US and EU Regulatory Authorities Accept PLEGRIDY™ (peginterferon beta-1a) Marketing Applications for Review

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WESTON, Mass.--(BUSINESS WIRE)--Today Biogen Idec (NASDAQ: BIIB) announced that U.S. and EU regulatory authorities have accepted the marketing applications for the review of PLEGRIDY™ (peginterferon beta-1a), the company's pegylated subcutaneous injectable candidate for relapsing forms of multiple sclerosis (MS). The U.S. Food and Drug Administration (FDA) has accepted Biogen Idec's Biologics License Application (BLA) for marketing approval of PLEGRIDY in the United States and granted the company a standard review timeline. The Marketing Authorisation Application (MAA) of PLEGRIDY for review in the European Union was also validated by the European Medicines Agency.

The regulatory applications included positive one-year results from the two-year global Phase 3 ADVANCE study. The data demonstrated that PLEGRIDY met all primary and secondary endpoints by significantly reducing disease activity including relapses, disability progression and brain lesions compared to placebo, and showed favorable safety and tolerability profiles at one year.

"We expect that interferons will remain an important and widely used option for patients with MS. At one-year, PLEGRIDY demonstrated significant reductions in relapses and disability progression, as well as a robust impact on several MRI endpoints," said Douglas E. Williams, Ph.D., Biogen Idec's executive vice president of Research and Development. "PLEGRIDY, if approved, could offer a less frequent dosing schedule, a favorable safety profile, and the potential to become the preferred interferon treatment."

About PLEGRIDY

PLEGRIDY is a new molecular entity in which interferon beta-1a is pegylated to extend its half-life and prolong its exposure in the body. PLEGRIDY is a member of the interferon class of treatments, which is often used as a first-line treatment for MS.

About ADVANCE

The two-year Phase 3 ADVANCE clinical trial is a global, multi-center, randomized, double-blind, parallel-group, placebo-controlled study designed to evaluate the efficacy and safety of PLEGRIDY in 1,516 patients with relapsing-remitting MS.

The study investigates two dose regimens of PLEGRIDY, 125 mcg administered subcutaneously every two weeks or every four weeks compared to placebo. The analysis for all primary and secondary efficacy endpoints occurred at one year. After the first year, patients on placebo are re-randomized to one of the PLEGRIDY arms for the duration of the second year of the study. After completing two years in the ADVANCE study, patients have the option of enrolling in an open-label extension study called ATTAIN and will be followed for up to four years.

About Biogen Idec

Through cutting-edge science and medicine, Biogen Idec discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hemophilia and autoimmune disorders. Founded in 1978, Biogen Idec is the world's oldest independent biotechnology company. Patients worldwide benefit from its leading multiple sclerosis therapies, and the company generates more than $5 billion in annual revenues. For product labeling, press releases and additional information about the company, please visit www.biogenidec.com.

Safe Harbor

This press release includes forward-looking statements, including statements about the potential of PLEGRIDY, including the dosage and related therapeutic effects of PLEGRIDY in MS. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "estimate," "expect," "forecast," "intend," "may," "plan," "will," and other words and terms of similar meaning. You should not place undue reliance on these statements. Drug development and commercialization involve a high degree of risk. Factors which could cause actual results to differ materially from our current expectations include the risk that unexpected concerns may arise from additional data or analysis, regulatory authorities may require additional information or further studies, or may fail 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. These statements are based on our current beliefs and expectations and speak only as of the date of this press release. We do not undertake any obligation to publicly update any forward-looking statements.

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