



## Biogen Idec Celebrates World MS Day

May 25, 2011

*-- Company's Unwavering Commitment to MS Highlighted By Innovative Patient Programs Worldwide and Groundbreaking R&D Initiatives--*

ZUG, Switzerland--([BUSINESS WIRE](#))--Today, [Biogen Idec](#) (NASDAQ: BIIB) will join the global multiple sclerosis (MS) community in celebrating the third annual World MS Day. Biogen Idec continues to be the industry leader in researching and providing groundbreaking therapies for MS. So far in 2011, the company has brought more hope to MS patients through a number of significant milestones. These milestones include:

- The positive CHMP opinion in Europe for FAMPYRA<sup>®</sup> (prolonged-release fampridine tablets) for the improvement of walking ability for adult patients with MS with walking disability (EDSS 4-7). FAMPYRA demonstrated efficacy in people with all types of the disease. FAMPYRA also received approval in Australia.
- Positive Phase 3 clinical results for its investigational oral compound BG-12 (dimethyl fumarate). If approved, BG-12 will be the company's first oral disease modifying therapy and may represent a new treatment option for relapsing remitting MS patients.
- Biogen Idec, along with its partner Elan Pharmaceuticals, this year anticipate the 1 millionth infusion of TYSABRI<sup>®</sup> (natalizumab), a therapy that has advanced the treatment of MS with its established efficacy. In addition, in June, the companies will celebrate the fifth anniversary of the reintroduction of TYSABRI in the United States.
- AVONEX<sup>®</sup> (interferon beta-1a), a medicine with more than 20 years of clinical experience, which has now been prescribed to more than 388,000 patients worldwide with almost 1.4 million patient years of experience, celebrates its 15<sup>th</sup> anniversary of FDA approval in the United States.

"Biogen Idec is proud to be a leader in the fight against MS and is committed to providing support and hope for all those affected by the disease," said John Richert, M.D., Vice President and Senior Neurology Fellow, Biogen Idec. "Our long-term goals are to continue working with the global community to raise awareness of the impact of MS on the lives of those affected, as well as provide convenient and effective treatment options."

In 2011, Biogen Idec is also intensifying its European awareness initiative, "Mobility Matters in MS," with the ambition to increase awareness about the significant impact mobility impairment has on the quality of life of people affected by MS. Mobility Matters in MS provides support to people affected by mobility challenges and helps to define, validate, and share mobility assessments and management techniques.

The program includes a comprehensive website ([www.mobilitymattersinms.com](http://www.mobilitymattersinms.com)), a Mobility Champions' Toolkit resource for physicians and MS centers to effectively identify, manage, and improve mobility impairment in people with MS. It includes patient support leaflets, assessment tests, and an exercise video, and will be available to download and order via the 'Mobility Matters in MS' website.

On World MS Day Biogen Idec is supporting a wide range of activities across the globe. Highlights include:

- Austria: Hosting a cinema night to showcase a much anticipated film developed by MS patients on the relationship among MS, travel, and mobility.
- Brazil: Hosting a patient event with one of Brazil's leading comedienne who has MS.
- Finland: Announcing survey data on MS patients' fears, expectations and desires.
- France: Bringing MS patients, family, and their caregivers together in a "House of MS" in various cities in France to discuss MS, to join yoga sessions, and to meet medical specialists.
- Japan: Organizing a writing competition where MS patients submit a short story telling about their life with MS and their dreams despite having MS.
- Netherlands: Sponsoring a MS recipe book created jointly by a MS nurse and a local patient group. In addition, an insightful MS patient documentary will be broadcast on national television.
- Spain: Colleagues are running a 10 kilometer race to raise money for charity and support patient organization initiatives that educate on current and future treatment options.
- Switzerland: Organizing a competitive "Step by Step" pedometer challenge for MS treating doctors. The proceeds will be donated to the Swiss MS Society.
- Sweden: Launching a Family Planning book, which highlights how to speak about difficult issues, such as receiving a MS diagnose and explaining the disease to their children.
- United Kingdom: Launching a "Mobility Matters in MS" Facebook page and Twitter feed with the aim of improving

understanding about the importance of mobility in MS.

- United States: Celebrating with the MS community the 15<sup>th</sup> anniversary of FDA approval for AVONEX.

#### **About MS**

Multiple sclerosis is a chronic, unpredictable, and progressive disease of the central nervous system that causes inflammation and destruction of the myelin sheath – the protective layer that surrounds the body's nerve fibers. This destruction may result in cognitive impairment, physical disability, and fatigue. According to the National MS Society, MS affects about 400,000 people in the U.S. and more than 2.5 million people worldwide. Relapsing-remitting MS (RRMS) affects about 85 percent of the MS population. RRMS is characterized by clearly defined flare-ups followed by periods of partial or complete recovery or remission.

#### **About Biogen Idec**

Biogen Idec uses cutting-edge science to discover, develop, manufacture and market therapies for serious diseases with a focus on neurology, immunology and hemophilia. 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 generates more than \$4 billion in annual revenues. For product labeling, press releases and additional information about the company, please visit [www.biogenidec.com](http://www.biogenidec.com).

#### **About TYSABRI**

TYSABRI is approved in more than 60 countries. In the U.S., it is approved for relapsing forms of multiple sclerosis (MS) and in the European Union for relapsing-remitting MS.

TYSABRI has advanced the treatment of MS patients with its established efficacy. It has been proven to reduce flare-ups and slow physical disability progression. Data from the Phase III 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 progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. The risk of PML increases with longer treatment duration and in patients treated with an immunosuppressant prior to 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 patients treated with TYSABRI in the post-marketing setting. Common adverse events reported in TYSABRI-treated MS patients include headache, fatigue, infusion reactions, urinary tract infections, joint and limb pain, and rash.

TYSABRI is co-marketed by Biogen Idec Inc. and Elan Corporation, plc. For more information about TYSABRI, please visit [www.tysabri.com](http://www.tysabri.com), [www.biogenidec.com](http://www.biogenidec.com) or [www.elan.com](http://www.elan.com), or call 1-800-456-2255.

#### **About AVONEX**

AVONEX is one of the most prescribed treatments for relapsing forms of MS worldwide. It is used worldwide as a treatment for relapsing forms of MS to slow the progression of physical disability and reduce relapses. AVONEX is also approved for patients who have their first clinical MS attack and have a brain MRI scan consistent with MS.

The most common side effects associated with AVONEX MS treatment are flu-like symptoms, including myalgia, fever, fatigue, headache, chills, nausea, vomiting, pain and asthenia.

AVONEX should be used with caution in patients with depression or other mood disorders and in patients with seizure disorders. AVONEX should not be used by pregnant women. Patients with cardiac disease should be closely monitored. Patients should also be monitored for signs of hepatic injury. Routine periodic blood chemistry and hematology tests are recommended during treatment with AVONEX. Rare cases of anaphylaxis have been reported.

For information regarding the European Summary of Product Characteristics visit <http://www.ema.europa.eu/ema>. For the complete United States prescribing information, please visit <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. This prolonged-release formulation was developed and is being commercialized in the U.S. by Acorda Therapeutics, Inc. under the trade name AMPYRA (dalfampridine) Extended Release Tablets, 10 mg. Biogen Idec plans to commercialize and further develop the product outside of the U.S. under a licensing agreement with Acorda.

FAMPYRA was developed using Elan's Matrix Drug Absorption System (MXDAS(TM)) technology and is manufactured by Elan.

In Australia, the use of FAMPYRA is contraindicated in patients: with hypersensitivity to fampridine or the tablet ingredients; with moderate or severe renal impairment; with a history of seizure or medically assessed as at high risk of seizure, and currently on treatment with other forms of fampridine / 4-aminopyridine.

FAMPYRA should not be administered at doses higher than the recommended dose of 10 mg, twice daily, 12 hours apart.

#### **About BG-12**

BG-12 (dimethyl fumarate) is an investigational oral therapy in clinical development for the treatment of RRMS, the most common form of MS. BG-12 is currently being evaluated as a monotherapy in two Phase 3 clinical trials, DEFINE and CONFIRM, and in combination with commonly used first-line treatments in the Phase 2 EXPLORE trial.

Top-line results from the DEFINE study showed that 240 mg of BG-12, administered either twice or three times a day, demonstrated a highly statistically significant reduction ( $p < 0.0001$ ) in the proportion of patients with RRMS who relapsed at two years compared with placebo. Both doses of BG-12 also demonstrated a statistically significant reduction in annualized relapse rate, in the number of new or newly enlarging T2 hyperintense lesions, in new gadolinium-enhancing lesions, and in the rate of disability progression as measured by the Expanded Disability Severity Scale at two

years. Initial data from the trial also showed that BG-12 demonstrated a favorable safety and tolerability profile consistent with the reported Phase II results.

Biogen Idec retains full worldwide commercial rights to BG-12.

**Safe Harbor**

This press release includes forward-looking statements, including statements about our product development and commercialization efforts. 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. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including meeting endpoints in clinical trials, obtaining regulatory approval, the occurrence of adverse safety events, product competition, the availability of reimbursement for our products, adverse market and economic conditions, problems with our manufacturing processes and our reliance on third parties, failure to comply with government regulation and possible adverse impact of changes in such regulation, our ability to protect our intellectual property rights and the cost of doing so, and the other risks and uncertainties that are described in the Risk Factors section of our most recent annual or quarterly report and in other reports we have filed with the SEC. 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.

**Contact:**

Biogen Idec  
MEDIA CONTACT:  
Claudia Matthes, +41 (0) 41 392 1981  
or  
INVESTOR CONTACT:  
Kia Khaleghpour, +1 781-464-2442