Biogen Provides Regulatory Update on the Supplemental Biologic License Application (sBLA) for Subcutaneous Administration of TYSABRI® (natalizumab)

April 28, 2021

CAMBRIDGE, Mass., April 28, 2021 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced that it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for its supplemental Biologic License Application (sBLA) for a new subcutaneous (SC) route of administration of TYSABRI® (natalizumab) to treat relapsing multiple sclerosis (MS). The CRL indicates that the FDA is unable to approve the Company's filing as submitted. Biogen is evaluating the CRL and will determine next steps in the U.S.

"We are committed to MS and pursuing innovations such as new routes of administration to help provide options that could address the individual needs of patients," said Maha Radhakrishnan, M.D., Chief Medical Officer at Biogen. "This response from the FDA does not affect the intravenous administration of TYSABRI, a well-established high-efficacy treatment with a well-characterized safety profile, which over the last 15 years has treated more than 200,000 people worldwide with relapsing MS."

The subcutaneous delivery of TYSABRI was approved by the European Commission in March 2021, and Biogen plans to pursue regulatory filings in additional countries.

About TYSABRI® (natalizumab)
TYSABRI is a well-established treatment indicated for relapsing forms of multiple sclerosis (MS) in adults that has been proven in clinical trials to slow physical disability progression, reduce the formation of new brain lesions and cut relapses. In the U.S., TYSABRI is indicated as monotherapy for the treatment of patients with relapsing forms of MS. In the European Union, it is indicated as a single disease modifying treatment (DMT) in adults with highly active relapsing-remitting MS (RRMS) for patients with highly active disease activity despite a full and adequate course of treatment with at least one DMT or patients with rapidly evolving severe RRMS. TYSABRI is approved in over 80 countries, and approximately 213,000 people worldwide have been treated with TYSABRI, with over 835,000 patient-years of experience, based on clinical trials and prescription data.[1]

TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), a rare opportunistic viral infection of the brain which has been associated with death or severe disability. Risk factors that increase the risk of PML are the presence of anti-JC virus antibodies, prior immunosuppressant use and longer TYSABRI treatment duration. Patients who have all three risk factors have the highest risk of developing PML. When initiating and continuing treatment with TYSABRI, physicians should consider whether the expected benefit of TYSABRI is sufficient to offset this risk.

TYSABRI also increases the risk of developing encephalitis and meningitis caused by herpes simplex and varicella zoster viruses, and serious, life-threatening and sometimes fatal cases have been reported in the post-marketing setting in MS patients receiving TYSABRI. Clinically significant liver injury, including acute liver failure requiring transplant, has also been reported in the post-marketing setting. Other serious adverse events that have occurred in TYSABRI-treated patients include hypersensitivity reactions (e.g., anaphylaxis), a decrease in lymphocyte counts and infections, including opportunistic, other atypical infections and a reduction in blood platelet counts.

Please click here for Important Safety Information, including Boxed Warning, and full Prescribing Information, including Medication Guide for TYSABRI 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, about potential regulatory discussions, submissions and approvals and the timing thereof; the potential benefits, safety and efficacy of TYSABRI; the results of certain real-world data; and the potential of Biogen's commercial business, including TYSABRI. 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. 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 actual timing and content of submissions to and decisions made by the regulatory authorities; regulatory submissions may take longer or be more difficult to complete than expected; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of our drug candidates or expansion of product labeling; failure to obtain regulatory approvals in other jurisdictions; the occurrence of adverse safety events; 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; 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. Combined post-marketing data based on prescriptions and clinical trials exposure to TYSABRI as of January 31, 2021.

MEDIA CONTACT:
David Caouette
+ 1 617 679 4945
public.affairs@biogen.com

INVESTOR CONTACT:
Mike Hencke
+1 781 464 2442
IR@biogen.com