18-Month, Pre-Specified Analysis Showing Consistent Reduction in Clinical Outcome Measures from a Lecanemab (BAN2401) Phase 2b Clinical Trial in Early Alzheimer's Disease Published in Peer-Reviewed Journal, Alzheimer's Research and Therapy

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Lecanemab Phase 3 Clarity AD Clinical Trial Completed Enrollment

TOKYO, April 19, 2021 /PRNewswire/ -- Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") and Biogen Inc. (Nasdaq: BIIB, Corporate headquarters: Cambridge, Massachusetts, CEO: Michel Vounatsos, "Biogen") today announced the publication of an article, A Randomized, Double-Blind Phase 2b Proof of Concept Clinical Trial in Early Alzheimer's Disease with Lecanemab, an Anti-Aβ Protofibril Antibody, in the peer-reviewed journal *Alzheimer's Research and Therapy.* The manuscript describes results from Study 201, a Phase 2b proof-of-concept clinical trial that explored the impact of treatment with lecanemab (BAN2401) on reducing brain amyloid beta (Aβ) and clinical decline. The manuscript concluded that the pre-specified analysis showed consistent reduction of clinical decline across several clinical and biomarker endpoints at the highest doses, which the Phase 3 clinical trial Clarity AD aims to confirm. The results of Study 201 were presented at the Alzheimer's Association International Conference and Clinical Trials on Alzheimer's Disease in 2018.

The lecanemab Clarity AD Phase 3 clinical trial completed enrollment last month with 1,795 symptomatic patients with early Alzheimer's disease (AD). Clarity AD is a placebo-controlled, double-blind, parallel-group, 18-month study with an open-label extension phase designed to confirm safety and efficacy of lecanemab in subjects with early AD. Additionally, the Phase 3 AHEAD 3-45 clinical study is currently exploring lecanemab in individuals with preclinical AD, defined as patients that are clinically asymptomatic, but have intermediate or elevated brain Aβ levels.

"Amyloid beta aggregates are thought to be more toxic than monomers, and we hypothesized that reducing these could represent an effective treatment approach in early stages of Alzheimer's disease," said Jeffrey Cummings, M.D., ScD, lecanemab manuscript author and director at the Chambers-Grundy Center for Transformative Neuroscience, Department of Brain Health, School of Integrated Health Sciences, University of Nevada Las Vegas. "These results from lecanemab's Phase 2b clinical trial are encouraging and the scientific community is looking forward to learning more in the Phase 3 studies, Clarity AD and AHEAD 3-45, currently underway."

"These supportive findings from the lecanemab Phase 2b study and the initiation of two Phase 3 studies are exciting for the field and provide the opportunity to further explore the key role of the amyloid beta pathway in the pathophysiology of Alzheimer's disease," said Michael Irizarry, M.D., Vice President, Deputy Chief Clinical Officer, Neurology Business Group, Eisai Inc. "Eisai's precision pipeline approach envisions an Alzheimer's disease treatment paradigm based on a person's pathophysiological biomarker profile along the disease continuum. We are working to advance lecanemab and our other targeted investigational compounds as quickly as possible in our commitment to bringing solutions to patients and their families."

[Notes to editors]

About Lecanemab (BAN2401)
Lecanemab is an investigational humanized monoclonal antibody for Alzheimer's disease 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 (protofibril) 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. 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. In March 2014, Eisai and Biogen entered into a joint development and commercialization agreement for lecanemab and the parties amended that agreement in October 2017. Currently, lecanemab is being studied in a pivotal Phase 3 clinical study in symptomatic early AD (Clarity-AD), following the outcome of the Phase 2 clinical study (Study 201). In July of 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, was initiated. AHEAD 3-45 is conducted as a public-private partnership between the Alzheimer's Clinical Trial Consortium, funded by the National Institute on Aging, part of the National Institutes of Health, and Eisai.

About the Joint Development between Eisai and Biogen for Alzheimer's Disease
Eisai and Biogen are collaborating on the joint development and commercialization of AD treatments. Biogen serves as the lead in the co-development of aducanumab, an anti- Aβ antibody, and Eisai serves as the lead in the co-development of lecanemab.

About the Collaboration between Eisai and BioArctic for Alzheimer's Disease
Since 2005, BioArctic has had a long-term collaboration with Eisai regarding the development and commercialization of drugs for the treatment of AD. The commercialization agreement on the lecanemab antibody was signed in December 2007, and the development and commercialization agreement on the antibody lecanemab back-up for AD, which was signed in May 2015. Eisai is responsible for the clinical development, application for market approval and commercialization of the products for AD. BioArctic has no development costs for lecanemab in AD.

About Eisai Co., Ltd.
Eisai Co., Ltd. is a leading global pharmaceutical company headquartered in Japan. Eisai's corporate philosophy is based on the *human health care*

(*hhc*) concept, which is to give first thought to patients and their families, and to increase the benefits that health care provides to them. With a global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to realize our *hhc* philosophy by delivering innovative products to target diseases with high unmet medical needs, with a particular focus in our strategic areas of Neurology and Oncology.

Leveraging the experience gained from the development and marketing of a treatment for Alzheimer's disease, Eisai aims to establish the "Eisai Dementia Platform." Through this platform, Eisai plans to deliver novel benefits to those living with dementia and their families through constructing a "Dementia Ecosystem," by collaborating with partners such as medical organizations, diagnostic development companies, research organizations, and bio-ventures in addition to private insurance agencies, finance industries, fitness clubs, automobile makers, retailers, and care facilities. For more information about Eisai Co., Ltd., please visit https://www.eisai.com.

About Biogen
At Biogen, our mission is clear: we are pioneers in neuroscience. Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological and neurodegenerative 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, Kenneth Murray and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today Biogen has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, commercializes biosimilars of advanced biologics and is focused on advancing research programs in multiple sclerosis and neuroimmunology, Alzheimer's disease and dementia, neuromuscular disorders, movement disorders, ophthalmology, neuropsychiatry, immunology, acute neurology and neuropathic pain.

We routinely post information that may be important to investors on our website at www.biogen.com(New Window). Follow us on social media – Twitter(New Window), LinkedIn(New Window), Facebook(New Window), YouTube(New Window).

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 results from the Phase 2b study of lecanemab; the potential clinical effects of lecanemab and aducanumab; the potential benefits, safety and efficacy of lecanemab and aducanumab; the treatment of Alzheimer's disease; Biogen's research and development program for the treatment of Alzheimer's disease; potential regulatory discussions, submissions and approvals and the timing thereof; 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 aducanumab; 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 trials may not be indicative of full results or results from later stage or larger scale clinical trials 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 trials; the occurrence of adverse safety events; risks of unexpected costs or delays; the risk of other unexpected hurdles; actual timing and content of submissions to and decisions made by the regulatory authorities regarding lecanemab and aducanumab; 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 and aducanumab; uncertainty of success in the development and potential commercialization of lecanemab and aducanumab; 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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