Biogen Data at 2016 AAN Annual Meeting Highlight Its Expansive Portfolio of MS Therapies That Meets Diverse Needs of Patients

April 12, 2016

− Strong and Sustained Efficacy of TECFIDERA® Supported by Clinical Data and Real-World Evidence –

− New ZINBRYTA™ Data Show Impact on Cognitive Outcomes and Reversibility of its Targeted MOA −

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Biogen (NASDAQ: BIIB) will present new data demonstrating the breadth and diversity of its marketed and pipeline multiple sclerosis (MS) therapies at the 68th annual meeting of the American Academy of Neurology (AAN) in Vancouver, Canada, the company announced today. These data support Biogen's established portfolio, which includes the most-prescribed oral MS treatment in the world, TECFIDERA® (dimethyl fumarate), and demonstrate the ability of its differentiated products to meet the distinct needs of people living with MS.

"MS is a complex, life-long disease that affects each person differently. Because people with MS have diverse treatment needs, it is critical that they have a variety of therapeutic options available that not only provide robust efficacy and different mechanisms of action, but also offer the flexibility to transition to another treatment, if needed," said Ralph Kern, M.D., senior vice president, Worldwide Medical. "With the world's leading MS portfolio and growing pipeline, Biogen continues to focus on MS care to impact the greatest number of people living with MS globally."

TECFIDERA data will showcase its strong and sustained efficacy in newly diagnosed MS patients, reinforcing that earlier treatment with TECFIDERA is critical to improve long-term clinical outcomes. In addition, real-world comparative effectiveness data will show that TECFIDERA is associated with significantly lower annualized relapse rates (ARR) relative to glatiramer acetate, interferon β and teriflunomide, and ARR were similar between TECFIDERA and fingolimod. These data support the established combination of benefits TECFIDERA offers, including strong and sustained efficacy, a well-characterized long-term safety profile and oral convenience.

With nearly 10 years of clinical experience, TYSABRI® (natalizumab) data will highlight real-world evidence demonstrating its proven long-term efficacy and safety, particularly when used earlier in the course of the disease. Additional Biogen data presentations will highlight the impact of ZINBRYTA™ (daclizumab HYP) on cognitive outcomes and its targeted mechanism of action (MOA), with data showing it did not cause broad immune cell depletion and that its effects on total lymphocyte counts were reversible within approximately eight to 12 weeks upon treatment discontinuation.

Highlights of Biogen's AAN Data for Presentation:

TECFIDERA

- Characterization of Absolute Lymphocyte Count Profiles in MS Patients Treated with Delayed-Release Dimethyl Fumarate: Considerations for Patient Management – *Poster P2.099 – Sunday, April 17, 8:30 a.m.-5:30 p.m. PT*
- Comparative Effectiveness Research of Disease Modifying Therapies in Multiple Sclerosis – Findings from a Large Health Insurance Claims Database – *Poster P3.116 – Monday, April 18, 8:30 a.m.-7 p.m. PT*
- Longer-Term Follow-Up of the Efficacy of Delayed-Release Dimethyl Fumarate in Newly Diagnosed Patients with Relapsing-Remitting Multiple Sclerosis: Integrated Analysis of DEFINE, CONFIRM, and ENDORSE – *Poster P3.033 – Monday, April 18, 8:30 a.m.-7 p.m. PT*

TYSABRI

- Real-World Safety and Efficacy of Natalizumab After Switching from Other Disease-Modifying Therapies (DMTs): Data from the TYSABRI® Observational Program (TOP) – *Poster P2.069 – Sunday, April 17, 8:30 a.m.- 5:30 p.m. PT*
- Four-Year Longitudinal Index Stability Data from STRATIFY-2 Support the Clinical Utility of Index for Risk Stratification of Natalizumab-Associated Progressive Multifocal Leukoencephalopathy – *Emerging Science Poster Session V, Poster P5.407 – Wednesday, April 20, 8:30 a.m.-7:00 p.m. PT*
- Natalizumab's Effects on Peripheral Immune Cells in Patients with Multiple Sclerosis (MS) Are Reversible by 16-20 Weeks After Treatment Discontinuation – *Emerging Science Poster Session V, Poster P5.408 – Wednesday, April 20, 8:30 a.m.-7:00 p.m. PT*

PLEGRIDY

- Peginterferon Beta-1a Reduces Conversion of MRI Lesions to Black Holes in Patients with Relapsing-Remitting Multiple Sclerosis – *Poster P3.091 – Monday, April 18, 8:30 a.m.-7 p.m. PT*
- ADVANCE Phase 3 Extension Study (ATTAIN): Peginterferon Beta-1a 125 mcg Every Two Weeks Demonstrated Sustained Efficacy in RMS Patients Treated up to Five Years – *Emerging Science Session Platform/Poster 010 – Tuesday, April 19, 5:45-7:15 p.m. PT*

ZINBRYTA

- Improved Cognitive Outcomes in Relapsing-Remitting Multiple Sclerosis with Daclizumab HYP in the Phase 3 DECIDE Study – *Poster P3.090 – Monday, April 18, 8:30 a.m.-7 p.m. PT*
- Reversible Effects of Daclizumab HYP on Lymphocyte Counts in RRMS Patients: Data from the SELECT Trilogy Studies – *Poster P5.281 – Wednesday, April 20, 8:30 a.m.-7 p.m. PT*

OPICINUMAB (ANTI-LINGO-1)

- Correlation of Brain Volume and Physical Measures with Cognitive Function Using Baseline Data from the Anti-LINGO-1 SYNERGY Trial in Multiple Sclerosis – *Poster P3.073 – Monday, April 18, 8:30 a.m.-7 p.m. PT*
- Correlation of Physical, Cognitive and MRI Measures with Multifocal Visual Evoked Potential Using Baseline Data from the Anti-LINGO-1 SYNERGY Trial in Multiple Sclerosis – *Poster P3.041 – Monday, April 18, 8:30 a.m.-7 p.m. PT*
- Evidence that the Anti-LINGO-1 Monoclonal Antibody BIIB033 Protects Against Multifocal Visual Evoked Potential Amplitude Loss in the Fellow Eye of Subjects with Unilateral Acute Optic Neuritis – *Poster I10.009 – Tuesday, April 19, 3-3:30 p.m. PT, Clinical Trials in Multiple Sclerosis 1: Platform S49.006 – Thursday, April 21, 2:15 p.m. PT*

About Biogen
Through cutting-edge science and medicine, Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological, autoimmune and rare diseases. Founded in 1978, Biogen is one of the world's oldest independent biotechnology companies and patients worldwide benefit from its leading multiple sclerosis and innovative hemophilia therapies. For more information, please visit www.biogen.com. Follow us on Twitter.

About TECFIDERA®
TECFIDERA is an oral therapy for relapsing forms of MS, including relapsing-remitting MS, the most common form of MS. TECFIDERA is currently approved in 24 countries including United States, the European Union, Canada, Australia and Switzerland. Through a robust clinical trial program and commercial launches starting with the United States in March 2013, more than 190,000 patients have been treated with TECFIDERA worldwide.[1]

TECFIDERA has been proven to reduce the rate of MS relapses, slow the progression of disability, and the number of MS brain lesions, while demonstrating a favorable benefit-risk profile in a broad range of patients with relapsing forms of MS.[2] In clinical trials, the most common adverse events associated with TECFIDERA were flushing and gastrointestinal (GI) events. Other side effects included a decrease in mean lymphocyte counts during the first year of treatment, which then plateaued. TECFIDERA is contraindicated in patients with a known hypersensitivity to dimethyl fumarate or any of the excipients of TECFIDERA. Rare cases of PML 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. It is believed that TECFIDERA treats MS by activating the Nrf2 pathway, although its exact mechanism of action is unknown. This pathway provides a way for cells in the body to defend themselves against inflammation and oxidative stress caused by conditions like MS.

For additional important safety information, and the United States full prescribing information, please visit www.tecfidera.com.

About TYSABRI®
TYSABRI is a DMT approved in more than 65 countries. In the United States, 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 therapy in highly active relapsing-remitting MS for adult patients who have high disease activity despite treatment with a beta interferon or glatiramer acetate or patients with rapidly evolving severe RRMS. TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML). When initiating and continuing treatment with TYSABRI, physicians should consider whether the expected benefit of TYSABRI is sufficient to offset this risk.

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 the *New England Journal of Medicine*, showed that at two years, TYSABRI treatment led to a 67 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 percent ($p<0.001$).

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 multiple sclerosis have not been fully defined.

TYSABRI increases the risk of PML, an opportunistic viral infection of the brain which usually leads to death or severe disability. Risk factors that increase the risk of PML are 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. Serious, life-threatening, and sometimes fatal cases have been reported in the postmarketing setting in multiple sclerosis 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. A list of adverse events can be found in the full TYSABRI product labeling for each country where it is approved.

For additional important safety information, and the United States full prescribing information, please visit www.TYSABRI.com or your respective country's website.

About PLEGRIDY®
PLEGRIDY is a subcutaneous pegylated interferon dosed once every two weeks for relapsing forms of MS,[3] including relapsing-remitting MS, the most common form of MS. PLEGRIDY is currently approved in the United States, 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. In clinical trials, the most common adverse events associated with PLEGRIDY were injection site reactions and flu-like symptoms. Other 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. A list of adverse events can be found in the full PLEGRIDY product labeling for each country where it is approved.

It is believed that PLEGRIDY modulates immune responses that are thought to play a role in MS although its exact mechanism of action is unknown.

For additional important safety information and United States full prescribing information, please visit www.plegridy.com, or your respective country's website.

About ZINBRYTA™ (daclizumab HYP)
ZINBRYTA (daclizumab HYP) is an investigational compound being developed for the treatment of relapsing forms of MS. ZINBRYTA is a new form of a humanized monoclonal antibody that selectively binds to the high-affinity interleukin-2 (IL-2) receptor subunit (CD25) that is expressed at high levels on T -cells that become activated in people with MS. ZINBRYTA modulates IL-2 signaling without causing general immune cell depletion.

ZINBRYTA is under regulatory review in the United States, the European Union, Switzerland, Canada and Australia. Biogen and AbbVie are jointly developing ZINBRYTA.

About OPICINUMAB (ANTI-LINGO-1)
Anti-LINGO-1 (BIIB033) is an investigational compound being developed for the treatment of multiple sclerosis. Anti-LINGO-1 is a fully human monoclonal antibody that targets LINGO-1, a protein expressed selectively in the central nervous system (CNS) that is known to play a central role in regulating axonal myelination and regeneration.

Two global Phase 2 trials, RENEW and SYNERGY, were designed to assess the biological activity and clinical potential of anti-LINGO-1 in acute optic neuritis (AON) and relapsing forms of MS. In RENEW, anti-LINGO-1 was evaluated in patients following a first episode of AON. Anti-LINGO-1 demonstrated an improvement in recovery of optic nerve latency (time for a signal to travel from the retina to the visual cortex) relative to placebo. RENEW was the first clinical study to provide evidence of biological repair in the CNS by facilitating remyelination following an acute inflammatory injury.

SYNERGY is a separate Phase 2 study which aims to measure the impact of anti-LINGO-1 in combination with an anti-inflammatory therapy on improving and slowing disease progression among participants with relapsing forms of MS (both relapsing-remitting MS and secondary-progressive MS). The study is ongoing with results expected in 2016.

Safe Harbor
This press release includes forward-looking statements, including statements about the potential benefits of our products and programs and expected timing of results from clinical trials. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "estimate," "expect," "forecast," "intend," "may," "plan," "will," and other words and terms of similar meaning. You should not place undue reliance on these statements. 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. There is a risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in early stage clinical trials may not be predictive of results in later stage or large scale clinical trials or trials in other potential indications. Other factors which could cause actual results to differ materially from our current expectations include the risk that unexpected concerns may arise from additional data or analysis, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates, or we may encounter other unexpected hurdles. For more detailed information on the risks and uncertainties associated with our drug development and commercialization activities, please review the Risk Factors section of our most recent annual or quarterly report filed with the 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.

[1] Combined post-marketing and clinical trials exposure to TECFIDERA as of December 31, 2015.

[2] TECFIDERA is approved in the European Union for relapsing-remitting multiple sclerosis.

[3] PLEGRIDY is approved in the European Union, Canada, Switzerland and Australia for relapsing-remitting multiple sclerosis.

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