CHMP Adopts Positive Opinion for PLEGRIDY™ (Peginterferon Beta-1a) as a Treatment for Multiple Sclerosis in the European Union

May 23, 2014

– European Commission Decision on Marketing Authorization Anticipated in 2H of 2014 –

– PLEGRIDY May Offer People with MS a Combination of Efficacy, Favorable Safety Profile and Low Frequency Dosing Schedule –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) today received a positive recommendation from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for the marketing authorization of PLEGRIDY™ (peginterferon beta-1a), a pegylated interferon administered subcutaneously for adults with relapsing-remitting multiple sclerosis (RRMS).

The CHMP's positive opinion is now referred to the European Commission (EC), which grants marketing authorization for medicines in the EU.

"The CHMP's positive opinion for PLEGRIDY marks an important milestone in bringing a meaningful treatment advance to people with MS in the EU," said Douglas E. Williams, Ph.D., Biogen Idec's executive vice president of Research and Development. "We believe PLEGRIDY will offer physicians and those living with MS a unique treatment option that combines efficacy, a favorable safety profile consistent with the established interferon class, and a once-every-two-week dosing schedule."

The CHMP opinion is primarily based on Phase 3 data from ADVANCE, one of the largest studies conducted with an interferon treatment in MS, which included more than 1,500 MS patients. Data from the first year of ADVANCE demonstrated that 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 (EDSS), by 38 percent (p=0.0383) compared to placebo. PLEGRIDY also significantly reduced the number of new or newly enlarging T2-hyperintense lesions compared to placebo. The ADVANCE two-year data was consistent with the positive efficacy and safety results observed in year one.

"In PLEGRIDY, we have a potential treatment that offers a less frequent dosing schedule, while providing robust clinical and MRI results," said Professor Dr. Bernd C. Kieseier, Heinrich-Heine Universität. "These factors combined with the known safety profile of the interferon class, make it a compelling option for patients with RRMS."

The safety and tolerability profile of PLEGRIDY observed in ADVANCE was consistent with that of established MS interferon therapies. The most commonly reported adverse drug reactions (ADRs) with PLEGRIDY treatment (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.

Following the opinion adopted by the CHMP, a decision from the EC is expected within the coming months.

For more information on PLEGRIDY, visit biogenidec.com.

About PLEGRIDY

PLEGRIDY is an investigational subcutaneous injectable therapy for relapsing-remitting multiple sclerosis (RRMS), in which interferon beta-1a is pegylated to extend its half-life and prolong its exposure in the body. 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.

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,[1] with more than 500,000 sufferers in the European Union.[2] Relapsing forms of MS include: relapsing-remitting MS (RRMS), the most common form of the disease accounting for 85 percent of cases, which is characterized by clearly defined acute attacks with full recovery or with residual deficit upon recovery;[3] and progressive-relapsing MS, which affects 5 percent of people with MS and is characterized by steadily worsening disease from the beginning with occasional acute attacks like those experienced by people with RRMS.[4]

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 contains forward-looking statements, including statements about the anticipated timing of the EC's decision on the marketing authorization for PLEGRIDY, and the potential impact of PLEGRIDY if approved. These statements may be identified by words such as "believe," "expect," "may," "plan," "potential," "will" and similar expressions, 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 the risk that the EC may fail to approve or may delay approval of PLEGRIDY or may not follow the recommendation of the CHMP, uncertainty of success in commercialization of PLEGRIDY 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 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] 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

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

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

[4] NMSS. *Progressive-Relapsing MS*. Date accessed: March 17, 2014. http://www.nationalmssociety.org/What-is-MS/Types-of-MS/Progressive-relapsing-MS

Contact:

MEDIA CONTACTS:
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 CONTACTS:
Biogen Idec
Claudine Prowse Ph.D., +1 781-464-2442
IR@biogenidec.com
or
Ben Strain, + 1 781-464-2442
IR@biogenidec.com