New Research Demonstrate Biogen's Continued Commitment to Improve Care of Patients with Multiple Sclerosis Across Treatment Spectrum

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- *Data highlight benefits of TYSABRI® (natalizumab) treatment in early multiple sclerosis for achieving NEDA (no evidence of disease activity) and improving disability and cognition*
- *An analysis of data from the TYSABRI Observational Program (TOP) demonstrates real-world effectiveness of extended interval dosing (every six weeks) with natalizumab*
- *Additional findings confirm exposure to interferon beta, including PLEGRIDY® (peginterferon beta-1a) and AVONEX® (interferon beta-1a), is not expected to impact pregnancy or infant outcomes*

CAMBRIDGE, Mass., Sept. 12, 2019 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) is highlighting new data that demonstrate the potential benefits of treatment with TYSABRI® (natalizumab), PLEGRIDY® (peginterferon beta-1a) and AVONEX® (interferon beta-1a) in specific multiple sclerosis (MS) patient populations. Results obtained in real-world clinical practice are being presented at the 35th Congress of the European Committee for Treatment and Research in MS (ECTRIMS) and 24th Annual Conference of Rehabilitation in MS in Stockholm (September 11-13).

"Biogen's long-standing leadership in MS presents an opportunity to continue evolving the paradigm of care through continued research of some of our most widely prescribed MS therapies, including TYSABRI, PLEGRIDY and AVONEX," said Alfred Sandrock, Jr., M.D., Ph.D., executive vice president and chief medical officer at Biogen. "Through thoughtful and rigorous exploration of potential new approaches, like TYSABRI extended interval dosing, we are working to optimize patient outcomes."

Data Further Support Early Treatment with TYSABRI and Extended Interval Dosing
Four-year data from the observational, open-label, single-arm STRIVE study support the real-world long-term effectiveness of TYSABRI in patients with early relapsing MS, who are within three years from diagnosis and are anti-JC virus antibody negative. Over the first two to four years of treatment (n/N=110/157), 70.1 percent of patients in the study achieved clinical NEDA (no evidence of disease activity), defined as no relapses or 24-week confirmed disability worsening. Additionally, 83.7 percent achieved MRI NEDA, defined as no gadolinium-enhancing or new/newly enlarging T2 lesions, and more than half (58 percent) achieved overall NEDA, which encompassed both clinical and MRI NEDA. Results also show TYSABRI was associated with significant improvements in disability and cognitive performance.

The effectiveness of every six weeks (Q6W) dosing with natalizumab was evaluated using data from the TYSABRI Observational Program (TOP), an ongoing, real-world study of natalizumab-treated patients. Analyses compared relapse outcomes in patients who switched to natalizumab Q6W dosing after at least one year on every four weeks (Q4W) dosing (n=135) to those who remained on the approved Q4W dosing (n=135). After propensity score matching, results indicate there was no significant difference in annualized relapse rate or risk of relapse between the two groups. These data complement the previously presented TOUCH database safety analysis showing that natalizumab extended interval dosing (EID; average of approximately six weeks) was associated with a significantly lower risk of the rare but serious brain infection progressive multifocal leukoencephalopathy (PML), compared to Q4W dosing. Biogen recently completed enrollment for the Phase 3b NOVA study, a two-year, randomized, prospective trial that will compare the effectiveness of natalizumab Q4W versus Q6W after at least one year of Q4W dosing.

Real-world Data Indicate Interferon Beta Treatment May Not Impact Some Pregnancy/Infant Outcomes
As women with MS are often diagnosed and treated at child-bearing age, family planning is frequently an important consideration for physicians and patients when choosing a treatment path. New data from two real-world observational studies provide further support that exposure to interferon beta treatment, including PLEGRIDY and AVONEX, before conception and/or during pregnancy is not expected to have an adverse effect on pregnancy or infant growth outcomes.

Researchers utilized healthcare data from Nordic registers (Finland and Sweden) to retrospectively analyze infant outcomes for women with MS treated with interferon beta compared to women with MS unexposed to disease-modifying therapies. Results show outcomes were similar between the two groups, with no evidence that exposure to interferon beta treatment before and/or during pregnancy affected the weight or head circumference of infants at birth. Data on pregnancy outcomes collected during the ongoing five-year PLEGRIDY Observational Program (POP), which is evaluating the long-term safety and effectiveness of PLEGRIDY in more than 1,200 relapsing MS patients worldwide, were consistent with previously reported pregnancy outcomes from both the Nordic registers study and the European Interferon Beta Pregnancy Registry.

Featured data presentation details:

- Natalizumab is Associated with No Evidence of Disease Activity and with Improvement in Disability and Cognitive Performance in Anti–JC Virus Seronegative Patients with Early Relapsing-Remitting Multiple Sclerosis: STRIVE 4-Year Results (P1348; Poster Session 3, Friday, September 13, 12:15-2:15 p.m. CET)
- No Significant Difference in Relapse Outcomes in Patients Switching to Natalizumab Extended Interval Dosing or Remaining on Standard Interval Dosing: Propensity Score Comparative Effectiveness Analysis of Patients in the TYSABRI Observational Program (P1033, Poster Session 2, Thursday, September 12, 5:15-7:15 p.m. CET)
- Prevalence of Infant Outcomes at Birth After Exposure to Interferon Beta Prior to or During Pregnancy: A Register-based Cohort Study in Finland and Sweden Among Women with MS (P1144; Poster Session 3, Friday, September 13, 12:15-2:15 p.m. CET)
- 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 (P1019; Poster Session 2, Thursday, September 12, 5:15-7:15 p.m. CET)

About TYSABRI®
TYSABRI is a well-established relapsing multiple sclerosis (RMS) treatment that has been proven in clinical trials to slow physical disability progression, reduce the formation of new brain lesions and cut relapses. TYSABRI is approved in 80 countries, and over 200,000 people worldwide have been treated with TYSABRI, with over 750,000 patient-years of experience, based on clinical trials and prescription data.[1] TYSABRI is indicated as monotherapy for the treatment of patients with relapsing forms of MS. In the European Union, it is indicated as single disease modifying therapy (DMT) in adults with highly active relapsing-remitting MS (RRMS) for patients despite a full and adequate course of treatment, with at least one DMT or patients with rapidly evolving severe RRMS.

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.

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) and infections, including opportunistic and other atypical infections.

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 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 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.[2] 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.[3] 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. There are no adequate and well-controlled studies in pregnant women. AVONEX should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The most common side effects associated with AVONEX treatment are flu-like symptoms, including chills, fever, myalgia, and asthenia.

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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, relating to the potential benefits, safety and efficacy of TYSABRI, PLEGRIDY and AVONEX; potential clinical effects of TYSABRI, PLEGRIDY and AVONEX; the results of certain real-world data; the clinical development program for natalizumab; clinical trial results and plans; our research and development program for the treatment of MS; the treatment of MS; the potential of our commercial business; and risks and uncertainties associated with drug development and commercialization. These forward-looking 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; risks of unexpected costs or delays; regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our products and expansion of product labeling; unexpected concerns may arise from additional data, analysis or results obtained during our clinical trials; 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] Combined post-marketing data based on prescriptions and clinical trials exposure to TYSABRI as of June 30, 2019

[2] Salvetti et al. ECTRIMS 2019, P1019.

[3] Benedict et al. ECTRIMS 2019, P420.