Biogen Demonstrates Commitment to Improving Patient Outcomes with Study on Burden of MS and New Clinical Data from Its Leading MS Portfolio

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Largest Study on MS Cost of Illness Reveals New Insights from Patients about the Impact of MS

Comparative Effectiveness Studies Reinforce Clinical Data Supporting the Strong, Sustained Efficacy of TECFIDERA ®

New ZINBRYTA™ NEDA Analysis Reinforces Efficacy vs. Interferon Beta-1a

CAMBRIDGE, Mass.--(BUSINESS WIRE)--New research collected from more than 16,000 multiple sclerosis (MS) patients across Europe, in the largest study to capture the widespread impact of the disease, along with updated clinical findings from the company's broad portfolio of MS therapies will be presented at the 32nd congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in London, 14-17 September 2016, Biogen (NASDAQ: BIIB) announced today.

The Biogen-sponsored MS Cost of Illness (COI) study further builds on the highly influential and frequently cited 2005 European COI study, which examined the burden of MS on patients and their caregivers in Europe. Gisela Kobelt, PhD, President, European Health Economics, the author of both the 2005 research and the new study, will present the data during the congress and share insights in a workshop attended by patient groups and the study's clinical advisors.

"We look forward to hearing from the patient community in our upcoming ECTRIMS workshop on the burden of illness in MS. We encourage an open discussion about how the community can apply the main findings of the study to engage and educate researchers, governments, and policy makers around the issues most critical to patients, and, ultimately, identify new ways to improve outcomes in the treatment of MS," said Ralph Kern, M.D., senior vice president, Worldwide Medical, Biogen.

Additional data to be presented at ECTRIMS will highlight Biogen's industry-leading portfolio including TECFIDERA ® (dimethyl fumarate), the world's most-prescribed oral MS treatment, and ZINBRYTA™ (daclizumab), a new once-monthly, self-administered, subcutaneous treatment recently approved in the United States and the European Union:

- Real-world data and new clinical evidence that demonstrate TECFIDERA consistently delivers strong, sustained efficacy in reducing disease activity among newly diagnosed and previously treated patients with relapsing-remitting multiple sclerosis (RRMS). Additional data affirm TECFIDERA's well-characterized safety profile in patients who have had up to nine years of treatment.
- A new analysis from the pivotal DECIDE study that further supports the positive impact of ZINBRYTA on no evidence of disease activity (NEDA), and the first interim results from the ongoing EXTEND study, providing up to five years of efficacy and safety data.
- Detailed results evaluating opicinumab (anti-LINGO-1) in people with relapsing forms of MS from the Phase 2 SYNERGY study, the largest study investigating remyelination conducted to date.

Highlights of Biogen's ECTRIMS Data:
MS Cost of Illness

- Cognition, Fatigue and Health-Related Quality of Life in Patients with Multiple Sclerosis: Results from a European-Wide Study – *Poster Session 2 (P871) – Friday, 16 September – 15:30-17:00 PM BST*
- Inability to Work and Need for Social and Family Support Drive Costs in Multiple Sclerosis – *Poster Session 2 (P908) – Friday, 16 September – 15:30-17:00 PM BST*

TECFIDERA

- Annual Relapse Rates in Multiple Sclerosis Patients Treated with Different Disease-Modify Therapies – Findings from a Real World Setting – *ePoster EP1481*
- Seven-Year 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 Session 1 (P631) – Thursday, 15 September – 15:45-17:00 PM BST*
- Comparative Analysis of MS Outcomes in Dimethyl Fumarate-Treated Patients Relative to Propensity Matched Fingolimod, Interferon, Glatiramer Acetate, or Teriflunomide – *Poster Session 2 (P1157) – Friday, 16 September – 15:30-17:00 PM BST*

ZINBRYTA

- Interim Report on the Safety and Efficacy of Long-Term Daclizumab Treatment for up to Five Years (EXTEND Trial) –

Poster Session 1 (P653) – Thursday, 15 September – 15:45-17:00 PM BST

- Achievement of No Evidence of Disease Activity by Time Interval with Daclizumab vs. Intramuscular Interferon Beta-1a Treatment in DECIDE – *Poster Session 1 (P664) – Thursday, 15 September – 15:45-17:00 PM BST*

TYSABRI

- Functional and Survival Outcomes of Asymptomatic Progressive Multifocal Leukoencephalopathy in Natalizumab-Treated Multiple Sclerosis Patients: 2015 Update – *ePoster EP1528*
- Long-Term Real-World Effectiveness of Natalizumab: Treatment Outcomes from the TYSABRI® Observational Program (TOP) Stratified by Baseline Disability – *Poster Session 2 (P1228) – Friday, 16 September – 15:30-17:00 PM BST*
- Long-Term Safety of Natalizumab Treatment in Multiple Sclerosis (MS) in Clinical Practice: Results from the TYSABRI Global Observational Program in Safety (TYGRIS) – *Poster Session 2 (P1229) – Friday, 16 September – 15:30-17:00 PM BST*
- New Algorithm to Estimate Risk of Natalizumab-Associated Progressive Multifocal Leukoencephalopathy (PML) in Anti-JCV Antibody Positive Patients: Analyses of Clinical Trial Data to Provide Further Temporal Precision and Inform Clinical Practice – *Poster Session 2 (P1249) – Friday, 16 September – 15:30-17:00 PM BST*

PLEGRIDY

- SC Peginterferon Beta-1a Every Two Weeks Demonstrated Better Clinical Outcomes than SC Interferon Beta-1a TIW in Patients with RMS, Using a Matching-Adjusted Comparison of Seven Phase 3 Trials – *ePoster EP1486*
- Peginterferon Beta-1a Every Two Weeks Increased Achievement of NEDA over Four Years in the ADVANCE and ATTAIN Studies in Patients with RRMS – *Poster Session 2 (P1171) – Friday, 16 September – 15:30-17:00 PM BST*

FAMPYRA

- Sustained Clinically Meaningful Improvements in Walking Ability with Prolonged-Release Fampridine: Results from the Placebo-Controlled ENHANCE Study – *Parallel Session 14: Late Breaking News (#254) – Saturday, 17 September – 9:30-9:42 AM BST*

OPICINUMAB (ANTI-LINGO-1)

- MRI Biomarkers of Opicinumab (Anti-LINGO-1) Repair in Relapsing MS: Results from the Phase 2b SYNERGY Trial – *Poster Session 1 (P588) – Thursday, 15 September – 15:45-17:00 PM BST*
- Safety and Tolerability of Opicinumab in Relapsing Multiple Sclerosis: the Phase 2b SYNERGY Trial – *Poster Session 1 (P675) – Thursday, 15 September – 15:45-17:00 PM BST*
- Efficacy Analysis of Opicinumab in Relapsing Multiple Sclerosis: the Phase 2b SYNERGY Trial – *Parallel Session 9 Remyelination: Mechanisms and Therapeutic Approaches (#192), Hall B – Friday, 16 September – 11:25-11:37 AM BST*

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 215,000 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 disease modifying therapy (DMT) approved in more than 80 countries including the United States, the European Union, Canada, Australia and Switzerland. In the United States, TYSABRI is indicated as monotherapy for the treatment of patients with relapsing forms of multiple sclerosis (MS). In the European Union, it is indicated as a single DMT in highly active relapsing-remitting MS (RRMS) 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 is proven

effective, with 10 years of experience in treating RRMS, and more than 149,000 people treated worldwide and 475,000 patient-years of experience.

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 the 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 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 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.

The overall benefit-risk profile of TYSABRI remains positive. For additional important safety information and the United States Prescribing Information which includes a full list of adverse events, 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 ™

ZINBRYTA is approved for the treatment of relapsing forms of multiple sclerosis (RMS) in the United States and the European Union. The recommended dosage of ZINBRYTA is 150 mg, self-administered subcutaneously on a monthly basis. ZINBRYTA is currently under regulatory review in Switzerland, Canada and Australia.

In clinical trials, ZINBRYTA demonstrated superior efficacy in reducing relapses and MRI lesions, compared to AVONEX® (interferon beta-1a) intramuscular injection and placebo.

ZINBRYTA is a humanized IgG1 monoclonal antibody that selectively binds to the high-affinity interleukin-2 (IL-2) receptor subunit (CD25). CD25 is expressed at high levels on T-cells that become activated in people with MS.

ZINBRYTA increases the risk of severe hepatic (liver) injury. It also increases the risk of immune-mediated events including lymphadenopathy (enlargement of the lymph nodes), cutaneous (skin) reactions and non-infectious colitis, acute hypersensitivity (allergic reactions), infections, depression and decreased lymphocyte (type of white blood cell) counts.

The most common adverse reactions that occurred in ZINBRYTA-treated patients were nasopharyngitis (inflammation of the nose and a part of the throat), upper respiratory tract infection, rash, influenza, dermatitis, oropharyngeal (part of the throat) pain, bronchitis, eczema, lymphadenopathy, pharyngitis (inflammation of part of the throat) and increased alanine aminotransferase (ALT; a type of liver enzyme).

ZINBRYTA is only available through a Risk Evaluation and Mitigation Strategy (REMS) Program in the U.S., and is under a Risk Management Plan (RMP) in the EU.

AbbVie and Biogen are co-promoting ZINBRYTA in the U.S. Biogen is responsible for commercialization in Canada, the EU and the rest of the world.

About FAMPYRA

FAMPYRA® is a prolonged-release (sustained release) tablet formulation of the drug fampridine (4-aminopyridine, 4-AP or dalfampridine). FAMPYRA is indicated in the European Union for the improvement of walking in adult patients with multiple sclerosis (MS) with walking disability (EDSS 4-7). In clinical trials, the highest incidence of adverse reactions identified with FAMPYRA given at the recommended dose was urinary tract infection, although infection was often not proven by culture. Other adverse drug reactions identified were mainly divided between neurological disorders, such as insomnia, balance disorder, dizziness, paraesthesia, headache and gastrointestinal disorders including nausea, dyspepsia and constipation. In post-marketing experience, there have been reports of seizure. Confounding factors may have contributed to the occurrence of seizure in some patients. This prolonged-release formulation was developed and is being commercialized in the United States by Acorda Therapeutics, Inc. (NASDAQ: ACOR) under the trade name AMPYRA® (dalfampridine) Extended Release Tablets, 10 mg. Biogen licensed rights from Acorda to develop and commercialize fampridine in all markets outside the United States.

For more information about FAMPYRA, please visit www.biogen.com

About Opicinumab (anti-LINGO-1)

Opicinumab (anti-LINGO-1) is a fully human monoclonal antibody being investigated as a potential neuroreparative therapy in people with relapsing

forms of multiple sclerosis (RMS). Opicinumab 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 opicinumab in acute optic neuritis (AON) and relapsing forms of MS, respectively. In RENEW, opicinumab was evaluated in patients following a first episode of AON. Opicinumab 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 was a separate Phase 2 study aiming to measure the impact of opicinumab 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). In the study, opicinumab missed the primary endpoint, a multicomponent measure evaluating improvement of physical function, cognitive function, and disability. Further study of the inverted U-shaped response seen in SYNERGY suggested a clinical effect of opicinumab.

Safe Harbor
This press release includes forward-looking statements, including statements about the potential benefits and effects of our products and programs. 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 30 June 2016.

[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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