Biogen Highlights at ECTRIMS 2018 Data on Its Industry-Leading Multiple Sclerosis Portfolio and a Range of Initiatives Aimed at Transforming Patient Care

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- *New research further supports the long-term efficacy and well-characterized safety of leading MS products*
- *Novel data generation initiatives aim to improve outcomes and support the continued move toward precision medicine in MS*

CAMBRIDGE, Mass., Oct. 02, 2018 (GLOBE NEWSWIRE) -- At the 34th Congress of the European Committee for Treatment and Research in MS in Berlin, Germany (ECTRIMS; 10-12 October), Biogen Inc. (Nasdaq: BIIB) will present data in more than 70 oral and poster presentations on its industry-leading portfolio of multiple sclerosis (MS) products and innovative research efforts aimed at transforming the care of people living with the disease.

Key updates at ECTRIMS include clinical data and real-world evidence that further support the long-term efficacy and well-characterized safety of Biogen's leading MS therapies, including data supporting the use of TECFIDERA ® (dimethyl fumarate) and TYSABRI® (natalizumab) early within the disease course. Additional data highlight the potential utility of serum neurofilament light (sNfL) as a biomarker of MS disease activity. Biogen will also share updates on its efforts to improve monitoring of cognition and other key MS outcomes through MS PATHS (Multiple Sclerosis Partners Advancing Technology and Health Solutions).

"Biogen believes the need for finding new approaches to treat MS is as important as ever," said Michael Ehlers, executive vice president, research & development at Biogen. "The research we are presenting at ECTRIMS reflects our proven track record of developing innovative medicines for MS, and our commitment to the pursuit of new clinical approaches aimed at generating data that will encourage more individualized treatment decisions to help meet the needs of people living with MS today and into the future."

Data Further Support Efficacy and Safety of Biogen's Industry-Leading MS Portfolio
TECFIDERA is the most prescribed oral MS medication in the world. Results from the ENDORSE study show that newly diagnosed patients treated with TECFIDERA experienced low annualized relapse rates and the majority of patients remained free from confirmed disability progression. Some of these patients have been treated for up to nine years. Similar benefits were seen in the ongoing real-world ESTEEM study that includes patients who are early in their MS disease course. New safety analyses found that among a majority of patients that experience lymphopenia during TECFIDERA treatment, meaningful lymphocyte reconstitution occurs after three months of treatment discontinuation, reinforcing the importance of absolute lymphocyte counts (ALC) monitoring as outlined in the product label.

Updated data from the TYSABRI Observational Program (TOP), the largest ongoing, real-world study of TYSABRI-treated patients, underscore the established and consistent effectiveness of TYSABRI over 10 years, especially for those patients earlier in their disease course. Safety findings are consistent with the known and well-established safety profile of TYSABRI, and no new safety concerns were identified.

Data presented at ECTRIMS reinforce the safety and efficacy profiles of PLEGRIDY® (peginterferon beta-1a) and AVONEX® (interferon beta-1a), two widely prescribed MS interferon beta treatments. The European Interferon Beta Pregnancy Registry and Nordic EPID MS Pregnancy Study demonstrated that exposure to interferon beta treatment (including PLEGRIDY and AVONEX) before conception and/or during pregnancy did not adversely affect pregnancy or infant outcomes. In a propensity score matching analysis of data from ADVANCE and CONFIRM, PLEGRIDY showed better clinical outcomes compared to glatiramer acetate. A newly diagnosed subgroup analysis of ADVANCE demonstrates PLEGRIDY lowered the risk of chronic black holes evolving from acute MRI lesions.

Seeking New Ways to Monitor and Manage MS
Biogen will also present research that further evaluates the potential of sNfL as a biomarker for MS disease activity and as a treatment monitoring tool. Researchers will discuss the current state, opportunity and paths to enable implementation of sNfL into MS clinical practice.

New results will also be presented from MS PATHS evaluating cognitive changes and showing the impact of clinically meaningful benchmarks of disease progression on patients' daily lives. MS PATHS is a research collaboration with 10 leading MS centers in Europe and the U.S. that generates real-world evidence at the point of care to enable physicians to make personalized decisions with the aim of improving the lives of those living with MS.

Highlights of Biogen's platform and poster presentations:

TECFIDERA

- Real-world Efficacy of Delayed-Release Dimethyl Fumarate in Early Multiple Sclerosis: Interim Results from ESTEEM – *Poster P595 – Wednesday, 10 October, 17:00-19:00 CET*
- Delayed-release Dimethyl Fumarate Demonstrates Sustained Efficacy over Nine Years in Newly Diagnosed Patients with Relapsing-Remitting Multiple Sclerosis – *Poster P920 – Thursday, 11 October, 17:15-19:15 CET*
- Among Real-world Multiple Sclerosis Patients That Experience Delayed-release Dimethyl Fumarate-associated Lymphopenia, Meaningful Lymphocyte Reconstitution Occurs Within 3 Months After Discontinuation of Delayed-release Dimethyl Fumarate – *Poster P1201– Friday, 12 October, 12:15-14:15 CET*
- Delayed-release Dimethyl Fumarate-associated Lymphopenia: On-treatment and Post-treatment Implications – *Poster P929 – Thursday, 11 October, 17:15-19:15 CET*

TYSABRI

- Incidence of Natalizumab-associated Progressive Multifocal Leucoencephalopathy and its Relationship with the Pattern of

Natalizumab Exposure Over Time – *Poster P604 – Wednesday, 10 October, 17:00-19:00 CET*
- Longitudinal Stability of Anti-JC Virus Antibody Index Over Two Years in Patients Treated with Natalizumab in the ASCEND Study – *Poster P924 – Thursday, 11 October, 17:15-19:15 CET*
- Real-world Data from Over 10 years in the TYSABRI® Observational Program: Long-term Safety and Effectiveness of Natalizumab in Relapsing-remitting Multiple Sclerosis Patients – *Poster P908 – Thursday, 11 October, 17:15-19:15 CET*

PLEGRIDY and AVONEX

- Pregnancy and Infant Outcomes with Interferon Beta: Data from the European Interferon Beta Pregnancy Registry and Population Based Registries in Finland and Sweden – Poster P1753 – *Friday, 12 October, 12:15-14:15 CET*
- Peginterferon Beta-1a Every 2 Weeks Demonstrated Better Clinical Outcomes Than Glatiramer Acetate Once-daily in Patients with RRMS: Propensity Score Matching of Phase 3 Data from ADVANCE and CONFIRM – *ePoster EP1595*
- Peginterferon Beta-1a Reduces the Number of Black Holes Evolved from Acute MRI Lesions in Newly Diagnosed Patients with Relapsing-remitting Multiple Sclerosis: A Post Hoc Analysis ADVANCE – *Poster P1262 – Friday, 12 October, 12:15-14:15 CET*

Advancements in MS Care

- Temporal Relationship of Serum Neurofilament Light Levels and Radiological Disease Activity in Patients with Multiple Sclerosis – *Poster P532 – Wednesday, 10 October, 17:00-19:00 CET*
- Prevalence of Isolated Cognitive Decline in a Large, Heterogeneous Multiple Sclerosis Population – *Poster P517 – Wednesday, 10 October, 17:00-19:00 CET*
- Serum Neurofilament Light (NfL) for Disease Prognosis and Treatment Monitoring in Multiple Sclerosis Patients: Is it Ready for Implementation into Clinical Care? – *Platform 5 – Thursday, 11 October, 11:16-11:28 CET*
- Benchmarks of Manual Dexterity and Walking Speed in a Large, Representative Patient Population – *Poster 1018 – Friday, 12 October, 12:15-14:15 CET*

About TECFIDERA®
TECFIDERA is an oral therapy for relapsing forms of MS, including relapsing-remitting MS, the most common form of MS. More than 340,000 patients have been treated with TECFIDERA worldwide with over 625,000 patient-years of experience, based on clinical trials and prescription data.[1] TECFIDERA has been proven to reduce the rate of MS relapses, slow the progression of disability, and impact the number of MS brain lesions, while demonstrating a favorable benefit-risk profile in people with relapsing forms of MS, notably newly diagnosed and early switch populations. In clinical trials, the most common adverse events associated with TECFIDERA were flushing and gastrointestinal (GI) events. Other side effects include a decrease in mean lymphocyte counts during the first year of treatment, which then plateaued, and liver function abnormalities, which resolved upon treatment discontinuation. TECFIDERA is contraindicated in patients with a known hypersensitivity to dimethyl fumarate or any of the excipients of TECFIDERA. Rare cases of progressive multifocal leukoencephalopathy (PML), a rare opportunistic viral infection of the brain which has been associated with death or severe disability, have been seen with TECFIDERA patients in the setting of prolonged moderate to severe lymphopenia.

The efficacy and safety of TECFIDERA have been studied in a large, global clinical program, which includes an ongoing long-term extension study.

Please click here for Important Safety Information and full Prescribing Information, including Patient Information for TECFIDERA in the U.S., or visit your respective country's product website.

About TYSABRI®
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 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 is proven effective, with over 10 years of experience in treating RRMS, and more than 190,800 people treated worldwide and over 658,169 patient-years of experience.[2]

TYSABRI is a monoclonal antibody that selectively binds to α4-integrin and is thought to interrupt the activity of inflammatory cells in MS patients by blocking the interaction between α4β1-integrin and vascular cell adhesion molecule-1. Disruption of these molecular interactions prevents transmigration of leukocytes across the endothelium into inflamed parenchymal tissue. The specific mechanism(s) by which TYSABRI exerts its effects in MS have not been fully defined.

TYSABRI has advanced the treatment of MS patients with its proven ability to slow the progression of disability, reduce relapse rates and impact the number of MRI brain lesions with a well-characterized safety profile. Data from the Phase 3 AFFIRM trial, which was published in t*he New England Journal of Medicine*, showed that at two years, TYSABRI treatment led to a 68 percent relative reduction ($p<0.001$) in the annualized relapse rate when compared with placebo and reduced the relative risk of disability progression by 42 to 54 percent (12-24-week sustained respectively, both $p<0.001$).

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 increases the risk of developing encephalitis and meningitis caused by herpes simplex and varicella zoster viruses and clinically significant liver injury has also been reported in the post-marketing setting. Serious, life-threatening and sometimes fatal cases have been reported in the postmarketing 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 has also been reported in the post-marketing setting.

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., the European Union, Canada, Australia, and

Switzerland. 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. 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.

Please click here for Important Safety Information and full Prescribing Information, including Medication Guide for AVONEX 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 press release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, about clinical studies and real-world data related to TECFIDERA, TYSABRI, PLEGRIDY and AVONEX; the potential benefits, safety and efficacy of TECFIDERA, TYSABRI, PLEGRIDY and AVONEX; the identification and treatment of MS; the potential of our commercial business, including TECFIDERA, TYSABRI, PLEGRIDY and AVONEX; the status of our current regulatory filings; and our plans for additional regulatory filings in other jurisdictions. These statements may be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "except," "forecast," "intend," "may," "plan," "possible," "potential," "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: unexpected concerns that may arise from additional data, analysis or results obtained during our clinical trials; 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; the occurrence of adverse safety events; risks of unexpected costs or delays; we may encounter other unexpected hurdles; failure to protect and enforce our data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; the risk that we may not fully enroll our clinical trials or enrollment will take longer than expected; product liability claims; and third party collaboration risks. 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 press 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.

MEDIA CONTACT:

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

INVESTOR CONTACT:

Matt Calistri
+1 781 464 2442
IR@biogen.com

[1] Combined post-marketing data based on prescriptions and clinical trials exposure to TECFIDERA as of 31 July 2018.

[2] Global Natalizumab (TYSABRI) Postmarketing PML Update, August 2018.