PLEGRIDY® (Peginterferon Beta-1a) Three-Year Data Presented at AAN Annual Meeting Support Long-Term Safety and Efficacy in Multiple Sclerosis Patients

April 21, 2015

Interim Results from Phase 3 Extension Study Affirm PLEGRIDY's Safety Profile and Robust Effect on Clinical, MRI, and NEDA Outcomes

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Today Biogen (NASDAQ: BIIB) announced new data from the ATTAIN study which demonstrate the long-term safety and efficacy of PLEGRIDY® (peginterferon beta-1a) over three years in people with relapsing-remitting multiple sclerosis (RRMS). The interim results from the first year of ATTAIN, a two-year extension study of the Phase 3 ADVANCE study, show the benefits of continued PLEGRIDY treatment on clinical outcomes and further define its safety profile. The study results will be presented at the 67th American Academy of Neurology's (AAN) Annual Meeting in Washington, DC.

"These data offer additional insights into the benefit-risk profile of PLEGRIDY by demonstrating a consistent safety profile and continued efficacy over three years," said Bruce Hughes, M.D., director of the Ruan Multiple Sclerosis Center at Mercy Ruan Neurology Clinic and Research Center in Des Moines, Iowa. "Long-term safety and robust efficacy are important considerations when evaluating treatment options for this chronic condition."

Safety and Tolerability Results

The safety and tolerability of PLEGRIDY observed in all patients enrolled in the ATTAIN study were in line with the profile demonstrated in the ADVANCE study. The most common AEs reported were injection site reactions and flu-like symptoms, the majority of which were mild or moderate. The rate of neutralizing antibodies was one percent after three years.

Efficacy Results

The efficacy data from the first year of the ATTAIN study represent patients who have three years of continuous, fixed-dose treatment with PLEGRIDY. The efficacy findings are consistent with the Phase 3 ADVANCE study and continue to support PLEGRIDY's robust efficacy over time:

- Patients with RRMS who were administered PLEGRIDY subcutaneously every two weeks over the three year period maintained positive efficacy results on clinical outcomes including annualized relapse rate (ARR), the proportion of patients suffering a relapse, and the proportion of patients with 24-week confirmed disability progression.
- PLEGRIDY also showed continued efficacy over the three year period across important MRI measures: number of gadolinium (Gd+) enhanced lesions, new T1-hypointense lesions, and new or newly enlarging T2-hyperintense lesions.

Additionally, the results from the study included a post-hoc analysis on NEDA outcomes, which in ATTAIN were defined as no evidence of disease activity on clinical and MRI measures, indicating no relapses and no onset of 24-week disability progression, no Gd+ lesions, and no new or enlarging T2-hyperintense lesions.

- The percentage of patients in the intent-to-treat (ITT) population who achieved NEDA were 34.8 percent in year one and 54.3 percent in year two of the ADVANCE study, and 48.7 percent in year one of the ATTAIN study, demonstrating continued efficacy over a period of three years.

"The ATTAIN data presented at AAN reinforce the known benefits PLEGRIDY provides people with MS – long-term efficacy paired with a well-defined safety profile," said Gilmore O'Neill, vice president, Multiple Sclerosis Research and Development, Biogen. "As we continue to introduce PLEGRIDY in markets around the world, we are proud to bring innovation to the interferon class in an effort to advance patient options and care."

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

- *Long-Term Safety and Tolerability of Peginterferon Beta-1a: Interim Analysis From ATTAIN, A Phase 3 Extension Study* (platform S4.002) will be presented on Tuesday, April 21, 2015 at 1:15 p.m. ET
- *Long-Term Efficacy in MRI and No Evidence of Disease Activity Outcomes in Patients with Relapsing-Remitting Multiple Sclerosis Treated with Peginterferon Beta-1a* (poster P7.266) will be available during poster session VII on Thursday, April 23, 2015 at 2:00 p.m. ET

About PLEGRIDY®

PLEGRIDY is approved in the U.S. and Australia for the treatment of relapsing forms of MS, and authorized by the European Commission for use in relapsing-remitting MS. Biogen continues to work toward making PLEGRIDY available in additional countries.

PLEGRIDY is a subcutaneous injectable therapy indicated for relapsing forms of MS, in which interferon beta-1a is pegylated, extending its half-life to permit a dosing schedule of once every two weeks. PLEGRIDY is a 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.

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.

In clinical studies, 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.

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

About ATTAIN

ATTAIN is a two-year, open-label, multi-center, extension of the Phase 3 ADVANCE study. The primary endpoint of ATTAIN is to evaluate the long-term safety and tolerability of PLEGRIDY in people with RRMS originally treated in ADVANCE who continued treatment with PLEGRIDY. Secondary endpoints included determining the efficacy of PLEGRIDY in reducing ARR, reducing the number of new or active lesions, 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 following the two-year, Phase 3 ADVANCE study.

About Biogen

Through cutting-edge science and medicine, Biogen discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hematologic conditions and autoimmune disorders. Founded in 1978, Biogen is one of 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.biogen.com.

Safe Harbor

This press release contains forward-looking statements, including statements about the potential benefits of PLEGRIDY and an on-going clinical trial. 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 and are based on our current beliefs and expectations. 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 unexpected concerns may arise from additional data or analysis of the full results or results obtained during our clinical trials, 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.

Contact:

Biogen
Media Contact:
Ligia Del Bianco, +1 781-464-3260
public.affairs@biogen.com
or
Investor Contact:
Carlo Tanzi, Ph.D., +1 781-464-2442
IR@biogen.com