Biogen and Eisai to Discontinue Phase 3 ENGAGE and EMERGE Trials of aducanumab in Alzheimer's Disease

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Independent data monitoring committee advises aducanumab unlikely to meet primary endpoints, leading to decision to discontinue the trials

CAMBRIDGE, Mass., March 21, 2019 (GLOBE NEWSWIRE) -- Biogen (Nasdaq: BIIB) and Eisai, Co., Ltd. (Tokyo, Japan) today announced the decision to discontinue the global Phase 3 trials, ENGAGE and EMERGE, designed to evaluate the efficacy and safety of aducanumab in patients with mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease dementia. The decision to stop the trials is based on results of a futility analysis conducted by an independent data monitoring committee, which indicated the trials were unlikely to meet their primary endpoint upon completion. The recommendation to stop the studies was not based on safety concerns.

"This disappointing news confirms the complexity of treating Alzheimer's disease and the need to further advance knowledge in neuroscience. We are incredibly grateful to all the Alzheimer's disease patients, their families and the investigators who participated in the trials and contributed greatly to this research," said Michel Vounatsos, Chief Executive Officer at Biogen. "Biogen's history has been based on pioneering innovation, learning from successes and setbacks. Driven by our steadfast commitment to patients and our strong business foundation, we will continue advancing our pipeline of potential therapies in Alzheimer's disease and innovative medicines for patients suffering from diseases of high unmet need."

Detailed data from the ENGAGE and EMERGE studies will be presented at future medical meetings to inform ongoing research. ENGAGE and EMERGE are global Phase 3 multicenter, randomized, double-blind, placebo-controlled, parallel-group studies designed to evaluate the efficacy and safety of aducanumab. The primary objective of the study was to evaluate the efficacy of monthly doses of aducanumab as compared with placebo in slowing cognitive and functional impairment as measured by changes in the Clinical Dementia Rating-Sum of Boxes (CDR-SB) score. Secondary objectives were to assess the effect of monthly doses of aducanumab as compared to placebo on clinical progression as measured by Mini-Mental State Examination (MMSE), AD Assessment Scale-Cognitive Subscale (ADAS-Cog 13), and AD Cooperative Study-Activities of Daily Living Inventory (ADCS-ADL-MCI).

As part of this decision, the EVOLVE Phase 2 safety study and the long-term extension of the PRIME Phase1b study of aducanumab will also be discontinued. Initiation of the aducanumab Phase 3 secondary prevention trial will be assessed while the data from ENGAGE and EMERGE are further evaluated.

About Aducanumab

Aducanumab (BIIB037) is an investigational compound being studied for the treatment of early Alzheimer's disease. Biogen licensed aducanumab from Neurimmune under a collaborative development and license agreement. Aducanumab is a human monoclonal antibody (mAb) derived from a de-identified library of B cells collected from healthy elderly subjects with no signs of cognitive impairment or cognitively impaired elderly subjects with unusually slow cognitive decline using Neurimmune's technology platform called Reverse Translational Medicine (RTM). Since October 2017, Biogen and Eisai have collaborated on the development and commercialization of aducanumab globally. In addition, the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the development of aducanumab, a process allowing priority reviews by the FDA for drugs deemed as having potential to treat serious conditions and tackle key unmet medical needs.

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. 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 and only approved treatment for spinal muscular atrophy, and is focused on advancing neuroscience research programs in Alzheimer's disease and dementia, MS and neuroimmunology, movement disorders, neuromuscular disorders, acute neurology, neurocognitive disorders, pain, and ophthalmology. Biogen also manufactures and commercializes biosimilars of advanced biologics.

We routinely post information that may be important to investors on our website at www.biogen.com. To learn more, please visit www.biogen.com and follow us on social media – Twitter, LinkedIn, Facebook, YouTube.

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 to not only develop next generation treatments but also to develop diagnosis methods and provide solutions.

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

Biogen Safe Harbor

This press release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities

Litigation Reform Act of 1995, the futility analysis for the Phase 3 studies of aducanumab, the identification and treatment of Alzheimer's disease, the anticipated benefits and potential of Biogen's collaboration arrangements with Eisai and the potential of Biogen's commercial business and pipeline programs, including aducanumab. These statements may be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "possible," "potential," "will" 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 our 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 aducanumab; 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 aducanumab and/or other Biogen drug candidates; failure to protect and enforce our 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 our expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in our most recent annual or quarterly report and in other reports we have filed with the Securities and Exchange Commission. These statements are based on our current beliefs and expectations and speak only as of the date of this press release. We do 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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