



## Biogen Idec Globally Commemorates Annual World MS Day

May 25, 2010

CAMBRIDGE, Mass.--([BUSINESS WIRE](#))--On May 26, [Biogen Idec](#) (NASDAQ: BIIB) will join the global multiple sclerosis (MS) community to commemorate the second annual World MS Day. Biogen Idec is a leader in the fight against MS, bringing hope to the thousands of patients across the globe who benefit from the company's MS therapies and ongoing research programs.

World MS Day was established by the Multiple Sclerosis International Federation to raise awareness of MS, national MS societies and those living with and affected by MS, to unite, broaden and mobilize the community and to support MS-directed fundraising. This year's World MS Day focuses on raising awareness of employment issues amongst those who are living with MS.

No company is doing more for people living with MS, and to support World MS Day, Biogen Idec will be sponsoring a number of events across the globe. Highlights include:

- In the United States, conducting a [MyMS Yoga](#) class for MS patients with world-renowned yoga instructor Baron Baptiste and teaming up with O'Jays singer Walter Williams as he shares his experiences about living with MS;
- In France, hosting an art exhibit with paintings from MS patients and partnering with local MS societies for the opening of the "House of MS" where patients and their families can go to learn more about MS and discuss living with their disease with physicians, psychologists, nurses and patient associations;
- In Germany, along with a local patient organization, hosting "Multiple Sclerosis: A Subject, that Concerns Us All," an MS awareness event with a climbing wall, artists, musicians and MS information booths;
- In Switzerland, providing yoga lessons to raise awareness of MS as part of the MS Yoga program;
- In Ireland, asking people to encourage employers to support people with MS in the workplace through a call to action;
- In Japan, distributing information about MS to the public to raise awareness of the disease; and
- In India, supporting chapters of a local patient organization through MS-educational events.

"Biogen Idec is committed to bringing hope to the MS community by developing more effective and convenient therapies for those living with MS," said John R. Richert, M.D., vice president and senior fellow, Neurology Research and Development, Biogen Idec. "Part of this effort is to set new standards to measure success and to redefine future success in MS treatment. As we continue to work with patient organizations, researchers, the medical community and industry colleagues, these goals are indeed within sight."

Biogen Idec's unwavering support for the MS community was recently acknowledged in Spain by the Sociedad Española de Neurología (SEN). The SEN awarded Dr. Guido Decap, vice president and managing director of Biogen Idec Iberia, with an Award of Honor for his contributions to and support of scientific and medical research in the field of neurology.

As a leader in the fight against MS, Biogen Idec has a comprehensive portfolio that includes two marketed therapies: [AVONEX®](#) (interferon beta-1a) and [TYSABRI®](#) (natalizumab). The company's late-stage pipeline includes four programs which have the potential to redefine future success for MS treatment:

- Fampridine, which Biogen Idec will commercialize as prolonged release tablets in markets outside of the U.S. Fampridine prolonged release tablets are undergoing marketing authorization review with the European Medicines Agency, Therapeutic Goods Administration in Australia, Medsafe in New Zealand and SwissMedic in Switzerland for the improvement of walking ability in adult patients with MS. The company has also filed a New Drug Submission with Health Canada;
- BG-12, an investigational oral therapy that has been shown to activate the Nrf2 transcriptional pathway, which, experimentally, has demonstrated both neuroprotective and anti-inflammatory properties;
- PEGylated interferon beta-1a, which through the process of PEGylation, protects the interferon beta-1a molecule from being degraded, extending the amount of time the drug remains in a patient's system; and
- Daclizumab, a monoclonal antibody that is believed to selectively target immune cells that become activated in response to MS without causing general immune cell depletion, potentially offering a distinct immunomodulatory approach to treating the disease.

### **About Multiple Sclerosis (MS)**

MS 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 Multiple Sclerosis Society in the U.S., MS affects more than 2.5 million people worldwide.

### **About Biogen Idec**

Biogen Idec creates new standards of care in therapeutic areas with high unmet medical needs. Biogen Idec is a global leader in the discovery, development, manufacturing, and commercialization of innovative therapies. Patients worldwide benefit from Biogen Idec's significant products that address diseases such as lymphoma, multiple sclerosis, and rheumatoid arthritis. 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 45 countries. In the U.S., it is approved for relapsing forms of MS and in the European Union for relapsing-remitting MS.

Data from the Phase III AFFIRM trial highlights TYSABRI's powerful efficacy. According to that data, which was published in the *New England Journal of Medicine*, 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 ( $p < 0.001$ ). In post-hoc analyses of the Phase III AFFIRM trial and as published in *The Lancet Neurology*, 37 percent of TYSABRI-treated patients remained free of their MS activity, based on MRI and clinical measures, compared to seven percent of placebo-treated patients.

TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain. The risk of PML increases with increasing duration of use, with limited experience beyond three years of treatment. 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 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, with nearly 140,000 patients on therapy. Biogen Idec estimates approximately 1.3 million person-years of exposure to AVONEX. 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 multiple sclerosis 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. Please see complete prescribing information available at [www.AVONEX.com](http://www.AVONEX.com).

### **About Fampridine**

Fampridine (4-aminopyridine or 4-AP) prolonged release tablet formulation is an investigational drug. Fampridine prolonged release tablets act by blocking the potassium channels in demyelinated nerves, which reduces the leakage of current from the axons, restoring neuronal conduction, and action potential formation.

This tablet formulation was developed and commercialized in the U.S. by Acorda Therapeutics under the brand name AMPYRA®. Biogen Idec will commercialize fampridine prolonged release tablets in markets outside of the U.S.

### **About BG-12**

BG-12 (BG00012, dimethyl fumarate) is an investigational oral therapy in Phase III clinical development for the treatment of relapsing-remitting multiple sclerosis (RRMS), the most common form of MS, and in Phase II clinical development for rheumatoid arthritis (RA). BG-12 received Fast Track designation in MS from the US Food and Drug Administration (FDA), which may expedite U.S. regulatory review. Biogen Idec retains full worldwide commercial rights to BG-12.

The Phase IIb study of BG-12, which was published in *The Lancet*, showed that BG-12 reduced the number of new gadolinium enhancing (Gd+) lesions by 69 percent in patients with RRMS when compared to treatment with placebo ( $p < 0.0001$ ). The presence of Gd+ lesions is thought to indicate continuing inflammatory activity within the central nervous system. Results from this study stimulated further evaluation of BG-12's potential for neuroprotection. BG-12 is the first compound in trials for the treatment of MS that has been shown to activate the Nrf2 pathway.

### **About PEGylated Interferon beta-1a**

PEGylated interferon beta-1a is under investigation for the treatment of RMS and is currently enrolling a Phase III clinical trial. PEGylation, administered via subcutaneous injection, protects the interferon beta-1a molecule from being degraded, extending the amount of time the drug remains in a patient's system.

### **About Daclizumab**

Daclizumab is a humanized monoclonal antibody that binds to the CD25 alpha subunit of the high affinity IL-2 receptor. CD25 is expressed at low levels on resting T-cells (immune cells) and at high levels on T-cells that can become activated in response to autoimmune conditions such as MS. Daclizumab is believed to work by selectively binding to and inhibiting this receptor on activated T-cells without causing T-cell depletion. Daclizumab is an investigational agent in clinical development for the treatment of MS under collaboration between Facet Biotech, acquired by Abbott in April 2010, and Biogen Idec. Daclizumab is currently being studied in two registrational clinical trials in patients with MS.

### **Safe Harbor**

This press release contains forward-looking statements about our products in development. Drug development and commercialization involves a high degree of risk, and all of our products are subject to a number of risks and uncertainties, including that we may be unable to adequately address concerns or questions raised by FDA or other regulatory authorities, the occurrence of adverse safety events with our products, that concerns may arise from additional data, that we may not be able to get the drugs in development approved and that the incidence or risk of any safety issues with respect to our products may be higher than observed in clinical trials. The company may also encounter other unexpected hurdles. Additional risks and uncertainties are described in the Risk Factors section of our reports on Form 10-K and Form 10-Q and in other reports we file with the SEC. These

forward-looking statements speak only as of the date of this press release, and we do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future events, or otherwise.

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