PLEGRIDY™ (Peginterferon Beta-1a) Two-Year Data Confirm Maintenance of Efficacy and Safety in Multiple Sclerosis Patients

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– Results Presented at Joint ACTRIMS-ECTRIMS Meeting Show Patients Continuously Treated with PLEGRIDY Over Two Years Demonstrate Improvement in Clinical and MRI Outcomes –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Today Biogen Idec (NASDAQ: BIIB) announced new data from the second year of its Phase 3 ADVANCE clinical trial that show the positive treatment effects of PLEGRIDY™ (peginterferon beta-1a) were maintained in people with relapsing forms of multiple sclerosis (RMS) beyond the first year of the study. These results were presented at the sixth Triennial Joint Meeting of the Americas Committee for Treatment and Research in Multiple Sclerosis and the European Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS-ECTRIMS) in Boston.

“These new, two-year data from ADVANCE further support the compelling efficacy and safety of PLEGRIDY, providing physicians and patients with additional confidence in the benefits of using PLEGRIDY to treat this chronic disease,” said Gilmore O’Neill, vice president, Multiple Sclerosis Research and Development at Biogen Idec.

Efficacy and Safety of PLEGRIDY Maintained Over Two Years

Post-hoc analyses from the two-year, Phase 3 ADVANCE clinical trial confirm that PLEGRIDY’s positive effects on reducing disease activity and disability progression were maintained in year two of the study. A significantly higher proportion of patients taking PLEGRIDY during both years of the study experienced no evidence of disease activity (NEDA) – defined as the absence of clinical and MRI disease activity over two years of treatment – compared to those who switched to PLEGRIDY from placebo. Also, those treated with PLEGRIDY for both years of the study had significant reductions in the risk of 24-week confirmed disability progression compared to patients treated with placebo during the first year.

In addition, new data from the second year of ADVANCE show that patients who took PLEGRIDY throughout the study experienced statistically significant improvements in clinical and MRI outcomes – including annualized relapse rate (ARR), risk of relapse, risk of 24-week confirmed disability progression, and number of brain lesions – when compared to those who switched to PLEGRIDY after taking placebo for the first year. This new data also showed that the safety profile of PLEGRIDY was consistent between years one and two of the study.

“The ADVANCE data suggest that treatment with PLEGRIDY offers benefits in reductions in relapses, confirmed disability progression and brain lesions over the course of two years,” said Douglas Arnold, M.D., professor, Montreal Neurological Institute, McGill University. “Results from the second year of ADVANCE also confirm the positive safety and tolerability profiles of PLEGRIDY seen in year one, which is very encouraging.”

These data will be presented in the following platform and poster presentations:

- *Clinical Efficacy of Peginterferon Beta-1a in Relapsing-Remitting Multiple Sclerosis: 2-year Data from the Phase 3 ADVANCE Study* (platform FC2.5) will be presented on Friday, Sept. 12 at 9:00 a.m. ET
- *Effect of Peginterferon Beta-1a on MRI Measures and Freedom from Measured Disease Activity: 2-year Results from the Phase 3 ADVANCE Study* (poster P067) will be available for viewing on Thursday, Sept. 11 from 3:30-5:00 p.m. ET

About PLEGRIDY

PLEGRIDY is a new subcutaneous injectable therapy indicated for relapsing forms of MS, in which interferon beta-1a is pegylated to extend its half-life to permit a less frequent dosing schedule. PLEGRIDY is a member of the interferon class of treatments for MS.

The recommended dosage of PLEGRIDY is 125 micrograms injected subcutaneously every 14 days. Patients should start treatment with 63 micrograms on day one. On day 15, the dose is increased to 94 micrograms, reaching the full dose of 125 micrograms on day 29.

Severe hepatic injury, including hepatitis, autoimmune hepatitis, and rare cases of severe hepatic failure have been reported with interferon beta. Elevations in hepatic enzymes and hepatic injury have been observed with the use of PLEGRIDY in clinical studies. Depression, suicidal ideation and suicide have been reported in patients receiving interferon beta. Seizures are also associated with the use of interferon beta. Anaphylaxis and other serious allergic reactions are rare complications of treatment with interferon beta. Injection site reactions, including injection site necrosis, can occur with the use of subcutaneous interferon beta.

Congestive heart failure, cardiomyopathy and cardiomyopathy with congestive heart failure occur in patients receiving interferon beta. Interferon beta can cause decreased peripheral blood counts in all cell lines, including rare instances of pancytopenia and severe thrombocytopenia. Autoimmune disorders of multiple target organs including idiopathic thrombocytopenia, hyper and hypothyroidism, and autoimmune hepatitis have been reported with interferon beta.

For complete PLEGRIDY prescribing information, please visit www.PLEGRIDY.com.

About ADVANCE

ADVANCE was a two-year, multi-center, randomized, double-blind, parallel-group, placebo-controlled (for the first year), Phase 3 study that evaluated the efficacy, safety and tolerability of PLEGRIDY compared to placebo in people with relapsing-remitting MS (RRMS). The primary endpoint of ADVANCE was to determine the efficacy of PLEGRIDY in reducing ARR. Secondary endpoints included determining the efficacy of PLEGRIDY in reducing the risk of 12-week confirmed disability progression, the proportion of patients who relapsed and MRI assessments. The analysis for all

primary and secondary efficacy endpoints occurred at the end of year one. After the first year, patients on placebo were randomized to one of PLEGRIDY's active treatment arms.

With more than 1,500 patients in over 180 sites in 26 countries, ADVANCE was one of the largest pivotal studies with interferons conducted in people living with RRMS. After completing two years in the ADVANCE study, patients had the option of enrolling in an open-label extension study called ATTAIN and may be followed for up to four years.

About Pegylation

Pegylation prolongs the circulation time of the molecule in the body by increasing its size, thus enabling a longer half-life, stabilizing the molecule by improving its solubility and shielding the molecule from enzymes in the body that try to break it down into smaller particles.[1] Pegylation is a well-established scientific process that has been used in other therapeutic categories.

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, hematologic conditions and autoimmune disorders. Founded in 1978, Biogen Idec is the world's oldest independent biotechnology company and patients worldwide benefit from its leading multiple sclerosis and innovative hemophilia therapies. For product labeling, press releases and additional information about the Company, please visit www.biogenidec.com.

Safe Harbor

This press release contains forward-looking statements, including statements about the potential benefits of PLEGRIDY. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "project," "target," "will" and other words and terms of similar meaning. You should not place undue reliance on these statements. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including uncertainty of success in commercialization of PLEGRIDY, intense competition in the MS market, unexpected hurdles or difficulties in launching PLEGRIDY, difficulties obtaining or changes in the availability of reimbursement for PLEGRIDY, problems with our manufacturing processes for PLEGRIDY, the occurrence of adverse safety events, failure to comply with government regulation or obtain regulatory approvals in other jurisdictions, failure to protect our intellectual property and other proprietary rights, product liability claims and the other risks and uncertainties that are described in the Risk Factors section of our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission (SEC). 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, whether as a result of new information, future events or otherwise.

[1] Fishburn CS. The Pharmacology of PEGylation: Balancing PD with PK to Generate Novel Therapeutics. *Journal of Pharmaceutical Sciences*. DOI 10.1002/jps.21278, 2008.

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