



## Biogen Idec to Present Extensive New Data from Its Robust Multiple Sclerosis Portfolio at ECTRIMS

September 23, 2013

– More than 55 company-sponsored presentations underscore Biogen Idec's commitment to treatment advances for people with MS –

- Company will also launch Registry Research Fellowship Programme -

WESTON, Mass.--(BUSINESS WIRE)--[Biogen Idec](#) (NASDAQ: BIIB) will present 58 data sets from the company's multiple sclerosis (MS) clinical portfolio of approved and investigational products at the 29<sup>th</sup> Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Copenhagen, Denmark, October 2-5.

The collection of data being presented at ECTRIMS represents Biogen Idec's industry-leading expertise in MS research and showcases the company's deep understanding of differing patient needs. Through decades of cutting-edge science, Biogen Idec has more experience than any other company in advancing the treatment of this disease, recognising that physicians need therapeutic choices to meet treatment goals.

"Biogen Idec is proud to be at the forefront of innovation in MS, which has been made possible through our research and development efforts over the past 30 years," said Douglas E. Williams, Ph.D., executive vice president, Research and Development at Biogen Idec. "Our commitment has enabled us to bring a number of therapy options to patients, and we are excited to be presenting data on some promising candidates which have the potential to broaden the treatment spectrum for people living with this chronic, debilitating disease."

Data at ECTRIMS will be presented from across Biogen Idec's portfolio, including:

Approved medicines:

**TYSABRI**<sup>®</sup> (natalizumab): offers established efficacy that has been proven to reduce relapses and slow disability progression.

**TECFIDERA**<sup>®</sup> (dimethyl fumarate): an oral treatment for relapsing forms of MS, including relapsing-remitting MS (RRMS), which has been clinically proven to significantly reduce important measures of disease activity with a favorable safety/tolerability profile. TECFIDERA is currently approved in the United States, Canada and Australia.

**FAMPYRA**<sup>®</sup> (prolonged-release fampridine tablets): the first approved treatment to address the unmet medical need of walking improvement in MS patients, demonstrating efficacy in patients with all MS types. Approved in the European Union.

Investigational medicines:

**PLEGRIDY**<sup>™</sup> (pegylated interferon beta-1a): a potential new molecular entity for relapsing forms of MS in which interferon beta-1a is pegylated to extend its half-life and prolong its exposure in the body. Pegylation offers a less-frequent dosing schedule.

**DACLIZUMAB HIGH-YIELD PROCESS (DAC HYP)**: is being developed as a once-monthly subcutaneous injection. DAC HYP is believed to target the activated immune cells that can play a key role in MS without causing general immune cell depletion. DAC HYP is being developed under a collaboration agreement with AbbVie, Inc.

**Anti-LINGO-1 (BIIB033)**: is the first candidate being investigated for its potential to repair neurons damaged by MS.

### Registry Research Fellowship Program opening for applications

At ECTRIMS, Biogen Idec will also launch The Multiple Sclerosis Registry Research Fellowship Program, an initiative which solidifies our ongoing commitment to clinical research in order to improve the lives of people living with MS. Grants awarded through the program will provide an annual stipend of up to €75,000 per fellow, for training in research with large real-world evidence datasets in MS.

Full session details of the 2013 Annual Meeting can be found on the ECTRIMS website: <http://www.ectrims-congress.eu/2013>.

The titles of key Biogen Idec abstracts are as follows:

**TYSABRI:**

**October 3**

- *Poster #519: Effects of natalizumab treatment on freedom from disease activity by baseline characteristics in AFFIRM*
- *Poster #524: Natalizumab reduces the disabling amplitude of multiple sclerosis relapses and improves post-relapse residual disability*

**October 4**

- *Poster #1050: Disease activity and disability progression decrease beyond two years on natalizumab in relapsing multiple sclerosis patients in the TYSABRI<sup>®</sup> (natalizumab) Observational Programme*

## **TECFIDERA:**

### **October 3**

- *Poster #538: 4-year follow-up of oral BG-12 (dimethyl fumarate) treatment in relapsing remitting multiple sclerosis (RRMS): integrated clinical efficacy data from the DEFINE, CONFIRM, and ENDORSE studies*

### **October 4**

- *Poster #1004: 4-year follow-up of oral BG-12 (dimethyl fumarate) treatment in relapsing remitting multiple sclerosis (RRMS): integrated magnetic resonance imaging (MRI) outcomes from DEFINE, CONFIRM, and ENDORSE*
- *Poster #1127: Interim analysis of quality of life in patients with relapsing remitting multiple sclerosis treated with BG-12 (dimethyl fumarate) in the ENDORSE study*
- *Poster #996: Safety profile of BG-12 (dimethyl fumarate) in relapsing remitting multiple sclerosis: long-term interim results from the ENDORSE extension study*
- *Poster #990: Effect of BG-12 (dimethyl fumarate) in newly diagnosed relapsing remitting multiple sclerosis (RRMS) patients from the DEFINE and CONFIRM studies*
- *Poster #1100: Dimethyl fumarate and monomethyl fumarate are distinguished by non-overlapping pharmacodynamic effects in vivo*

## **FAMPYRA:**

### **October 3**

- *Poster #665: Long-term prolonged-release fampridine treatment and health-related quality of life outcomes: nine-month interim analysis of the ENABLE study*
- *Poster #658: Health-related quality of life outcomes following long-term treatment with prolonged-release fampridine: impact on psychological outcomes in the ENABLE study*

### **October 4**

- *Poster #1128: Changes in physical functioning and activity following long-term treatment with prolonged-release fampridine in the ENABLE study*

## **PLEGRIDY:**

### **October 3**

- *Poster #514: Peginterferon beta-1a provides improvements in clinical and radiological disease activity in relapsing-remitting multiple sclerosis: year 1 findings from the phase 3 ADVANCE study*

### **October 4**

- *Poster #989: Magnetic resonance imaging results from the first year of the ADVANCE study, a pivotal phase 3 trial of peginterferon beta-1a in patients with relapsing-remitting multiple sclerosis*

## **Anti-LINGO-1:**

### **October 3**

- *Poster #545: The use of magnetic resonance imaging to monitor the safety of anti-LINGO-1: findings from phase I studies in healthy volunteers and subjects with multiple sclerosis*
- *Poster #378: Blocking LINGO1 promotes axonal regeneration in the rat optic nerve crush model*

## **DACLIZUMAB HYP:**

### **October 4**

- *Poster #977: Reduction in brain atrophy with extended daclizumab HYP treatment: results of SELECT and the SELECT extension study*
- *Poster #864: Evaluation of immunogenicity in multiple sclerosis patients continuously treated with daclizumab-HYP during the SELECT and SELECTION clinical trials.*

## **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, and the company generated more than \$5 billion in annual revenues in 2012. For product labeling, press releases and additional information about the company, please visit: <http://www.biogenidec.com/>

### **About TYSABRI**

TYSABRI is approved in more than 65 countries. TYSABRI is approved in the United States as a monotherapy for relapsing forms of MS, generally for patients who have had an inadequate response to, or are unable to tolerate, an alternative MS therapy due to the risk of progressive multifocal leukoencephalopathy (PML). In the European Union, it is approved for highly active relapsing-remitting MS (RRMS) in adult patients who have failed to respond to beta interferon or glatiramer acetate or have 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. 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.

As a result of the acquisition from Elan, TYSABRI will be marketed and distributed solely by Biogen Idec. For full prescribing information and more information about TYSABRI, please visit [www.biogenidec.com](http://www.biogenidec.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 trial, 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.

For more information about FAMPYRA, 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, Canada and Australia, and is under review by regulatory authorities in the European Union.

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 with more than 3,600 MS patients, 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 more information about TECFIDERA, please visit [www.biogenidec.com](http://www.biogenidec.com)

### **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 is a member of the interferon class of treatments, which is often used as a first-line treatment for MS.

Regulatory authorities in the US and the EU accepted the marketing applications for the review of PLEGRIDY in relapsing forms of MS in July 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.

### **About the Registry Research Fellowship Program**

Information about the Biogen Idec Multiple Sclerosis Registries Research Fellowship Program is available online at [www.grantsoffice.biogenidec.com](http://www.grantsoffice.biogenidec.com) or by contacting the company Grants Office by phone at 617-914-1299 or by email via [grantsoffice@biogenidec.com](mailto:grantsoffice@biogenidec.com).

**Contact:**

MEDIA:

Annabel Cowper, +41 79 737 66 04

[public.affairs@biogenidec.com](mailto:public.affairs@biogenidec.com)

or

INVESTORS:

Carlo Tanzi, Ph.D., +1 781-464-2442

[IR@biogenidec.com](mailto:IR@biogenidec.com)