ANTITHROMBOTIC MEDICATION AND OTHER RISK FACTORS FOR INTRACEREBRAL HEMORRHAGE
Patients were excluded from enrollment in Study 201 for baseline use of anticoagulant medications. Antiplatelet medications such as aspirin and clopidogrel were allowed. Patients who received LEQEMBI and an antithrombotic medication (aspirin, other antiplatelets, or anticoagulants) did not have an increased risk of ARIA-H compared to patients who received placebo and an antithrombotic medication. The majority of exposures to antithrombotic medications were to aspirin; few patients were exposed to other antiplatelet drugs or anticoagulants, limiting any meaningful conclusions about the risk of ARIA or intracerebral hemorrhage in patients taking other antiplatelet drugs or anticoagulants. Because intracerebral hemorrhages greater than 1 cm in diameter have been observed in patients taking LEQEMBI, additional caution should be exercised when considering the administration of antithrombotics or a thrombolytic agent (e.g., tissue plasminogen activator) to a patient already being treated with

LEQEMBI. Additionally, patients were excluded from enrollment in Study 201 for the following risk factors for intracerebral hemorrhage: prior cerebral hemorrhage greater than 1 cm in greatest diameter, more than 4 microhemorrhages, superficial siderosis, evidence of vasogenic edema, evidence of cerebral contusion, aneurysm, vascular malformation, infective lesions, multiple lacunar infarcts or stroke involving a major vascular territory, and severe small vessel or white matter disease. Caution should be exercised when considering the use of LEQEMBI in patients with these risk factors.

"The FDA's approval of LEQEMBI under the Accelerated Approval pathway is an important milestone in Eisai's four decades of research in Alzheimer's disease and reflects our continued commitment to alleviating the burden of Alzheimer's disease for patients and their families. Eisai has made great efforts to understand the reality of the challenges and concerns facing patients and their families who are living in the various stages of Alzheimer's disease, and we are incredibly pleased to offer LEQEMBI as a new treatment option to help with the tremendous unmet needs of this community," said Haruo Naito, Chief Executive Officer at Eisai Co., Ltd. "The challenges of Alzheimer's disease reach beyond medical implications for patients and considerations for their families, but also impact society as a whole through reduced productivity, elevated social costs and anxiety. Upon receiving this Accelerated Approval, we will focus on providing important information on proper usage of LEQEMBI to healthcare professionals. Eisai will also engage with various payers to provide access to LEQEMBI, offer a patient support program, and will do its utmost to complete submission for traditional approval as soon as possible to serve more people living with early Alzheimer's disease."

"The approval of LEQEMBI provides new hope to patients with Alzheimer's disease. Patients at an early stage of the disease and their caregivers can now consider a new treatment option with their doctors. Our focus now is on the path forward, working alongside Eisai with the goal of making LEQEMBI available to patients who may benefit from this treatment as soon as possible," said Christopher A. Viehbacher, President and Chief Executive Officer of Biogen. "This approval is also a recognition of the many scientists and doctors who have, over many years, patiently and persistently worked to find a treatment for this highly complex disease. Eisai and Biogen have collaborated for nearly a decade to advance research to improve the lives of those suffering from Alzheimer's, and we know that this commitment must and will continue in the fight against Alzheimer's disease."

LEQEMBI's ACCESS AND INITIATIVES TO SUPPORT PEOPLE LIVING WITH AD

The Eisai Patient Support Program offers several support programs to help patients and care partners. Dedicated Patient Navigators will work directly with patients and families to navigate treatment and coverage for eligible and appropriate patients and to help with what to expect regarding insurance coverage, co-pay and patient access programs. To learn more visit LEQEMBI.com, call 1-833-4-LEQEMBI (1-833-453-7362), Monday-Friday, 8 a.m. to 8 p.m. Eastern Time or fax to 1-833-770-7017.

In addition, to support access to LEQEMBI for certain financially disadvantaged patients, Eisai's Patient Assistance Program (PAP) will provide LEQEMBI at no cost, for eligible uninsured and underinsured patients, including Medicare beneficiaries, who meet financial need and other program criteria.

Eisai looks forward to continuing to engage constructively with various payors, including the Centers for Medicare and Medicaid (CMS), TRICARE, the U.S. Veteran's Health Administration and private health insurance companies to ensure appropriate beneficiaries have access to this new therapy. Currently, Medicare patients do not have access to LEQEMBI. Medicaid sole beneficiaries who are diagnosed by a healthcare professional with mild cognitive impairment or mild dementia stage of disease, and with confirmed presence of amyloid plaque in the brain will have access to LEQEMBI under the Medicaid program post accelerated approval, depending on individual state processes.

Eisai is developing a multi-faceted educational initiative to further advance the understanding in the AD healthcare community of the real-world management and monitoring of ARIA. This initiative, Understanding ARIA™, will provide resources and programs that will include peer-to-peer education, individual and group educational sessions and subject-matter-expert evaluation of historical case studies. Understanding ARIA will include engagements with leading experts in medical imaging as well as major professional societies. Initial resources will be available by January 2023.

LEQEMBI will be available during or before the week of January 23, 2023. Eisai announced the U.S. pricing and rationale for LEQEMBI today.

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

*Protofibrils are large Aβ aggregated soluble species of 75-500 Kd. [1, 2]

INDICATION, DOSAGE AND ADMINISTRATION, AND IMPORTANT SAFETY INFORMATION IN THE U.S.

INDICATION

LEQEMBI is indicated for the treatment of Alzheimer's disease. 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 amyloid beta plaques observed in patients treated with LEQEMBI. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial.

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS

Amyloid Related Imaging Abnormalities

- LEQEMBI can cause amyloid related imaging abnormalities-edema (ARIA-E) and -hemosiderin deposition (ARIA-H). ARIA-E can be observed on MRI as brain edema or sulcal effusions, and ARIA-H as microhemorrhage and superficial siderosis. ARIA is usually asymptomatic, although serious and life-threatening events, including seizure and status epilepticus, rarely can occur. Reported symptoms associated with ARIA may include headache, confusion, visual changes, dizziness, nausea, and gait difficulty. Focal neurologic deficits may also occur. Symptoms associated with ARIA usually resolve over time.

ARIA Monitoring and Dose Management Guidelines

- Obtain recent (within one year) brain magnetic resonance imaging (MRI) prior to initiating treatment with LEQEMBI. Obtain an MRI prior to the 5th, 7th, and 14th infusions.
- Recommendations for dosing in patients with ARIA-E and ARIA-H depend on clinical symptoms and radiographic severity. Depending on ARIA severity, use clinical judgment in considering whether to continue dosing, temporarily discontinue treatment, or permanently discontinue LEQEMBI.

- Enhanced clinical vigilance for ARIA is recommended during the first 14 weeks of treatment with LEQEMBI. If a patient experiences symptoms suggestive of ARIA, clinical evaluation should be performed, including MRI if indicated. If ARIA is observed on MRI, careful clinical evaluation should be performed prior to continuing treatment.
- There is no experience in patients who continued dosing through symptomatic ARIA-E or through asymptomatic, but radiographically severe, ARIA-E. There is limited experience in patients who continued dosing through asymptomatic but radiographically mild to moderate ARIA-E. There are limited data in dosing patients who experienced recurrent ARIA-E.

Incidence of ARIA

- In Study 1 (Study 201), symptomatic ARIA occurred in 3% (5/161) of LEQEMBI-treated patients. Clinical symptoms associated with ARIA resolved in 80% of patients during the period of observation.
- Including asymptomatic cases, ARIA was observed in LEQEMBI: 12% (20/161); placebo: 5% (13/245). ARIA-E was observed in LEQEMBI: 10% (16/161); placebo: 1% (2/245). ARIA-H was observed in LEQEMBI: 6% (10/161); placebo: 5% (12/245). There was no increase in isolated ARIA-H for LEQEMBI compared to placebo.
- Intracerebral hemorrhage >1 cm in diameter was reported after one treatment in LEQEMBI: 1 patient; placebo: zero patients. Events of intracerebral hemorrhage, including fatal events, in patients taking LEQEMBI have also been reported in other studies.

Apolipoprotein E ε4 (ApoE ε4) Carrier Status and Risk of ARIA

- In Study 1, 6% (10/161) of patients in the LEQEMBI group were ApoE ε4 homozygotes, 24% (39/161) were heterozygotes, and 70% (112/161) were noncarriers.
- The incidence of ARIA was higher in ApoE ε4 homozygotes than in heterozygotes and noncarriers among patients treated with LEQEMBI. Of the 5 LEQEMBI-treated patients who had symptomatic ARIA, 4 were ApoE ε4 homozygotes, 2 of whom experienced severe symptoms. An increased incidence of symptomatic and overall ARIA in ApoE ε4 homozygotes compared to heterozygotes and noncarriers in LEQEMBI-treated patients has been reported in other studies.
- The recommendations on management of ARIA do not differ between ApoE ε4 carriers and noncarriers.
- Consider testing for ApoE ε4 status to inform the risk of developing ARIA when deciding to initiate treatment with LEQEMBI.

Radiographic Findings

- The majority of ARIA-E radiographic events occurred early in treatment (within the first 7 doses), although ARIA can occur at any time and patients can have more than 1 episode. The maximum radiographic severity of ARIA-E in patients treated with LEQEMBI was mild in 4% (7/161) of patients, moderate in 4% (7/161) of patients, and severe in 1% (2/161) of patients. Resolution on MRI occurred in 62% of ARIA-E patients by 12 weeks, 81% by 21 weeks, and 94% overall after detection. The maximum radiographic severity of ARIA-H microhemorrhage in patients treated with LEQEMBI was mild in 4% (7/161) of patients and severe in 1% (2/161) of patients; 1 of the 10 patients with ARIA-H had mild superficial siderosis.

Concomitant Antithrombotic Medication and Other Risk Factors for Intracerebral Hemorrhage

- Patients were excluded from enrollment in Study 1 for baseline use of anticoagulant medications. Antiplatelet medications such as aspirin and clopidogrel were allowed. If anticoagulant medication was used because of intercurrent medical events that required treatment for ≤4 weeks, treatment with LEQEMBI was to be temporarily suspended.
- Most exposures to antithrombotic medications were to aspirin; few patients were exposed to other antiplatelet drugs or anticoagulants, limiting any meaningful conclusions about the risk of ARIA or intracerebral hemorrhage in patients taking other antiplatelet drugs or anticoagulants. Because intracerebral hemorrhages >1 cm in diameter have been observed in patients taking LEQEMBI, additional caution should be exercised when considering the administration of antithrombotics or a thrombolytic agent (e.g., tissue plasminogen activator) to a patient already being treated with LEQEMBI.
- Patients were excluded from enrollment in Study 1 for the following risk factors for intracerebral hemorrhage: prior cerebral hemorrhage >1 cm in greatest diameter, more than 4 microhemorrhages, superficial siderosis, evidence of vasogenic edema, evidence of cerebral contusion, aneurysm, vascular malformation, infective lesions, multiple lacunar infarcts or stroke involving a major vascular territory, and severe small vessel or white matter disease. Caution should be exercised when considering the use of LEQEMBI in patients with these risk factors.

Infusion-Related Reactions

- Infusion-related reactions were observed in LEQEMBI: 20% (32/161); placebo: 3% (8/245), and the majority of cases in LEQEMBI-treated patients (88%, 28/32) occurred with the first infusion. All infusion-related reactions were mild (56%) or moderate (44%) in severity. Infusion-related reactions resulted in discontinuations in 2% (4/161) of patients treated with LEQEMBI. Symptoms of infusion-related reactions included fever and flu-like symptoms (chills, generalized aches, feeling shaky, and joint pain), nausea, vomiting, hypotension, hypertension, and oxygen desaturation.
- After the first infusion, 38% of LEQEMBI-treated patients had transient decreased lymphocyte counts to $<0.9 \times 10^9$/L compared to 2% on placebo, and 22% of LEQEMBI-treated patients had transient increased neutrophil counts to $>7.9 \times 10^9$/L compared to 1% on placebo.
- In the event of an infusion-related reaction, the infusion rate may be reduced, or the infusion may be discontinued, and appropriate therapy initiated as clinically indicated. Prophylactic treatment with antihistamines, acetaminophen, nonsteroidal

anti-inflammatory drugs, or corticosteroids prior to future infusions may be considered.

ADVERSE REACTIONS

- In Study 201, 15% of LEQEMBI-treated patients, compared to 6% of placebo-treated patients, stopped study treatment because of an adverse reaction. The most common adverse reaction leading to discontinuation of LEQEMBI was infusion-related reactions that led to discontinuation in 2% (4/161) of patients treated with LEQEMBI compared to 1% (2/245) of patients on placebo.
- The most common adverse reactions reported in ≥5% of patients treated with LEQEMBI (N=161) and ≥2% higher than placebo (N=245) in Study 1 were infusion-related reactions (LEQEMBI: 20%; placebo: 3%), headache (LEQEMBI: 14%; placebo: 10%), ARIA-E (LEQEMBI: 10%; placebo: 1%), cough (LEQEMBI: 9%; placebo: 5%), and diarrhea (LEQEMBI: 8%; placebo: 5%).

Please see full Prescribing Information.

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Notes to Editors

1. About LEQEMBI™ (lecanemab-irmb)
LEQEMBI™ (lecanemab-irmb) is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble (protofibril) and insoluble forms of amyloid-beta (Aβ). LEQEMBI is indicated for the treatment of Alzheimer's disease (AD) in the U.S. 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.

LEQEMBI is the result of a strategic research alliance between Eisai and BioArctic. Eisai has been initiated submission of data for BLA to the National Medical Products Administration (NMPA) of China in December 2022. Eisai plans to file for marketing authorization applications of lecanemab in Japan and Europe by the end of Eisai's FY2022.

Since July 2020 Eisai's 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. Eisai has completed a LEQEMBI subcutaneous bioavailability study, and subcutaneous dosing is currently being evaluated in the Clarity AD (Study 301) OLE.

2. 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.

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

4. 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 LEQEMBI for the treatment of AD pursuant to an agreement with BioArctic in December 2007. The development and commercialization agreement on the antibody LEQEMBI back-up was signed in May 2015.

5. 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), by 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.

6. 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 developed the first 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.

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.

References

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