First Patient Enrolled in Biogen's Phase 3b Study to Evaluate Extended Interval Dosing (EID) with Natalizumab in Multiple Sclerosis

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Study will provide the first randomized, controlled efficacy and safety data of every-six-week dosing for natalizumab

CAMBRIDGE, Mass., Jan. 03, 2019 (GLOBE NEWSWIRE) -- The first patient has been enrolled in a global Phase 3b study evaluating the efficacy and safety of extended interval dosing (EID; every six weeks) for natalizumab compared to standard interval dosing (SID) in patients with relapsing multiple sclerosis (MS), Biogen Inc. (Nasdaq: BIIB) announced. Currently commercialized under the brand name TYSABRI®, natalizumab 300 mg dosed every four weeks is the only approved dosing regimen.

The new study, NOVA (NCT03689972), is a two-year, prospective, randomized, interventional, controlled, open-label, rater-blinded, international Phase 3b study that will assess the efficacy, safety and tolerability of six-week natalizumab dosing intervals in people with relapsing-remitting MS. Patients who switch to EID after one year of treatment with natalizumab SID will be evaluated in relation to patients receiving continued SID treatment. The study will enroll approximately 480 patients worldwide. The primary endpoint is the number of new or newly enlarging T2 hyperintense lesions at week 48.

"For more than a decade, natalizumab has been considered a highly effective treatment option for patients with relapsing forms of MS," said Alfred Sandrock, Jr., M.D., Ph.D., executive vice president and chief medical officer at Biogen. "The NOVA study may generate valuable data that we hope will answer questions for the scientific community about the efficacy of natalizumab when its dosing schedule is extended to every six weeks, and in conjunction with prior safety analyses, may inform on the drug's benefit-risk profile."

NOVA was initiated following analyses that showed that EID was associated with a significant reduction in the risk of progressive multifocal leukoencephalopathy (PML), a rare but serious brain infection. The pre-specified, retrospective analysis of the U.S. TOUCH (TYSABRI® Outreach: United Commitment to Health) REMS program examined the impact of EID as compared to SID on the risk of PML, and the NOVA study aims to assess the efficacy of EID natalizumab to further evaluate the drug's benefit-risk profile.

About TYSABRI® (natalizumab)
TYSABRI is a disease modifying therapy (DMT) approved in more than 80 countries, including the U.S., the European Union, Canada, Australia and Switzerland. 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 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 has been used to treat RRMS for more than 10 years, with nearly 191,000 people treated worldwide and over 650,000 patient-years of experience.[1]

TYSABRI increases the risk of 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-JCV antibodies, prior immunosuppressant use and longer TYSABRI treatment duration. Patients who have all three risk factors have the highest risk of developing PML.

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. Other serious adverse events that have occurred in TYSABRI-treated patients include hypersensitivity reactions (e.g., anaphylaxis) and infections, including opportunistic and other atypical infections. Clinically significant liver injury, including acute liver failure requiring transplant, has also been reported in the post-marketing setting.

Please see full Prescribing Information, including Boxed Warning, and Medication Guide as well as Important Safety Information 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. 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 and only approved treatment for spinal muscular atrophy and is focused on advancing neuroscience research programs in Alzheimer's disease and dementia, multiple sclerosis and neuroimmunology, movement disorders, neuromuscular disorders, pain, ophthalmology, neuropsychiatry and acute neurology. Biogen also manufactures and commercializes biosimilars of advanced biologics.

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 EID natalizumab; the treatment of multiple sclerosis; the clinical development program for EID natalizumab; the enrollment of the NOVA study of EID natalizumab; risks and uncertainties associated with drug development and commercialization; and the potential of Biogen's commercial business, including natalizumab. These forward-looking statements may be accompanied by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "possible," "will" 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, risks that Biogen may not fully enroll the NOVA study or it will take longer than expected; uncertainty of success in the development and potential commercialization of EID natalizumab; unexpected concerns that may arise from additional data, analysis or results obtained during the NOVA study; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of EID natalizumab; the occurrence of adverse safety events; risks of unexpected costs or delays; the risks of other unexpected hurdles; failure to protect and enforce Biogen's 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 Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the Securities and Exchange Commission. These statements are based on Biogen's current beliefs and expectations and speak only as of the date of this news release. Biogen does 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] Global Natalizumab (TYSABRI) Postmarketing PML Update, August 2018.