PLEGRIDY™ (Peginterferon beta-1a) Approved in the European Union for the Treatment of Multiple Sclerosis

July 23, 2014

– Reduces Relapses, Disability Progression, and MRI Brain Lesions, with a Favorable Safety Profile Consistent with the Established Interferon Class –

– Initial Country Launches Expected to Begin in the Coming Weeks –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Today Biogen Idec (NASDAQ: BIIB) announced that the European Commission (EC) has granted marketing authorization for PLEGRIDY™ (peginterferon beta-1a) as a treatment for adults with relapsing-remitting multiple sclerosis (RRMS), the most common form of multiple sclerosis (MS). PLEGRIDY is dosed once every two weeks and is administered subcutaneously with the PLEGRIDY PEN, a new ready-to-use autoinjector, or a prefilled syringe.

“PLEGRIDY offers people living with MS an interferon with compelling efficacy that requires considerably fewer injections than other platform therapies," said George A. Scangos, Ph.D., chief executive officer at Biogen Idec. “The approval of PLEGRIDY demonstrates our commitment to improving the lives of patients by providing innovative therapies that meet their individual needs, including flexibility in managing their disease.”

PLEGRIDY, the only pegylated interferon approved for use in RRMS, has been proven to significantly reduce important measures of disease activity, including number of relapses, MRI brain lesions, and disability progression.

The EC approval of PLEGRIDY is based on results from one of the largest pivotal studies of a beta interferon conducted, ADVANCE[1], which involved more than 1,500 patients with relapsing forms of MS.

In 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 sustained disability progression confirmed at twelve weeks by 38 percent (p=0.0383) and at twenty four weeks by 54 percent (p=0.0069, post-hoc analysis). In addition, the number of gadolinium-enhancing [Gd+] lesions was significantly reduced by 86 percent (p<0.0001) compared to placebo.

Results over two years of ADVANCE confirm that its robust efficacy was maintained beyond the placebo-controlled first year of the study.

“The safety and efficacy that PLEGRIDY has demonstrated, combined with its less frequent dosing schedule offers MS patients an option to put their treatment in the background for longer stretches of time,” said Professor Bernd C. Kieseier, M.D., Heinrich-Heine Universität, Dusseldorf.

The safety and tolerability profile of peginterferon beta-1a observed in ADVANCE[1] was consistent with that of established MS interferon therapies. The most commonly reported adverse drug reactions with peginterferon beta-1a treatment (incidence ≥10% and at least 2% more frequent on peginterferon beta-1a than on placebo) were injection site reaction, flu-like illness, fever, headache, muscle pain, chills, injection site pain, weakness, injection site itching, and joint pain.[1]

PLEGRIDY is the fifth therapy to be offered by Biogen Idec to people living with MS, expanding on a portfolio that addresses individual patient needs.

For more information on PLEGRIDY, visit biogenidec.com. Additional resources on PLEGRIDY are available for the media upon request.

About PLEGRIDY™

PLEGRIDY is a subcutaneous injectable therapy for relapsing-remitting multiple sclerosis (RRMS), 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.

According to the EU Summary of Product Characteristics (SmPC), the recommended starting dose of PLEGRIDY is 63 micrograms at dose 1, increasing to 94 micrograms at dose 2, reaching the full dose of 125 micrograms by dose 3 and continuing with the full dose (125 micrograms) every 2 weeks thereafter.

The safety and tolerability profile of PLEGRIDY observed in ADVANCE[1] was consistent with that of established MS interferon therapies. PLEGRIDY should be administered with caution to patients with previous depressive disorders, seizures, severe hepatic impairment and severe renal impairment. Cytopenias, including rare severe neutropenia and thrombocytopenia, have been observed in patients treated with PLEGRIDY. The following have been reported with interferon beta medicinal products including PLEGRIDY: Elevations in hepatic enzymes, serious hypersensitivity reactions, injection site reactions with subcutaneous administration, including injection site necrosis, and worsening of cardiac disease.

In addition, the EU SmPC indicates that the use of interferon beta products is associated with cases of nephrotic syndrome, thrombotic microangiopathy manifested as thrombotic thrombocytopenic purpura (TTP) or haemolytic uraemic syndrome (HUS), hyper and hypothyroidism, hepatitis, autoimmune hepatitis, rare cases of severe hepatic failure, and decreased peripheral blood counts, including rare pancytopenia.

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.[3] Pegylation is a well-established scientific process that has been used for more than 20 years.[2,3]

About 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. MS affects more than 2.3 million people worldwide,[4] with more than 600,000 sufferers in the European Union.[5] Relapsing-remitting MS (RRMS) is the most common form of MS accounting for 85 percent of cases. It is characterized by clearly defined acute attacks with full recovery or with residual deficit upon recovery.[6]

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 and the expected timing of commercial launch in the EU. 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, 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.

References

[1] Calabresi PA et al. Peginterferon Beta-1a Provides Improvements in Clinical and Radiological Disease Activity in Relapsing-Remitting Multiple Sclerosis: Year 1 Findings from the Phase 3 ADVANCE. Poster presented at 29th Congress of the European Committee for Research and Treatment in Multiple Sclerosis, 2013.

[2] Bailon P and Won CY. PEG-modified biopharmaceuticals. *Expert Opin Drug Deliv* 6: 1-16, 2009.

[3] Reuss R. PEGylated interferon beta-1a in the treatment of multiple sclerosis – an update. Biologics: Targets and Therapy 7: 131-139, 2013. Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3686537/pdf/btt-7-131.pdf. Accessed March 2014.

[4] Multiple Sclerosis International Federation, Atlas of MS 2013. *Epidemiology of MS*. Page 8. Date Accessed: Mar. 17, 2014. http://www.msif.org/includes/documents/cm_docs/2013/m/msif-atlas-of-ms-2013-report.pdf?f=1

[5] Multiple Sclerosis International Federation. Atlas of MS 2013. *Epidemiology of MS*. Date Accessed: Mar. 17, 2014. http://www.atlasofms.org/query.aspx

[6] NMSS. *Relapsing-Remitting MS*. Date accessed: Mar. 17, 2014. http://www.nationalmssociety.org/What-is-MS/Types-of-MS/Relapsing-remitting-MS

Contact:

MEDIA CONTACT:
Biogen Idec
Ligia Del Bianco, +1 781-464-3260
public.affairs@biogenidec.com
or
Annabel Cowper, +41 41 392 17 05
publicaffairs.eu@biogenidec.com
or
INVESTOR CONTACT:
Biogen Idec
Ben Strain, +1 781-464-2442
IR@biogenidec.com
or
Claudine Prowse Ph.D., +1 781-464-2442
IR@biogenidec.com