Biogen Idec Receives Fast Track Designation from FDA for PEGylated Interferon Beta-1a for Relapsing Multiple Sclerosis

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) today announced the U.S. Food and Drug Administration (FDA) has granted PEGylated interferon beta-1a (BIIB017) Fast Track designation for relapsing multiple sclerosis (RMS). Biogen Idec is currently enrolling patients in a global Phase III study evaluating the efficacy and safety of either bi-weekly or once-monthly injections of PEGylated interferon beta-1a in this patient population.

“Early-stage clinical trials suggest that PEGylated interferon beta-1a has the potential to offer less frequent dosing without compromising efficacy, which would be a significant development for people living with multiple sclerosis,” said Michael Panzara, M.D., M.P.H., vice president and chief medical officer of neurology at Biogen Idec. “We look forward to working closely with the FDA to expedite the compound’s development and review process.”

The FDA's Fast Track program is designed to expedite the review of new drugs that are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs.

Biogen Idec plans to enroll more than 1,200 patients in the Phase III, randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy and safety of PEGylated interferon beta-1a in patients with RMS. The global trial, called ADVANCE, will determine the efficacy of PEGylated interferon beta-1a in reducing relapse rates in patients with RMS at one year. The study will also examine if, over time, treatment with PEGylated interferon beta-1a can slow disease progression and lead to a decrease in the number of T2 hyperintense brain lesions commonly seen in MS patients.

Patients interested in learning more about the ADVANCE trial may speak with their physician or e-mail ADVANCEstudy@biogenidec.com.

About Biogen Idec

Biogen Idec creates new standards of care in therapeutic areas with high unmet medical needs. Founded in 1978, Biogen Idec is a global leader in the discovery, development, manufacturing, and commercialization of innovative therapies. Patients in more than 90 countries benefit from Biogen Idec's significant products that address diseases such as lymphoma, multiple sclerosis, and rheumatoid arthritis. For product labeling, press releases and additional information about the company, please visit www.biogenidec.com.

Biogen Idec Safe Harbor

This press release contains forward-looking statements regarding the development of PEGylated interferon beta-1a as a potential treatment for various indications. These statements are based on the company’s current beliefs and expectation. Drug development involves a high degree of risk. Factors which could cause actual results to differ materially from the company's current expectations include the risk that we may not fully enroll our planned clinical trials, unexpected concerns may arise from additional data or analysis, that regulatory authorities may require additional information, further studies, or may fail to approve the drug, or that the company may encounter other unexpected hurdles. For more detailed information on the risks and uncertainties associated with Biogen Idec's drug development and other activities, see the periodic reports of Biogen Idec filed with the Securities and Exchange Commission. Biogen Idec assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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