Update on FDA Advisory Committee's Meeting on Aducanumab in Alzheimer's Disease

November 6, 2020

CAMBRIDGE, Mass. and TOKYO, Nov. 06, 2020 (GLOBE NEWSWIRE) -- Today, the U.S. Food and Drug Administration (FDA) Peripheral and Central Nervous System Drugs Advisory Committee voted 1 yes, 8 no and 2 uncertain on the question, "Does Study 302 (EMERGE), viewed independently and without regard for Study 301 (ENGAGE), provide strong evidence that supports the effectiveness of aducanumab for the treatment of Alzheimer's disease?". The Advisory Committee also voted 0 yes, 7 no and 4 uncertain on the question, "Does Study 103 (PRIME) provide supportive evidence of the effectiveness of aducanumab for the treatment of Alzheimer's disease?", and 5 yes, 0 no and 6 uncertain on the question, "Has the Applicant presented strong evidence of a pharmacodynamic effect of aducanumab on Alzheimer's disease pathophysiology?". Finally, the Advisory Committee voted 0 yes, 10 no and 1 uncertain on the question, "In light of the understanding provided by the exploratory analyses of Study 301 and Study 302, along with the results of Study 103 and evidence of a pharmacodynamic effect on Alzheimer's disease pathophysiology, it is reasonable to consider Study 302 as primary evidence of effectiveness of aducanumab for the treatment of Alzheimer's disease?"

"Biogen thanks the many patients and advocates who shared their personal thoughts and experience at today's Advisory Committee meeting, reflecting the significant unmet need for a treatment for Alzheimer's," said Michel Vounatsos, Chief Executive Officer at Biogen. "We appreciated the opportunity to share our data with the Advisory Committee, and we will continue to work with the FDA as it completes its review of our application."

FDA Advisory Committees provide non-binding recommendations for consideration by the FDA. With the opinions expressed at the Advisory Committee and the data presented, the FDA will continue the review process with a decision on whether to approve the aducanumab Biologics License Application by March 7, 2021.

About Aducanumab

Aducanumab (BIIB037) is an investigational human monoclonal antibody studied for the treatment of Alzheimer's disease. Based on clinical data from patients with mild cognitive impairment due to Alzheimer's disease and mild Alzheimer's disease, aducanumab has the potential to impact underlying disease pathophysiology, slow cognitive and functional decline and provide benefits on patients' ability to perform activities of daily living, including conducting personal finances, performing household chores, such as cleaning, shopping and doing laundry, and independently traveling out of the home. If approved, aducanumab would be the first treatment to meaningfully change the course of the disease for individuals living with Alzheimer's.

Biogen licensed aducanumab from Neurimmune under a collaborative development and license agreement. Since October 2017 Biogen and Eisai have collaborated on the development and commercialization of aducanumab globally.

About Aducanumab's Clinical Program

EMERGE and ENGAGE were Phase 3 multicenter, randomized, double-blind, placebo-controlled, parallel-group studies designed to evaluate the efficacy and safety of aducanumab. Enrolled patients had mild cognitive impairment (MCI) due to Alzheimer's disease and mild Alzheimer's disease dementia with Mini-Mental State Examination (MMSE) scores of 24-30. The primary objective of the studies was to evaluate the efficacy of monthly doses of aducanumab as compared with placebo in reducing 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 decline as measured by the MMSE, Alzheimer's Disease Assessment Scale-Cognitive Subscale 13 Items (ADAS-Cog 13) and Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory Mild Cognitive Impairment Version (ADCS-ADL-MCI).

PRIME was a Phase 1b randomized, multicenter study that included a 12-month, double-blind, placebo-controlled period followed by a dose-blinded long-term extension period. Enrolled patients had prodromal Alzheimer's disease or mild Alzheimer's disease dementia with MMSE scores of 20-30. The safety and tolerability of aducanumab was the primary aim of the study. Secondary outcomes were: (1) the effect of aducanumab on brain amyloid plaque content as measured by [18F]-florbetapir PET, (2) the pharmacokinetics of aducanumab and (3) the immunogenicity of aducanumab. Clinical efficacy endpoints were prespecified in the study protocol as exploratory.

About Alzheimer's Disease

Alzheimer's disease is a progressive neurological condition that impairs thinking, memory and independence, leading to premature death. The disease currently cannot be stopped, delayed or prevented and is a growing global health crisis, affecting those living with the disease and their families. According to the World Health Organization (WHO), tens of millions of people worldwide live with Alzheimer's disease, and the number will grow in the years ahead, outpacing the healthcare resources needed to manage it and costing billions of dollars.

Alzheimer's disease is characterized by changes in the brain, including the abnormal accumulation of toxic amyloid beta plaque, which begins approximately 20 years before patients exhibit symptoms of the disease. Mild cognitive impairment due to Alzheimer's disease is one of the earliest stages of the disease when symptoms start to be more visible and can be detected and diagnosed. Current research efforts are focused on catching and treating patients as early as possible for the best chance of slowing or stopping the progression of Alzheimer's disease.

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, immunology, neurocognitive disorders, acute neurology and pain.

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

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.

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 potential regulatory discussions, submissions and approvals and the timing thereof; the potential clinical effects of aducanumab; the potential benefits, safety and efficacy of aducanumab; 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 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 actual timing and content of submissions to and decisions made by the regulatory authorities regarding 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 aducanumab; 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; uncertainty of success in the development and potential commercialization of aducanumab; risks relating to the potential launch of aducanumab, including preparedness of healthcare providers to treat patients, the ability to obtain and maintain adequate reimbursement for aducanumab and other unexpected difficulties or hurdles; 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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