# Biogen Idec Data at Joint ACTRIMS-ECTRIMS Meeting Highlight Robust Multiple Sclerosis Portfolio and Commitment to Advancing Patient Care

September 3, 2014

*- Data Further Support Industry-Leading Portfolio of MS Treatments and Innovative Pipeline Therapies -*

*- Innovative Programs Reinforce Commitment to Improving the Lives of People Living with MS -*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) will present more than 90 company-sponsored platform and poster presentations on data supporting its marketed and investigational therapies for multiple sclerosis (MS), as well as the company's programs to address unmet needs in patient management, at the sixth Triennial Joint Meeting of ACTRIMS and ECTRIMS in Boston, September 10 – 13, 2014. The breadth and volume of data exemplify Biogen Idec's industry-leading expertise in research and development, comprehensive product portfolio, and enduring commitment to the MS community. ACTRIMS-ECTRIMS is the joint meeting of the Americas Committee for Treatment and Research in Multiple Sclerosis and the European Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS-ECTRIMS).

"We are dedicated to advancing MS care through innovative clinical research on promising CNS targets with the potential for treating this disease and through novel initiatives that address critical disease management issues," said Douglas E. Williams, Ph.D., executive vice president, Research and Development at Biogen Idec. "This includes our collaboration with the MS community to better understand the patient experience to help patients and physicians better work together to manage the disease."

Biogen Idec data to be presented at ACTRIMS-ECTRIMS include results from studies of its currently approved products, TECFIDERA® [delayed-release dimethyl fumarate (DMF; also known as gastro-resistant DMF)], TYSABRI® (natalizumab), FAMPYRA® (prolonged-release fampridine tablets) and PLEGRIDY™ (peginterferon beta-1a), as well as findings from the clinical programs of its MS pipeline candidates, ZINBRYTA™ [daclizumab high-yield process (DAC HYP)] and Anti-LINGO-1 (BIIB033).

Biogen Idec will also present information on several of the company's initiatives that seek novel solutions to improve MS patient management, reinforcing the company's commitment to comprehensively meet the needs of people with MS. These include highlights from the Value-Based Medicine (VBM) group, focused on developing and deploying new technology to help enhance individualized treatment decisions and a consensus opinion study of U.S. neurologists to assess practice patterns in the management of MS, and to inform U.S. consensus guidelines for treatment initiation. Additionally, highlights from an international survey of patients and neurologists designed to understand the current "State of MS," including the quality of communication between MS patients and their physicians, will be presented.

Biogen Idec will also host a journalist and advocacy group briefing about the "State of MS" survey findings on Wednesday, September 10 at 11:30 a.m. – 1 p.m. EST. The discussion will focus on the relationship and communication between neurologists and people living with MS.

**Highlights of Biogen Idec's ACTRIMS-ECTRIMS Data**

EMERGING APPROACHES TO MS MANAGEMENT

- Consensus Opinion of U.S. Neurologists on Practice Patterns in Radiologically and Clinically Isolated Syndrome and Relapsing-Remitting MS – *Poster #295 – Thursday, September 11, 2014 – 3:30-5:00 PM*
- The State of MS: Current Insight Into Patient-Neurologist Relationships, Barriers to Communication, and Treatment Satisfaction – *Poster P824 – Friday, September 12, 2014 – 2:45-4:15 PM*
- Value Based Medicine: Enabling Evidence-Based and Individualized Treatment Decisions for Patients With Multiple Sclerosis – *Poster P825 – Friday, September 12, 2014 – 2:45-4:15 PM*

TECFIDERA

- Five-Year Follow-up of Delayed-Release Dimethyl Fumarate in RRMS: Integrated Clinical Efficacy Data from the DEFINE, CONFIRM, and ENDORSE Studies – *Poster P110 – Thursday, September 11, 2014 – 3:30-5:30 PM*
- Long-term Follow-up of the Effect of Delayed-Release Dimethyl Fumarate on No Evident Disease Activity in Patients with Multiple Sclerosis – *Platform FC3.5 – Friday, September 12, 2014 – 9:03 AM*

TYSABRI

- Correlations Between Patient-reported Ambulatory Function (MSWS-12) and Objective Disability Measurements in SPMS: Analysis of ASCEND Baseline Data – *Poster P777 – Friday, September 12 – 2:45 – 4:15 PM*

PLEGRIDY

- Effect of Peginterferon Beta-1a on MRI Measures and Freedom From Measured Disease Activity: 2-year Results From the Phase 3 ADVANCE Study – *Poster P067 – Thursday, September 11, 2014 – 3:30-5:00 PM*
- Clinical Efficacy of Peginterferon Beta-1a in Relapsing-Remitting Multiple Sclerosis: 2-year Data From the Phase 3

ADVANCE Study – *Platform FC2.5– Friday, September 12, 2014 – 9:03 AM*

FAMPYRA

- Psychometric Testing of the Early Mobility Impairment Questionnaire for Multiple Sclerosis – *Poster P784 – Friday, September 12, 2014 – 2:45-4:15 PM*
- Walking Ability and Balance in Patients with Multiple Sclerosis Treated with Prolonged-Release Fampridine: Randomized, Double-Blind MOBILE Study – *Poster P922 – Friday, September 12, 2014 – 2:45-4:15 PM*

ZINBRYTA

- Safety and Tolerability of Daclizumab HYP Treatment in Relapsing-Remitting Multiple Sclerosis: Results of the DECIDE Study – *Poster P094 – Thursday, September 11, 2014 – 3:30-5:30 PM*
- Primary Results of DECIDE: A Randomized, Double-Blind, Double-Dummy, Active-Controlled Trial of Daclizumab HYP vs. Interferon B-1a in RRMS Patients – *Platform FC1.1 – Friday, September 12, 2014 – 8:15 AM*

Anti-LINGO -1

- A Phase II Study of the Anti-LINGO-1 Monoclonal Antibody, BIIB033, in Subjects With Acute Optic Neuritis: Baseline Data – *Poster P731 – Friday, September 12, 2014 – 2:45-4:15 PM*

Full session details and data presentation listings for the 2014 Joint ACTRIMS-ECTRIMS Meeting can be found at the meeting website, http://www.msboston2014.org/.

**About Biogen Idec**

Through cutting-edge science and medicine, Biogen Idec discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hematologic conditions and autoimmune disorders. Founded in 1978, Biogen Idec is the world's oldest independent biotechnology company 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.biogenidec.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 100,000 patients have been treated with TECFIDERA worldwide[1].

TECFIDERA has been proven to reduce MS relapses, progression of disability, and MS brain lesions, while demonstrating a favorable safety and tolerability 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. The efficacy and safety of TECFIDERA has been studied in a large, global clinical program, which includes an ongoing long-term extension study. It is believed that TECFIDERA provides a new approach to treating 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 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. TYSABRI increases the risk of PML. When initiating and continuing treatment with TYSABRI, physicians should consider whether the expected benefit of TYSABRI is sufficient to offset this risk. In the European Union, it is indicated as a single disease modifying therapy 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 has advanced the treatment of MS patients with its established efficacy. Data from the Phase 3 AFFIRM trial, which was published in the *New England Journal of Medicine*, showed that after 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 42-54 percent ($p<0.001$).

TYSABRI increases the risk of PML, an opportunistic viral infection of the brain which usually leads to death or severe disability. Infection by the JC virus (JCV) is required for the development of PML and patients who are anti-JCV antibody positive have a higher risk of developing PML. 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

**About PLEGRIDY**

PLEGRIDY is a new subcutaneous injectable interferon therapy indicated for relapsing forms of multiple sclerosis, in which interferon beta-1a is pegylated to extend its half-life to permit a less frequent dosing schedule. PLEGRIDY was recently approved by the European Commission in July 2014 and the U.S. FDA in August 2014.

Severe hepatic injury, including hepatitis, autoimmune hepatitis, and rare cases of severe hepatic failure have been reported with interferon beta.

Elevations in hepatic enzymes and hepatic injury have been observed with the use of PLEGRIDY in clinical studies. Depression, suicidal ideation and suicide have been reported in patients receiving interferon beta. Seizures are also associated with the use of interferon beta. Anaphylaxis and other serious allergic reactions are rare complications of treatment with interferon beta. Injection site reactions, including injection site necrosis, can occur with the use of subcutaneous interferon beta.

Congestive heart failure, cardiomyopathy, and cardiomyopathy with congestive heart failure occur in patients receiving interferon beta. Interferon beta can cause decreased peripheral blood counts in all cell lines, including rare instances of pancytopenia and severe thrombocytopenia. Autoimmune disorders of multiple target organs including idiopathic thrombocytopenia, hyper and hypothyroidism, and autoimmune hepatitis have been reported with interferon beta.

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

**About FAMPYRA**

FAMPYRA is a prolonged-release (sustained release) tablet formulation of the drug fampridine (4-aminopyridine, 4-AP or dalfampridine). FAMPYRA has been developed to improve walking in adult patients with MS. In MS, damaged myelin exposes channels in the membrane of axons allowing potassium ions to leak, weakening the electrical current sent through nerves. Studies have shown that fampridine can increase conduction along damaged nerves, which may result in improved walking ability.

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 Idec has a license from Acorda Therapeutics to develop and commercialize fampridine in all markets outside the United States. Biogen Idec commercializes fampridine in these markets under the trade name Fampyra®.

**About ZINBRYTA**

ZINBRYTA (daclizumab high yield process) is an investigational drug and 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. 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.

Biogen Idec and AbbVie are jointly developing ZINBRYTA.

[1] Biogen Idec data on file

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

## Contact:

MEDIA CONTACT:
Biogen Idec
Annabel Cowper, Ph: +41 41 392 17 05
public.affairs@biogenidec.com
OR
Lindsey Smith, Ph: +1 781-464-3260
public.affairs@biogenidec.com
OR
INVESTOR CONTACT:
Biogen Idec
Carlo Tanzi, Ph.D., Ph: +1 781-464-2442
IR@biogenidec.com
OR
Claudine Prowse, Ph.D., Ph: +1 781-464-2442
IR@biogenidec.com