Biogen Idec to Present New Two-Year Data from the PLEGRIDY™ (Peginterferon Beta-1a) Phase 3 ADVANCE Study at AAN Annual Meeting

April 29, 2014

– Two-Year Data Consistent with Positive Efficacy and Safety Observed in Year One –

– Additional Analyses of Year-One ADVANCE Results Show High Rates of Freedom from Measured Disease Activity and Recovery from Relapses –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Today Biogen Idec (NASDAQ: BIIB) announced two-year data from its Phase 3 ADVANCE clinical trial for PLEGRIDY™ (peginterferon beta-1a) in people with relapsing forms of multiple sclerosis (RMS). These data, which will be presented at the 66th American Academy of Neurology (AAN) annual meeting, indicate PLEGRIDY dosed once every two weeks demonstrated favorable results on relapse rates, magnetic resonance imaging (MRI) findings and disease progression. Over two years, the safety profile of PLEGRIDY was consistent with other multiple sclerosis (MS) interferon therapies.

“The two-year data from ADVANCE further establish the efficacy and safety profile of PLEGRIDY demonstrated in the first year of the pivotal trial,” said Gilmore O’Neill, vice president, Global Neurology Clinical Development at Biogen Idec. “If approved, we believe that PLEGRIDY dosed once every two weeks will provide MS patients with one of the most significant developments in the interferon class in over a decade.”

ADVANCE was a two-year, Phase 3, placebo-controlled (in year one) study that evaluated the efficacy and safety of PLEGRIDY administered subcutaneously. The analysis for all primary and secondary efficacy endpoints occurred at the end of year one. After the first year, patients on placebo received PLEGRIDY for the duration of the study.

New Analysis of ADVANCE Data Showed PLEGRIDY Benefits Maintained Over Two Years
A new analysis of data from the second year of ADVANCE presented at AAN demonstrated:

- The efficacy of PLEGRIDY dosed once every two weeks was maintained throughout year two. Relative to year one, the annualized relapse rate (ARR) was further reduced and the number of new or newly-enlarging T2 lesions was numerically lower in year two
- The safety and tolerability profile of PLEGRIDY was consistent between years one and two

These data will be presented in a platform presentation on Tuesday, April 29 at 2:00 p.m. EDT:

- *Analysis of 2-year Clinical Efficacy and Safety of Peginterferon Beta-1a in Patients with Relapsing-Remitting Multiple Sclerosis: Data from the Pivotal Phase 3 ADVANCE Study* (S4.005)

“ADVANCE provides us with insight about the efficacy and safety of PLEGRIDY and its every two-week dosing schedule,” said Dr. Bruce L. Hughes, MD, Neurology, Mercy Ruan Neuroscience Center in Des Moines, Iowa. “The reduced dosing regimen of this investigational treatment could be an attractive option for many patients with relapsing forms of MS.”

Additional Year-One Analyses Affirmed Efficacy of PLEGRIDY
Two new post-hoc analyses from year one of the ADVANCE study will also be presented at the AAN annual meeting:

- The first analysis showed that PLEGRIDY increased the proportion of patients with RMS who achieved freedom from measured disease activity (FMDA), defined as no relapses, no disability progression, no Gd+ lesions and no new or newly enlarging T2-hyperintense lesions compared to baseline
  - Results show the proportion of patients with overall-, clinical- and MRI-FMDA were significantly higher with PLEGRIDY dosed once every two weeks compared to placebo
- A second analysis showed treatment with PLEGRIDY was associated with improved recovery from relapses compared to placebo (as measured by the proportion of patients with a relapse associated with sustained disability progression)

The first analysis will be presented in a platform presentation on Tuesday, April 29 at 2:30 p.m. EDT:

- *Peginterferon Beta-1a Significantly Increases the Proportion of Patients with Freedom from Measured Disease Activity in Relapsing-Remitting Multiple Sclerosis: Findings from the ADVANCE Study* (S4.007)

The second analysis will be presented in a platform presentation on Tuesday, April 29 at 1:30 p.m. EDT, followed by a poster presentation on Wednesday, April 30 at 4:30 p.m. EDT:

- *Peginterferon Beta-1a May Improve Recovery Following Relapses: Data from the Pivotal Phase 3 ADVANCE Study in Patients with Relapsing-Remitting Multiple Sclerosis – Platform* (S4.003)*; Poster* (I7-1.002)

For members of the media interested in more information and additional resources, please visit biogenidec.com/us_media_corner.

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 an investigational member of the interferon class of treatments for MS.

Clinical and MRI data from the ADVANCE study of PLEGRIDY demonstrated a reduction in relapses, disability progression and the number of MS lesions when compared to placebo, and further support its clinical efficacy profile. The most common adverse reactions (incidence ≥10% and at least 2% more frequent on PLEGRIDY than on placebo) were injection site erythema, influenza-like illness, pyrexia, headache, myalgia, chills, injection site pain, asthenia, injection site pruritus, and arthralgia.

Regulatory applications are currently under review with the Food and Drug Administration (FDA) and European Medicines Agency (EMA).

About ADVANCE
The two-year Phase 3 ADVANCE clinical trial was 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 RMS. The study investigated 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 year one.

In the ADVANCE clinical trial, PLEGRIDY dosed once every two weeks met all primary and secondary endpoints by significantly reducing disease activity, including relapses and disability progression, and showed favorable safety and tolerability profiles at one and two years. PLEGRIDY also reduced the number of new or newly enlarging T2-hyperintense lesions and the number of Gd+ lesions on brain MRI scans after one and two years.

After completing two years in the ADVANCE study, patients had the option of enrolling in an open-label extension study called ATTAIN and will be followed for up to four years.

About Pegylation
Pegylation is a well-established scientific process that has been used for more than 20 years. Pegylation prolongs the circulation time of the molecule in the body by increasing its size, thus enabling a longer half-life. It also stabilizes the molecule by improving its solubility and shields the molecule from enzymes in the body that try to break it down into smaller particles.

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. 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 advances PLEGRIDY may offer if approved. 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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