Biogen to Highlight Broad Research Commitment to MS Care at ECTRIMS Congress, Including New TECFIDERA® Data Demonstrating Importance of Early Treatment

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TECFIDERA® Data Will Show Strong Efficacy on Key Measures of Disease Activity, Including Disability;

Six-Year Data to Reinforce Well-Established Safety and Efficacy Profile

New Data on Pipeline Therapies ZINBRYTA™ and Anti-LINGO-1 Will Underscore Commitment to Advancing Care for People with MS

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Biogen (NASDAQ: BIIB) will present new clinical data for its multiple sclerosis (MS) portfolio of therapies, including the most-prescribed oral treatment, TECFIDERA® (dimethyl fumarate), at the 31st meeting of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Barcelona, Spain, 7-10 October 2015.[1] TECFIDERA data will demonstrate its strong and sustained efficacy in relapsing-remitting multiple sclerosis (RRMS) among patients who were early in the course of their disease or newly diagnosed.

Previous studies have suggested that delaying MS treatment may put some patients at a higher risk of disease progression than those treated with an effective disease modifying therapy (DMT) early in their disease course. With a chronic condition like MS, initiating treatment early may help slow disease activity.[2,3]

"TECFIDERA's compelling combination of benefits has made it the most-prescribed oral MS medication globally. [1] At ECTRIMS, Biogen will present data that underscore the benefits of early treatment of RRMS with TECFIDERA and reaffirm its favorable benefit-risk profile in a broad range of patients," said Gilmore O'Neill, M.D., vice president of Multiple Sclerosis Research and Development at Biogen.

Biogen will also present additional findings from studies of its marketed and investigational MS therapies that aim to improve patient outcomes. Highlights include results from new analyses of the Phase 3 study of ZINBRYTA™ (daclizumab high-yield process) and additional Phase 2 results for anti-LINGO-1 (BIIB033) in acute optic neuritis. Further clinical data presentations from company initiatives and collaborative research will focus on exploring innovations and technologies to enhance individualized treatment outcomes.

Highlights of Biogen's ECTRIMS Data for Presentation:

TECFIDERA

- Efficacy of Delayed-Release Dimethyl Fumarate in Early Multiple Sclerosis: Post-Hoc Analysis of the Phase 3 DEFINE and CONFIRM Studies According to Baseline Disability – *Poster P565 – Thursday, 8 October – 15:45-17:00 CEST*
- Longer-Term Follow-Up of the Efficacy of Delayed-Release Dimethyl Fumarate in Newly Diagnosed Patients with RRMS: An Integrated Analysis of DEFINE, CONFIRM, and ENDORSE – *Poster P564 – Thursday, 8 October – 15:45-17:00 CEST*
- Long-Term Follow-Up of the Safety of Delayed-Release Dimethyl Fumarate in RRMS: Interim Results From the ENDORSE Extension Study – *Poster P544 – Thursday, 8 October – 15:45-17:00 CEST*
- Efficacy of Delayed-Release Dimethyl Fumarate Versus Glatiramer Acetate on a Novel Composite Outcome Measure of Inflammatory Disease Activity: Post-Hoc Analysis of the CONFIRM Study – *Poster P1063 – Friday, 9 October – 15:30-17:00 CEST*

TYSABRI

- Comparative Efficacy of First-Line Natalizumab Versus IFNb or Glatiramer Acetate in Relapsing Multiple Sclerosis – *Poster P559 – Thursday, 8 October – 15:45-17:00 CEST*
- No Evidence of an Increased Risk for Malignancy Associated with Natalizumab Therapy in Nine Years of Postmarketing Surveillance – *Poster P1094 – Friday, 9 October – 15:30-17:00 CEST*
- Progression to Disability Milestones in Multiple Sclerosis with Long-Term Natalizumab Treatment – *Poster P1092 – Friday, 9 October – 15:30-17:00 CEST*

PLEGRIDY

- COMPARE: A Phase 1 Pharmacokinetic Study of Subcutaneous Peginterferon Beta-1a Versus Subcutaneous Interferon Beta-1a Over Two Weeks in Healthy Subjects – *Poster P1147 – Friday, 9 October – 15:30-17:00 CEST*
- Peginterferon Beta-1a Dosed Every Two Weeks Maintained Efficacy Over Three Years in Patients with Relapsing-Remitting Multiple Sclerosis – *Poster P1098 – Friday, 9 October – 15:30-17:00 CEST*

ZINBRYTA

- Effect of Daclizumab HYP Versus Intramuscular Interferon Beta-1a on No Evidence of Disease Activity in Patients with Relapsing-Remitting Multiple Sclerosis: Analysis of the DECIDE Study – *Parallel Session 2:89 – Thursday, 8 October – 12:00 CEST*
- Daclizumab HYP Provided Clinically Meaningful Benefits on Cognitive Outcomes Versus Intramuscular Interferon Beta-1a Over Two Years: Results from the DECIDE Study – *Poster P535 – Thursday, 8 October – 15:45-17:00 CEST*
- Efficacy of Daclizumab HYP Versus Intramuscular Interferon Beta-1a on Disability Progression Across Patient Demographic and Disease Activity Subgroups in DECIDE – *Poster P561 – Thursday, 8 October – 15:45-17:00 CEST*

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 P629 – Thursday, 8 October – 15:45-17:00 CEST*
- Anti-LINGO-1 Monoclonal Antibody BIIB033 Improves Optic Nerve Latency in Acute Optic Neuritis: Primary Efficacy Analysis of the RENEW Study – *Free Communications 3: Platform 165 – Friday, 9 October – 10:03-10:15 CEST*
- 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 – *Parallel Session 13:231– Saturday, 10 October – 9:25-9:36 CEST*

EMERGING APPROACHES TO MS MANAGEMENT

- The Self-Administered, iPad®-Based Processing Speed Test: Impact of Technician Presence on Task Performance – *Poster P517 – Thursday, 8 October – 15:45-17:00 CEST*
- Harnessing Real-Time Patient Data to Improve Clinical Outcomes and Research: The Multiple Sclerosis Partners Advancing Technology and Healthcare Solutions (MS PATHS) Initiative – *Poster P821 – Friday, 9 October – 15:30-17:00 CEST*

ABOUT BIOGEN

Through cutting-edge science and medicine, Biogen discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hematologic conditions and autoimmune disorders. 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 product labeling, press releases and additional information about the company, please visit http://www.biogen.com.

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 the 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 165,000 patients have been treated with TECFIDERA worldwide.[4]

TECFIDERA has been proven to reduce 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. [5] 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 severe and prolonged 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,[6] 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 high-yield process)

ZINBRYTA (daclizumab high-yield process) 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 abnormally activated in MS. ZINBRYTA modulates IL-2 signaling without causing general immune cell depletion. Biogen and AbbVie are jointly developing ZINBRYTA.

ZINBRYTA is believed to work by decreasing abnormally-activated T-cells and pro-inflammatory lymphoid tissue inducer cells, and increasing $CD56^{bright}$ natural killer (NK) cells, important cells that help regulate the immune system.

ZINBRYTA is currently under regulatory review in the United States and the European Union.

ABOUT ANTI-LINGO-1 (BIIB033)

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 July 31, 2015

[2] Kappos, L., Freedman, M., Polman, C., et, al. (2007). Effect of early versus delayed interferon beta-1b treatment on disability after a first clinical event suggestive of multiple sclerosis: A 3-year follow-up analysis of the BENEFIT study. The Lancet, 389-397.

[3] Goodin, D., & Bates, D. (2009). Review: Treatment of early multiple sclerosis: The value of treatment initiation after a first clinical episode.*Multiple Sclerosis*, 1175-1182.

[4] Pozzilli C, Phillips JT, Fox RJ, et. al. (2015, October). Long-Term Follow-up of the Safety of Delayed-Release Dimethyl Fumarate in RRMS: Interim Results From the ENDORSE Extension Study. Poster session presented at the 31st meeting of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), Barcelona, Spain.

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

[6] PLEGRIDY is approved in the European Union and Canada for relapsing-remitting multiple sclerosis.

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