Biogen Idec Announces First Patient Enrolled in the Global Phase III Study of PEGylated Interferon Beta-1a for Relapsing Multiple Sclerosis

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–Less Frequent Injections would be a Significant Advancement for People Living with MS–

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) today announced enrollment of the first patient in a Phase III, randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy and safety of PEGylated interferon beta-1a (BIIB017) in patients with relapsing multiple sclerosis (RMS). The trial, called ADVANCE, will determine the efficacy of PEGylated interferon beta-1a in reducing relapse rates in patients with RMS.

“A major issue with patient adherence to injectable therapies for MS is the frequency of injections,” said Peter Calabresi, M.D., principal investigator of the ADVANCE trial and professor of neurology and director of The Johns Hopkins Multiple Sclerosis Center, Baltimore, MD. “Examined in Phase I studies, PEGylated interferon beta-1a was shown to be much longer acting than intramuscular interferon beta-1a and thus offers the possibility of every two or four week dosing without compromising efficacy. This could greatly increase the convenience of this first line class of therapy."

Interferon beta-1a has been successfully used to treat patients with relapsing-remitting multiple sclerosis for more than 10 years. PEGylation protects the interferon beta-1a molecule from being degraded, extending the amount of time the drug remains in a patient's system. The process has been used in other therapeutic areas, and Biogen Idec is studying this innovation in interferon therapy for MS. Administered via subcutaneous injection, PEGylated interferon beta-1a is being studied to evaluate its potential to reduce the frequency of treatment injections and provide patients with an effective and more convenient dosing option.

“Bringing PEGylation to the interferon-class of MS treatments would be an innovation welcomed by the MS community,” said Michael Panzara, M.D., M.P.H., vice president, chief medical officer of neurology, Biogen Idec. “Biogen Idec is committed to improving the lives of MS patients by delivering first-in-class treatments, unparalleled patient support, and cutting-edge research as we continue to work towards a cure and redefine success in the treatment of this debilitating disease.”

About the ADVANCE Phase III Clinical Trial

The ADVANCE trial is a two-year multicenter, randomized, double-blind, parallel-group, placebo-controlled trial designed to evaluate the efficacy and safety of PEGylated interferon beta-1a in patients with RMS. The global study will enroll more than 1,200 patients with RMS between the ages of 18 and 55. The primary objective is to determine the efficacy of PEGylated interferon beta-1a in reducing the annualized relapse rate 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.

In order to ensure complete blinding, each participant will receive a subcutaneous injection of either PEGylated interferon beta-1a or placebo every two weeks for 96 weeks. Participants will be randomized between three treatment arms:

- The first treatment arm will receive 125 mcg of PEGylated interferon beta-1a every two weeks;
- The second treatment arm will receive 125 mcg PEGylated interferon beta-1a every four weeks and subcutaneous placebo in the alternate weeks; and
- The third treatment arm will receive placebo every two weeks for 48 weeks followed by 125 mcg PEGylated interferon beta-1a every two or four weeks for 48 weeks.

All study participants will receive active treatment after the first 48 weeks.

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 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 Inc. 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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