Biogen Idec's PLEGRIDY™(Peginterferon Beta-1a) Approved in the US for the Treatment of Multiple Sclerosis

August 15, 2014

− Reduces Relapses, Disability Progression and Brain Lesions with a Favorable Safety Profile −

− Only Pegylated Interferon in MS, Dosed Once Every Two Weeks –

− Complements Biogen Idec's Industry-Leading Portfolio of MS Products –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Today Biogen Idec (NASDAQ: BIIB) announced that the U.S. Food and Drug Administration (FDA) has approved PLEGRIDY™ (peginterferon beta-1a), a new treatment for people with relapsing forms of multiple sclerosis (RMS). PLEGRIDY, the only pegylated beta interferon approved for use in RMS, is dosed once every two weeks and can be administered subcutaneously with the PLEGRIDY PEN, a new, ready-to-use autoinjector, or a prefilled syringe.

"PLEGRIDY offers people with MS robust efficacy, a safety profile consistent with the established interferon class, and significantly fewer injections than other beta interferon treatments," said George A. Scangos, Ph.D., chief executive officer of Biogen Idec. "PLEGRIDY represents the most significant innovation in the interferon class in over a decade, and is the result of our deep commitment to improving the lives of people with MS and those who care for them."

The FDA approval of PLEGRIDY is based on results from one of the largest pivotal studies of beta interferon conducted, ADVANCE, which involved more than 1,500 MS patients. 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.

In the first year of the ADVANCE clinical trial, PLEGRIDY dosed once every two weeks significantly reduced annualized relapse rate (ARR) at one year by 36 percent compared to placebo (p=0.0007). PLEGRIDY reduced the risk of 12-week confirmed disability progression, as measured by the Expanded Disability Status Scale, by 38 percent (p=0.0383) compared to placebo. PLEGRIDY also significantly reduced the number of new gadolinium-enhancing [Gd+] lesions by 86 percent (p<0.0001) and reduced new or newly enlarging T2-hyperintense lesions by 67 percent (p<0.0001) compared to placebo.

The most common adverse reactions were injection site reaction, flu-like illness, fever, headache, muscle pain, chills, injection site pain, weakness, injection site itching and joint pain. The ADVANCE two-year safety data were consistent with safety results observed in year one.

"PLEGRIDY is a compelling new treatment option for people living with MS that offers a proven safety profile, strong efficacy and an every two week dosing schedule administered by an innovative delivery system," said Peter Wade, M.D., medical director for neurology at the Mandell Center for Comprehensive Multiple Sclerosis Care and Neuroscience Research in Hartford, CT. "As a treating neurologist, I believe these attributes will appeal to MS patients who look for less frequent dosing with proven effectiveness."

PLEGRIDY has been recently approved by the European Commission.

"It is always encouraging to have additional treatment options that may help people with MS manage their disease as we move towards our ultimate goal of ending MS forever," said Dr. Timothy Coetzee, chief advocacy, services and research officer at the National MS Society.

For more information on PLEGRIDY, prescribing information and financial assistance programs visit PLEGRIDY.com or biogenidec.com.

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.

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 safety and tolerability profile of PLEGRIDY observed in ADVANCE was consistent with that of established MS interferon therapies.

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 PLEGRIDY.com.

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.

Biogen Idec Patient Support

As part of its ongoing commitment to the MS community, Biogen Idec provides a variety of support services for patients and caregivers through MS *ActiveSource*®. These world-class services are thoughtfully crafted around the informational, emotional, financial and logistical needs that come with living with MS.

MS *ActiveSource* is available via phone (Monday-Friday 8:30 a.m. – 8:00 p.m. ET) at 1-800-456-2255 or via web at MSActiveSource.com.

What is Multiple Sclerosis

Multiple sclerosis (MS) is a chronic, often disabling disease that attacks the central nervous system, which is made up of the brain, spinal cord and optic nerves. Symptoms may be mild or severe, ranging from numbness in the limbs to paralysis or loss of vision. The progression, severity and specific symptoms of MS are unpredictable and vary from one person to another. [2] MS affects more than 2.3 million people worldwide.[3] Best current estimates indicate that there are at least 400,000 people with MS in the United States.[4] Relapsing forms of MS include: relapsing-remitting MS (RRMS), the most common form of the disease, which is characterized by clearly defined acute attacks with full recovery or with residual deficit upon recovery and progressive-relapsing MS which is characterized by steadily worsening disease from the beginning with occasional acute attacks like those experienced by people with RRMS.[5]

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 http://www.biogenidec.com.

Safe Harbor

This press release contains forward-looking statements, including statements about the benefits and impact 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.

[2] NMSS. Frequently Asked Questions about Multiple Sclerosis. 2012. Accessed March 2014. Available at http://www.nationalmssociety.org/What-is-MS/MS-FAQ-s

[3] Multiple Sclerosis International Federation, Atlas of MS 2013. *Epidemiology of MS*. Page 8. Date Accessed: May 14, 2014. http://www.msif.org/includes/documents/cm_docs/2013/m/msif-atlas-of-ms-2013-report.pdf?f=1

[4] NMSS. *Relapsing-Remitting MS*. Date accessed: August 15, 2014. http://www.nationalmssociety.org/About-the-Society/MS-Prevalence

[5] NMSS. *Progressive-Relapsing MS*. Date accessed: August 15, 2014. http://www.nationalmssociety.org/What-is-MS/Types-of-MS

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Preview image

An Administration Pack which holds two doses of PLEGRIDY(TM)(peginterferon beta-1a) 125 mcg which was approved by the U.S. FDA in August 2014 for relapsing forms of multiple sclerosis. (Photo: Business Wire)
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Image of the PLEGRIDY(TM)(peginterferon beta-1a) PEN, a ready-to-use autoinjector for subcutaneous administration. (Photo: Business Wire)
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PLEGRIDY(TM)(peginterferon beta-1a) was approved by the U.S. FDA in August 2014 for relapsing forms of multiple sclerosis (Graphic: Business Wire)
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This simple animation video about pegylation was created for educational purposes only and is not intended to make clinical claims for PLEGRIDY(TM)(peginterferon beta-1a) or any other drug or process.
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Overview of key milestones for Biogen Idec's PLEGRIDY(TM)(peginterferon beta-1a) which was approved by the U.S. FDA in August 2014 for relapsing forms of multiple sclerosis.
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