



## Biogen Idec to Present New Clinical Data from Its Robust Neurology Portfolio at AAN Annual Meeting

April 14, 2014

- Two-Year Data from Pivotal Phase 3 ADVANCE Study for PLEGRIDY™ (Peginterferon Beta-1a) to Be Presented -

- New TECFIDERA® (dimethyl fumarate) Data Underscore Efficacy, Consistent with Growing Global Experience with Greater than 65,000 Patients Treated Worldwide<sup>1</sup> -

- Presentations Demonstrate Breadth of Company's Innovative Neurology Pipeline -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--[Biogen Idec](#) (NASDAQ: BIIB) will present more than 60 company-sponsored platform and poster presentations on data supporting its marketed and investigational therapies for neurological diseases at the 66<sup>th</sup> American Academy of Neurology (AAN) Annual Meeting in Philadelphia, April 26 – May 3, 2014. The scope and rigor of the data reflects Biogen Idec's leadership in advancing neurological research and enhancing patient outcomes in multiple sclerosis (MS) and other diseases.

"For more than 20 years, Biogen Idec has been dedicated to improving the lives of people with MS," said Alfred Sandrock, M.D., Ph.D., group senior vice president, and chief medical officer at Biogen Idec. "We have a broad portfolio and pipeline of innovative MS medicines, we perform important research that continues to advance our understanding of this disease, and we provide meaningful support services for people living with MS. The breadth of data we are presenting at AAN reinforces our enduring commitment to reducing the impact of MS and other serious neurodegenerative diseases."

As part of its ongoing commitment to further understand the underlying causes of neurological disease, Biogen Idec is presenting new data to help patients and their healthcare providers make optimal treatment decisions and improve patient outcomes. In addition, data at AAN will include results from studies of its currently marketed products, TECFIDERA® (dimethyl fumarate), TYSABRI® (natalizumab), AVONEX® (interferon beta-1a) and FAMPYRA® (prolonged-release fampridine tablets), as well as findings from the clinical programs of its MS pipeline candidates PLEGRIDY™ (peginterferon beta-1a), daclizumab high-yield process (DAC HYP) and Anti-LINGO-1 (BIIB033).

In addition to data presented at the meeting, Biogen Idec will support the American Brain Foundation's 2014 Brain Health Fair. On Saturday, April 26 Biogen Idec will help sponsor a free, day-long family event that aims to connect thousands of patients, families and caregivers affected by neurological disease. The Brain Health Fair will offer scientific presentations and discussions, educational activities, and a film festival competition that aims to increase public awareness and understanding of neurological disease. Registration is free at [BrainHealthFair.com](#).

Notable data from Biogen Idec at AAN 2014 in MS and Alzheimer's disease:

### EMERGING APPROACHES TO MS MANAGEMENT

- Do MRI Lesions Predict MS Relapses? – *Poster P3.190 – Tuesday, April 29, – 3:00 PM*
- Multiple Sclerosis Decision Model (MSDM): A Multifactorial Model To Monitor Treatment Response And Disease Course In Relapsing Remitting Multiple Sclerosis – *Poster P3.133 - Tuesday, April 29 – 3:00 PM*
- Epidemiological Study To Identify Factors That Influence Clinical Decision Making In Patients With Relapsing Remitting Multiple Sclerosis (RRMS) After At Least 2 Years Of Treatment With Immunomodulators In Germany (EPIDEM) – *Poster P7.243 – Thursday, May 1 – 3:00 PM*

### TECFIDERA

- Gastrointestinal Tolerability of Delayed-Release Dimethyl Fumarate in a Multicenter, Open-Label Study of Patients With Relapsing Forms of Multiple Sclerosis – *Poster P2.227 – Tuesday, April 29 – 7:30 AM*
- Clinical Efficacy of Delayed-Release Dimethyl Fumarate in Relapsing-Remitting Multiple Sclerosis (RRMS) Patients with Highly Active Disease: An Integrated Analysis of the Phase 3 DEFINE and CONFIRM Studies – *Poster P3.189 – Tuesday, April 29 – 3:00 PM*
- Clinical Efficacy of Delayed-Release Dimethyl Fumarate in Minority Patients with Relapsing-Remitting Multiple Sclerosis (RRMS): An Integrated Analysis of the Phase 3 DEFINE and CONFIRM Studies – *Poster P3.171 – Tuesday, April 29 – 3:00 PM*
- Dimethyl Fumarate Utilizes Nrf2-independent and Nrf2-dependent Pathways for Immune Modulation – *Platform S53.006 – Thursday, May 1 – 2:15 PM*

### TYSABRI

- Natalizumab Treatment Improves Walking Speed in MS Patients: A Post Hoc Analysis of AFFIRM – *Platform S4.006 –*

Tuesday, April 29 – 2:15 PM

- Comparative Efficacy of Switching to Natalizumab Versus Switching to Interferon-Beta or Glatiramer Acetate after On-Treatment MS Relapse Using Propensity-Matched Registry Data – *Poster P3.175 – Tuesday, April 29 – 3:00 PM*
- Comparison of Switching to Natalizumab Versus Remaining on Interferon-Beta or Glatiramer Acetate after On-Treatment MS Relapse Using Propensity-Matched Registry Data – *Poster P7.208 – Thursday, May 1 – 3:00 PM*

#### AVONEX

- Prospective Evaluation of Persistence, Treatment Adherence, Quality of Life, and Treatment Satisfaction in Patients Treated with an Intramuscular Interferon Beta-1a Autoinjector in a Real-World Clinical Setting – *Poster P7.231 – Thursday, May 1 – 3:00 PM*

#### FAMPYRA

- Prolonged-Release Fampridine Treatment and Walking Ability and Balance in Patients with Multiple Sclerosis: Results of the Randomized, Double-Blind MOBILE Study- *Data Blitz Presentation 010 – Wednesday, April 30 – 6:42 PM; Poster 010 – Wednesday, April 30 – 6:15 PM*

#### PLEGRIDY

- Analysis of 2-year Clinical Efficacy and Safety of Peginterferon Beta-1a in Patients with Relapsing-Remitting Multiple Sclerosis: Data from the Pivotal Phase 3 ADVANCE Study – *Platform S4.005 – Tuesday, April 29 – 2:00 PM*
- Peginterferon Beta-1a Significantly Increases the Proportion of Patients with Freedom from Measured Disease Activity in Relapsing-Remitting Multiple Sclerosis: Findings from the ADVANCE Study – *Platform S4.007 – Tuesday, April 29 – 2:30 PM*
- Peginterferon Beta-1a May Improve Recovery Following Relapses: Data from the Pivotal Phase 3 ADVANCE Study in Patients with Relapsing-Remitting Multiple Sclerosis – *Platform S4.003 – Tuesday, April 29 – 1:30 PM; Poster 17-1.002 – Wednesday, April 30 – 4:30 PM*

#### DACLIZUMAB HIGH-YIELD PROCESS

- Decrease in T1 black hole volume over 2 years of daclizumab high-yield process treatment – *Poster P3.188 – Tuesday, April 29 – 3:00 PM*
- Reduction in brain atrophy with extended daclizumab HYP treatment: Results of SELECT and the SELECT extension study – *Poster P3.187 – Tuesday, April 29 – 3:00 PM*

#### Anti-LINGO-1

- Efficacy and Safety of Anti LINGO-1 for the Treatment of Relapsing Forms of Multiple Sclerosis: Design of the Phase 2 SYNERGY Trial – *Poster P3.154, – Tuesday, April 29 – 3:00 PM*

#### BIIB037

- Experience in a Phase 1b Clinical Trial – *Poster P3.207 – Tuesday, April 29, 2014 – 3:00 PM*

Full session details and data presentation listings for the 2014 Annual Meeting can be found through the AAN website <https://www.aan.com/conferences/2014-annual-meeting/>.

#### **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, hemophilia and autoimmune disorders. Founded in 1978, Biogen Idec is the world's oldest independent biotechnology company. Patients worldwide benefit from its leading multiple sclerosis therapies. For product labelling, press releases and additional information about the Company, please visit [www.biogenidec.com](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 and Australia. Through a robust clinical trial program and commercial launches starting with the United States in March 2013, greater than 65,000 patients have been treated with TECFIDERA worldwide <sup>2</sup>.

TECFIDERA has been proven to reduce MS relapses, progression of disability and MS brain lesions, while demonstrating a favourable safety and tolerability profile. 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](http://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](http://www.TYSABRI.com)

### **About AVONEX**

AVONEX is one of the most prescribed treatments for relapsing forms of MS worldwide. 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. 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.

For additional important safety information, and the United States full prescribing information, please visit [www.AVONEX.com](http://www.AVONEX.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 licensed rights from Acorda 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 PLEGRIDY**

PLEGRIDY is a new molecular entity in which interferon beta-1a is pegylated to extend its half-life and prolong its exposure in the body. PLEGRIDY, an investigational candidate, is a member of the interferon class of treatments, which is often used as a first-line treatment for MS.

Regulatory authorities in the United States and the European Union accepted the marketing applications for the review of PLEGRIDY in relapsing forms of MS in 2013.

### **About Daclizumab High-Yield Process**

Daclizumab high-yield process (DAC HYP) is in late-stage clinical development for the treatment of RRMS, the most common form of MS. DAC HYP is a humanized monoclonal antibody that binds to CD25, a receptor subunit that is expressed at high levels on T cells that are thought to become abnormally activated in autoimmune conditions, such as MS. Data from previous clinical trials showed that DAC HYP increases CD56bright Natural Killer (NK) cells, which target the activated immune cells that can play a key role in MS without causing general immune cell depletion.

DAC HYP is currently being studied in the DECIDE Phase 3 clinical trial, which is evaluating the efficacy and safety of once-monthly subcutaneous DAC HYP as a monotherapy compared to interferon beta-1a therapy.

Biogen Idec is developing DAC HYP in collaboration with AbbVie, Inc.

<sup>1</sup> Biogen Idec data on file

<sup>2</sup> Biogen Idec data on file

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