Interferon Beta Treatments, Including PLEGRIDY® (peginterferon beta-1a) and AVONEX® (interferon beta-1a), Receive Positive CHMP Opinion for Use During Pregnancy and Breastfeeding

September 23, 2019

- *Positive opinion is supported by data from more than 1,000 real-world pregnancy outcomes*
- *Data indicate no increased risk of major congenital anomalies after exposure to interferon beta before conception and/or during first trimester*
- *Data show pregnancy outcomes are in line with general population*

CAMBRIDGE, Mass., Sept. 23, 2019 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced that the Committee for Medicinal Products for Human Use (CHMP), part of the of the European Medicines Agency (EMA), recommended an update to marketing authorizations of approved interferon beta treatments, including PLEGRIDY® (peginterferon beta-1a) and AVONEX® (interferon beta-1a), to remove pregnancy contraindications and, where clinically needed, to allow use during pregnancy and breastfeeding in women with relapsing multiple sclerosis (MS).

"Women are diagnosed with MS at least two to three times more frequently than men, [1] and the disease may strike during their child-bearing years.[2] Choosing a treatment plan that allows women to continue or start their MS therapy while pregnant or breastfeeding is a step forward for those living with this chronic, debilitating disease and their partners," said Alfred Sandrock, Jr., M.D., Ph.D., executive vice president and chief medical officer at Biogen. "This CHMP opinion gives physicians and their patients added confidence when considering treatment with PLEGRIDY or AVONEX, two important therapies for relapsing MS that have been prescribed to more than half a million people living with the disease."

The CHMP opinion is based on data from the European Interferon Beta Pregnancy Registry, as well as the national health registers in Finland and Sweden, which together created the largest cohort studies providing safety data related to interferon beta exposure in women of child-bearing age with MS.

Data collected from more than 1,000 pregnancy outcomes from registries and post-marketing experience indicate no increased risk of major congenital anomalies following exposure to interferon beta before conception or during the first trimester of pregnancy. However, the duration of exposure during the first trimester is uncertain, because data were collected when interferon beta use was contraindicated during pregnancy, and treatment was likely interrupted when the pregnancy was detected and/or confirmed. Additionally, experience with exposure in the second and third trimesters is very limited. The risk of spontaneous abortions in pregnant women exposed to interferon beta cannot adequately be evaluated based on the currently available data, but the data do not suggest an increased risk so far. Limited data suggest the levels of interferon beta-1a excreted in human milk are negligible, and no harmful effects on the breastfed newborn/infant are anticipated.

About PLEGRIDY®
PLEGRIDY is a subcutaneous pegylated interferon dosed once every two weeks for relapsing forms of MS, including relapsing-remitting MS (RRMS), the most common form of MS. PLEGRIDY is currently approved in over 60 countries, including the U.S., Canada, Australia and Switzerland, and across the European Union. Nearly 50,000 people worldwide have been treated with PLEGRIDY, with over 88,000 patient-years of experience, based on prescription data.[3] Biogen continues to work toward making PLEGRIDY available in additional countries across the globe.

The efficacy and safety of PLEGRIDY is supported by one of the largest pivotal studies with interferons conducted in people living with RRMS. In clinical studies, PLEGRIDY has been proven to significantly reduce the rate of MS relapses, slow the progression of disability and reduce the number of MS brain lesions while demonstrating a favorable safety profile for patients with relapsing forms of MS. Side effects reported include liver problems, including liver failure and increases in liver enzymes; depression or suicidal thoughts; serious allergic reactions; cardiac problems, including congestive heart failure; autoimmune disorders; decreases in white blood cell or platelet counts; and seizures. In clinical trials, the most common adverse events associated with PLEGRIDY were injection site reactions and flu-like symptoms. A list of adverse events can be found in the full PLEGRIDY product labeling for each country where it is approved.

Please click here for Important Safety Information and full Prescribing Information, including Medication Guide for PLEGRIDY in the U.S., or visit your respective country's product website.

About AVONEX®
AVONEX is one of the most prescribed treatments for relapsing forms of MS worldwide and is currently approved in over 90 countries. Over 550,000 people worldwide have been treated with AVONEX, with over 2.6 million patient-years of experience, based on prescription data.[4] AVONEX is indicated for the treatment of patients with relapsing forms of MS to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations. Patients with MS in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with MS.

Symptoms of depression, suicidal ideation or psychosis, and cases of suicide, have been reported with increased frequency with patients receiving AVONEX. Severe hepatic injury, including cases of hepatic failure has been reported rarely in patients. Rare cases of anaphylaxis have been reported. While beta interferons do not have any known direct cardiac toxicity, cases of congestive heart failure, cardiomyopathy and cardiomyopathy with congestive heart failure have been reported in patients without known predisposition. Decreased peripheral blood counts have been reported from postmarketing experience. Seizures have been reported in patients using AVONEX, including patients with no prior history of seizure. Autoimmune disorders of multiple target organs have been reported. Routine periodic blood chemistry, hematology, liver function and thyroid function tests are recommended.

Please click here for Important Safety Information and full Prescribing Information, including Medication Guide for AVONEX in the U.S., or visit your respective country's product website.

About Biogen
At Biogen, our mission is clear: we are pioneers in neuroscience. Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases as well as related therapeutic adjacencies. One of the world's first global biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Kenneth Murray and Nobel Prize winners Walter Gilbert and Phillip Sharp, and today has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, commercializes biosimilars of advanced biologics and is focused on advancing research programs in multiple sclerosis and neuroimmunology, neuromuscular disorders, movement disorders, Alzheimer's disease and dementia, ophthalmology, immunology, neurocognitive disorders, acute neurology and pain.

We routinely post information that may be important to investors on our website at www.biogen.com. To learn more, please visit www.biogen.com and follow us on social media – Twitter, LinkedIn, Facebook, YouTube.

Biogen Safe Harbor
This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, about the potential benefits, safety and efficacy of PLEGRIDY and AVONEX; the results of certain real-world data; our research and development program for the treatment of MS; plans for additional regulatory filings in other jurisdictions; and risks and uncertainties associated with drug development and commercialization. These statements may be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "except," "forecast," "goal," "intend," "may," "plan," "possible," "potential," "will," "would" and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including without limitation the occurrence of adverse safety events and/or unexpected concerns that may arise from additional data or analysis; failure to obtain regulatory approvals in other jurisdictions; regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of expansion of product labeling; risks of unexpected costs or delays; failure to protect and enforce our data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; and product liability claims. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission. These statements are based on our current beliefs and expectations and speak only as of the date of this news release. We do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

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[1] Multiple Sclerosis Coalition. The Use of Disease-modifying Therapies in Multiple Sclerosis Principles and Current Evidence. Updated March 2017. http://www.nationalmssociety.org/getmedia/1e64b96c-9e55-400e-9a64-0cdf5e2d60fe/summaryDMTpaper_-final

[2] Coyle PK. Pregnancy and multiple sclerosis. Neurol Clin. 2012 Aug;30(3):877-88. doi: 10.1016/j.ncl.2012.05.002. Epub 2012 Jun 22.

[3] Salvetti M et al. Safety, Pregnancy Outcomes, and Clinical Effectiveness of Peginterferon Beta-1a for Patients with Newly Diagnosed and Non-Newly Diagnosed Relapsing Multiple Sclerosis: Third Interim Analysis of the Plegridy Observational Program. Poster presented at: 35th Annual ECTRIMS Congress; 2019 Sept 11-13; Stockholm, Sweden.

[4] Benedict R et al. Change in Cognitive Processing Speed is Associated with Cortical Grey Matter and Thalamic Volume Loss in Patients with Relapsing-remitting Multiple Sclerosis. Poster presented at: 35th Annual ECTRIMS Congress; 2019 Sept 11-13; Stockholm, Sweden.

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