Biogen Idec Submits Application to FDA for Approval of PLEGRIDY™ (Peginterferon Beta-1a) in Multiple Sclerosis

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— EMA Submission Planned in the Coming Weeks —

WESTON, Mass.--(BUSINESS WIRE)--Today Biogen Idec (NASDAQ: BIIB) announced it has submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for approval of PLEGRIDY™ (peginterferon beta-1a), the company's pegylated subcutaneous injectable candidate for relapsing forms of multiple sclerosis (RMS).

This regulatory submission was based on the results from the first year of 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.

"This filing demonstrates our dedication to the treatment of MS, both through the discovery of new medications and the development of innovative solutions that enhance treatment for people living with this disease," said Douglas E. Williams, Ph.D., Biogen Idec's executive vice president of Research and Development. "We believe that based on the efficacy and safety PLEGRIDY has demonstrated, in addition to its less frequent dosing schedule, it has the potential to become a preferred interferon treatment option."

In addition to the BLA filing with the FDA, Biogen Idec plans to submit a Marketing Authorisation Application (MAA) for PLEGRIDY to the European Medicines Agency (EMA) in the coming weeks.

Biogen Idec has been the leader in the development of MS therapies for three decades and its robust treatment portfolio and development pipeline provides options that may help manage the disease from its earliest signs through its later stages.

The company anticipates hearing from regulatory authorities regarding the status and acceptance of these submissions within the next couple of months.

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, enabling study of a less frequent dosing schedule. PLEGRIDY is a member of the interferon class of treatments and, if approved, would be a new addition to this class, 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 regulatory filings and actions and 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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