Eisai And Biogen To Discontinue Phase III Clinical Studies Of BACE Inhibitor Elenbecestat In Early Alzheimer's Disease

September 13, 2019

Discontinuation of studies based on Data Safety Monitoring Board recommendation

WOODCLIFF LAKE, N.J., Sept. 13, 2019 /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 decision to discontinue the Phase III clinical studies (MISSION AD1, AD2) on the investigational oral BACE (beta amyloid cleaving enzyme) inhibitor elenbecestat (development code: E2609) in patients with early Alzheimer's disease (AD). The decision is based on the results of a safety review conducted by the Data Safety Monitoring Board (DSMB), which recommended to discontinue these trials due to unfavorable risk-benefit ratio. Detailed data of these studies will be presented at future medical meetings.

Investigators are being informed of the decision and they will be contacting their study participants to discontinue the investigational treatment.

Dr. Lynn Kramer, Chief Clinical Officer, Neurology Business Group, Eisai Co., Ltd., said: "We would like to thank the patients and the families, as well as medical professionals, that participated in the MISSION AD studies. Without their contributions we would not be able to advance Alzheimer's disease research. We are very disappointed with the news, and intend to learn from these data and continue engaging with patients and investigators, to pursue the discovery of new medicines for Alzheimer's disease."

The Phase III clinical trial program for elenbecestat (MISSION AD) consisted of two global Phase III clinical studies with identical protocols, MISSION AD1 (Study 301) and MISSION AD2 (Study 302). Both studies were multicenter, placebo-controlled, double-blind, parallel-group Phase III clinical studies designed to assess the efficacy and safety of elenbecestat for treatment in a total of about 2,100 patients with mild cognitive impairment (MCI) or mild AD (collectively known as early AD) with confirmed amyloid pathology in the brain. Patients were randomized to receive either 50 mg of elenbecestat or placebo daily during the treatment period of 24 months, and the primary endpoint was the Clinical Dementia Rating Sum of Boxes (CDR-SB).

As part of this decision, the long-term extension of the Phase II clinical trial of elenbecestat (Study 202) will also be discontinued. This determination does not impact the program of the anti-amyloid beta (Aβ) protofibril monoclonal antibody BAN2401, and the Phase III Clarity AD trial of BAN2401 will continue.

Biogen Safe Harbor Statement

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, regarding the Phase III studies of elenbecestat; the clinical effects of elenbecestat; the potential benefits, safety and efficacy of elenbecestat; the clinical development program for elenbecestat; the identification and 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 BAN2401; the timing and scope of future clinical trials; 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," "goal," "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; 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 BAN2401; the occurrence of adverse safety events; risks of unexpected costs or delays; the risk of other unexpected hurdles; uncertainty of success in the development and potential commercialization of BAN2401 and/or other Biogen drug candidates; 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; and third party collaboration risks. 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.

Contacts	
Eisai Co., Ltd. Public Relations Department TEL: +81-(0)3-3817-5120 Investor Relations Department TEL: +81-(0)3-3817-3016	Biogen Inc. Media Contact: David Caouette +1 617 679 4945 public.affairs@biogen.com Investor Contact: Joe Mara +1 781 464 2442 IR@biogen.com

Notes to Editors

1. About Elenbecestat (generic name, development code: E2609)

Discovered by Eisai, elenbecestat is an investigational next-generation oral candidate for the treatment of Alzheimer's disease (AD) that inhibits BACE (beta amyloid cleaving enzyme). By inhibiting BACE, a key enzyme in the production of Aβ peptides, elenbecestat reduces Aβ production. It is

hypothesized that reducing amyloid plaque formations in the brain might exert disease modifying effects and potentially slow the progression of AD.

2. About joint development agreement between Eisai and Biogen for Alzheimer's disease
Eisai and Biogen are collaborating on the joint development and commercialization of Alzheimer's disease treatments. Eisai serves as the lead in the co-development of elenbecestat, a BACE inhibitor, and BAN2401, an anti-amyloid beta (Aβ) protofibril antibody, and the companies plan to pursue marketing authorizations for BAN2401 worldwide. If approved, the companies will also co-promote BAN2401 in major markets, such as the United States, the European Union and Japan. Both companies will equally split overall costs, including research and development expenses. Eisai will book all sales for BAN2401 following marketing approval and launch, and profits will be equally shared between the companies.

3. About Eisai Co., Ltd.
Eisai Co., Ltd. is a leading global research and development-based pharmaceutical company headquartered in Japan. We define our corporate mission as "giving first thought to patients and their families and to increasing the benefits health care provides," which we call our human health care (*hhc*) philosophy. With approximately 10,000 employees working across our global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to realize our *hhc* philosophy by delivering innovative products to address 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 Aricept®, a treatment for Alzheimer's disease and dementia with Lewy bodies, Eisai has been working to establish a social environment that involves patients in each community in cooperation with various stakeholders including the government, healthcare professionals and care workers, and is estimated to have held over ten thousand dementia awareness events worldwide. As a pioneer in the field of dementia treatment, Eisai is striving not only to develop next generation treatments but also to develop diagnosis methods and provide solutions.

For more information about Eisai Co., Ltd., please visit www.eisai.co.jp.

4. About Biogen Inc.
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, and today 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, neuromuscular disorders, movement disorders, Alzheimer's disease and dementia, ophthalmology, immunology, neurocognitive disorders, acute neurology and pain. For more information about Biogen Inc., please visit www.biogen.com and follow on the social media – Twitter, LinkedIn, Facebook, YouTube.

View original content:http://www.prnewswire.com/news-releases/eisai-and-biogen-to-discontinue-phase-iii-clinical-studies-of-bace-inhibitor-elenbecestat-in-early-alzheimers-disease-300917734.html

SOURCE Eisai Inc.