Biogen Enrolls First Patient in Global Phase 3 Study of Investigational Treatment Aducanumab (BIIB037) for Early Alzheimer's Disease

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Biogen (NASDAQ: BIIB) announced today that the first patient has been enrolled in the Phase 3 clinical program for its investigational treatment aducanumab. The Phase 3 program includes two global, placebo-controlled studies named ENGAGE and EMERGE, which are designed to evaluate the efficacy and safety of aducanumab in slowing cognitive impairment and the progression of disability in people with early Alzheimer's disease (AD).

"Since the initial readout of our Phase 1b study, we have accelerated our aducanumab clinical program so that we can more fully characterize and confirm the benefit-risk profile of this investigational treatment for Alzheimer's disease," said Alfred Sandrock, M.D., Ph.D., group senior vice president and chief medical officer at Biogen. "Understanding the urgency to find effective treatments for this devastating disease, we are excited that we have enrolled our first patient in the Phase 3 program and we continue to work with our colleagues around the world to advance the study of aducanumab."

ENGAGE and EMERGE will assess the efficacy and safety of aducanumab in approximately 2,700 people with early AD. The studies are identical in design and eligibility criteria. Each study will be conducted in more than 20 countries in North America, Europe and Asia. For more information about the Phase 3 studies, including information about participating centers visit www.aducanumabclinicaltrials.com or clinicaltrials.gov (NCT02477800 or NCT02484547).

About Aducanumab

Aducanumab (BIIB037) is an investigational compound being developed for the treatment of AD. Aducanumab is a human recombinant 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). Biogen licensed aducanumab from Neurimmune under a collaborative development and license agreement.

Aducanumab is thought to target aggregated forms of beta amyloid including soluble oligomers and insoluble fibrils deposited into the amyloid plaque in the brain of AD patients. Based on pre-clinical and interim Phase 1b data, treatment with aducanumab has been shown to reduce amyloid plaque levels.

Neurimmune Collaboration Update

The enrollment of the first patient in the Phase 3 program for aducanumab triggers a $60 million milestone payment to Neurimmune in the third quarter of 2015.

About Alzheimer's Disease

Alzheimer's disease (AD) is a progressive neurodegenerative disorder characterized by cognitive decline and behavioral disturbances that eventually result in a person's inability to perform daily activities. In 2010, it was estimated that 25 million individuals were living with AD worldwide [1]. Evidence suggests that pathophysiological changes typically begin years prior to the symptoms that lead to a clinical diagnosis. As the disease progresses, cognitive impairments, behavioral changes and functional disability commonly associated with AD begin to manifest.

About Biogen

Through cutting-edge science and medicine, Biogen discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hematologic conditions and autoimmune disorders. Founded in 1978, Biogen is one of the world's oldest independent biotechnology companies and patients worldwide benefit from its leading multiple sclerosis and innovative hemophilia therapies. For product labeling, press releases and additional information about the company, please visit www.biogen.com.

Biogen Safe Harbor

This press release contains forward-looking statements, including statements about the potential safety and clinical effects of aducanumab and the continuing enrollment of our Phase 3 clinical studies. These statements may be identified by words such as "believe," "expect," "may," "plan," "potential," "will" and similar expressions, and are based on our current beliefs and expectations. 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 does not ensure regulatory approval. Factors which could cause actual results to differ materially from our current expectations include the risk that we may not fully enroll our clinical trials or enrollment will take longer than expected, unexpected concerns 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 our drug candidates, or we may encounter other unexpected hurdles. For more detailed information on the risks and uncertainties associated with our drug development and commercialization activities, please review the Risk Factors section of our most recent annual or quarterly report filed with the Securities and Exchange Commission. Any forward-looking statements speak only as of the date of this press release and we assume no obligation to update any forward-looking statements.

[1] World Health Organization Dementia a Public Health Priority. http://www.who.int/mental_health/publications/dementia_report_2012/en/. Accessed 10 Dec 2014.

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