The European Commission Grants Marketing Authorization for PLEGRIDY® (peginterferon beta-1a) Intramuscular Administration for Relapsing-Remitting Multiple Sclerosis

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- *PLEGRIDY is now approved in the European Union for intramuscular injection, offering individuals with relapsing multiple sclerosis (MS) a differentiated, reliable treatment option combining safety and efficacy to help optimize their treatment experience with significantly reduced injection site reactions*
- *The only pegylated interferon for MS, PLEGRIDY has a well-characterized efficacy and safety profile with less frequent administration compared to other platform therapies*
- *Biogen continues to innovate across its robust MS portfolio to help address the diverse needs of the community*

CAMBRIDGE, Mass., Dec. 21, 2020 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced that the European Commission (EC) has approved a new intramuscular (IM) injection route of administration for PLEGRIDY® (peginterferon beta-1a) for the treatment of relapsing-remitting multiple sclerosis (MS). The new IM administration of PLEGRIDY provides the well-characterized efficacy and safety of the platform injectable along with the potential for reduction in injection site reactions. It is estimated that 2.5 million people live with MS across the globe, with some European countries demonstrating the highest prevalence of MS in the world.[1] This approval adds to Biogen's broad MS portfolio which includes the subcutaneous (SC) injection of PLEGRIDY and expands the range of treatment options available for people living with MS.

"The availability of a new intramuscular route of administration offers individuals living with relapsing MS an additional choice of a platform therapy, combining the safety and efficacy of PLEGRIDY, with the potential to significantly reduce injection site reactions," said Maha Radhakrishnan, M.D., Chief Medical Officer at Biogen. "As leaders in MS with our broad portfolio of therapies, we are focused on advancing the science to address the needs of patients by providing more treatment choices."

The EC's approval of PLEGRIDY for IM administration is based on data evaluating bioequivalence and adverse reactions associated with IM administration compared to SC administration in healthy volunteers. Bioequivalence between the two dosing regimens was confirmed and data show that participants receiving PLEGRIDY through IM administration experienced fewer injection site reactions in comparison to participants receiving SC administration (14.4 percent vs. 32.1 percent). The overall safety profiles were similar, and the frequency of injection site reactions and adverse events were comparable in participants who were dosed with IM followed by SC, compared to SC followed by IM.[2]

PLEGRIDY, the only pegylated interferon approved for use in relapsing MS, was first approved in the European Union in 2014 and is proven to significantly reduce important measures of MS disease activity with a well-characterized safety and tolerability profile. Biogen has also submitted a regulatory filing in the U.S. for the IM administration. The SC administration of PLEGRIDY is available in more than 60 countries.

About PLEGRIDY® (peginterferon beta-1a)
PLEGRIDY is a pegylated interferon dosed once every two weeks for relapsing forms of multiple sclerosis (MS) in adults, 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. Over 57,000 people worldwide have been treated with PLEGRIDY, with over 107,000 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 are supported by one of the largest pivotal studies with interferons conducted in people living with relapsing-remitting MS. 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 well-characterized 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. PLEGRIDY can be considered for use in MS patients throughout the full course of pregnancy and during breast-feeding, if clinically needed.

For information on PLEGRIDY prescribing information in the EU, please visit: https://ec.europa.eu/health/documents/community-register/html/h934.htm
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 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. Today Biogen 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, Alzheimer's disease and dementia, neuromuscular disorders, movement disorders, 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, relating to the potential benefits, safety and efficacy of PLEGRIDY; the results of certain real-world data; our research and development program for the treatment of MS; and potential regulatory discussions, submissions and approvals and the timing thereof. These

forward-looking statements may be identified by words such as “aim,” “anticipate,” “believe,” “could,” “estimate,” “expect,” “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. 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; risks of unexpected costs or delays; unexpected concerns may arise from additional data, analysis or results obtained during clinical trials; failure to protect and enforce our data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates or expansion of product labeling; failure to obtain regulatory approvals in other jurisdictions; product liability claims; and the direct and indirect impacts of the ongoing COVID-19 pandemic on our business, results of operations and financial condition. 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.

References:

[1] Tullman MJ. Overview of the epidemiology, diagnosis, and disease progression associated with multiple sclerosis. Am J Manag Care. 2013 Feb;19(2 Suppl): S15-20.

[2] Zhao Y, et al. A phase 1, open-label, crossover study to evaluate the bioequivalence of intramuscular and subcutaneous peginterferon beta-1a in healthy volunteers. Poster presented at: Americas Committee for Treatment and Research in Multiple Sclerosis - 2020 Forum; 2020 Feb 27-29; West Palm Beach, Florida, USA.

[3] Combined post-marketing data based on prescriptions for PLEGRIDY as of March 31, 2020.

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