Biogen Announces FDA Approval of PLEGRIDY® (peginterferon beta-1a) Intramuscular Administration for Multiple Sclerosis

February 1, 2021

- *Intramuscular injection PLEGRIDY (peginterferon beta-1a) is now approved in the U.S. and the European Union, offering individuals with relapsing multiple sclerosis (MS) a treatment option with significantly reduced injection site reactions*
- *PLEGRIDY has a well-characterized safety and efficacy profile with a proven ability to reduce relapses and delay disability progression*
- *Treatment access and options have become increasingly important for MS patients in the COVID-19 environment*

CAMBRIDGE, Mass., Feb. 01, 2021 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced that the U.S. Food and Drug Administration (FDA) has approved a new intramuscular (IM) injection route of administration for PLEGRIDY® (peginterferon beta-1a) for the treatment of relapsing forms of multiple sclerosis (MS). The new IM administration offers people living with relapsing MS the well-characterized efficacy and safety of PLEGRIDY with the potential for significantly reduced injection site reactions. This approval expands Biogen's industry-leading portfolio of MS treatments, which also includes the subcutaneous (SC) administration of PLEGRIDY, and follows the European Commission's marketing authorization for the IM administration in December 2020.

"At Biogen, we are committed to continued innovation to give people with MS more choices and more options to meet their individual preferences and needs," said Maha Radhakrishnan, M.D., Chief Medical Officer at Biogen. "PLEGRIDY is a proven, effective therapy for relapsing MS, and this approval gives new and current MS patients a different delivery method that has the potential to significantly reduce injection site reactions."

MS is an autoimmune disorder that affects more than 2.3 million people worldwide. Access to and availability of treatment options have become increasingly important in the current COVID-19 environment. The addition of the IM administration of PLEGRIDY to Biogen's MS portfolio offers another important option at a time when MS patients are being encouraged to discuss their MS treatment and considerations around COVID-19 vaccination with their physicians.[1,2]

The FDA's approval of the IM administration for PLEGRIDY 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 generally similar and there were no new safety signals observed.[3]

PLEGRIDY is the only approved pegylated interferon for MS with a proven ability to delay the progression of MS disability and reduce relapses. PLEGRIDY was first approved by the FDA in 2014 and is proven to significantly reduce MS relapses, disability progression and brain lesions with a well-understood safety and tolerability profile. It 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 61,000 people worldwide have been treated with PLEGRIDY, with over 120,000 patient-years of experience, based on prescription data.[4] 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; injection site reactions, cardiac problems, including congestive heart failure; blood problems, such as decreases in white blood cell or platelet counts; autoimmune disorders; 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 relapsing MS patients throughout the full course of pregnancy and during breast-feeding, if clinically needed.

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, neuropsychiatry, immunology, acute neurology and neuropathic pain.

We routinely post information that may be important to investors on our website at www.biogen.com. 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; and the results of certain real-world data. 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. 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; 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] National Multiple Sclerosis Society. COVID-19 Guidance for People Living with MS. Available at: https://www.nationalmssociety.org/coronavirus-covid-19-information/multiple-sclerosis-and-coronavirus/covid-19-vaccine-guidance. Accessed: January 2021.

[2] Multiple Sclerosis International Federation**.** MS, the coronavirus and vaccines – updated global advice.. Available at: https://www.msif.org/news/2020/02/10/the-coronavirus-and-ms-what-you-need-to-know/. Accessed: January 2021.

[3] 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.

[4] Combined post-marketing data based on prescriptions for PLEGRIDY as of September 30, 2020.

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