Biogen's Investigational Alzheimer's Disease Treatment Aducanumab Granted FDA Fast Track Designation

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Company Also Provides Update On New Interim Analysis From Phase 1b Study

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Today Biogen (NASDAQ: BIIB) announced that aducanumab, its investigational treatment for early Alzheimer's disease (AD), was granted Fast Track designation by the U.S. Food and Drug Administration (FDA). The FDA's Fast Track program supports the development of new treatments for serious conditions with an unmet medical need such as Alzheimer's disease.

"By collaborating with regulators through programs like Fast Track, we hope to bring effective treatments to patients and families affected by Alzheimer's disease as quickly as possible," said Alfred Sandrock, M.D., Ph.D., executive vice president and chief medical officer at Biogen.

Aducanumab is currently being evaluated in two global Phase 3 studies, ENGAGE and EMERGE, which are designed to evaluate its safety and efficacy in slowing cognitive impairment and the progression of disability in people with early Alzheimer's disease.

For more information about the Phase 3 studies, including information about participating centers, visit www.ClinicalTrials.gov (NCT02477800 or NCT02484547).

Update: Phase 1b Data
PRIME is the ongoing Phase 1b randomized, double-blind, placebo-controlled, multiple-dose study evaluating the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD) and clinical effects of aducanumab in patients with prodromal or mild AD.

The placebo-controlled portion of the study included fixed doses of aducanumab at 1, 3, 6 and 10 mg/kg and a titration regimen. PRIME also has a long-term extension for patients who completed the one-year placebo-controlled portion of the study.

In a recently completed interim analysis from PRIME, efficacy and safety data were consistent with results previously reported. These data support the design of the ongoing Phase 3 ENGAGE and EMERGE studies. Biogen plans to share detailed information about these results at upcoming medical meetings.

About Aducanumab
Aducanumab (BIIB037) is an investigational compound being developed for the treatment of early 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**.**

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 worldwide innovative therapies for people living with serious neurological, autoimmune and rare diseases. 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 more information, please visit www.biogen.com. Follow us on Twitter.

Biogen Safe Harbor
This press release contains forward-looking statements, including statements about the potential benefits of acceptance of aducanumab to the FDA's Fast Track program, and the potential clinical effects of aducanumab. 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. Acceptance into the FDA's Fast Track Program 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 23 May 2016.

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