

# Biogen Idec Features Data on AVONEX(R) and TYSABRI(R) and Showcases the Company's Multiple Sclerosis Development Pipeline at the World Congress On Treatment and Research in Multiple Sclerosis

September 18, 2008

Company's Commitment to Multiple Sclerosis Patients Remains Strong

MONTREAL--(<u>BUSINESS WIRE</u>)--Biogen Idec (NASDAQ: BIIB) will present new data on the company's leading multiple sclerosis (MS) franchise at the World Congress on Treatment and Research in Multiple Sclerosis taking place this week in Montreal, Canada. Nearly 20 presentations will focus on the company's products: TYSABRI<sup>®</sup> (natalizumab), which offers MS patients a new level of efficacy, and AVONEX<sup>®</sup> (Interferon beta-1a), the most prescribed MS therapy worldwide, as well as its pipeline featuring compounds targeting unique approaches for development in MS. These data will provide physicians with important new information on the benefits of TYSABRI and AVONEX, and update the MS community on the company's progress with three of its investigational compounds for MS: daclizumab, RITUXAN<sup>®</sup> (rituximab) and BG-12 (dimethyl fumarate), the company's novel, oral compound in Phase III trials.

Biogen Idec also announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to BG-12. The FDA's fast track programs are designed to expedite the review of new drugs that are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. The benefits of Fast Track include scheduled meetings to seek FDA input into development plans, the option of submitting a New Drug Application in sections rather than all components simultaneously, and the option of requesting evaluation of studies using surrogate endpoints. The Fast Track designation is intended for the combination of a product and a claim that addresses an unmet medical need.

"With TYSABRI and AVONEX, Biogen Idec has provided treatments that have transformed the lives of many patients with MS," said Michael Panzara, MD, MPH, Vice President, Chief Medical Officer of Neurology, Biogen Idec. "However, the need for additional therapies has led to our continued focus on developing new and exciting products that seek to combat MS in unique ways, including BG-12, an oral MS therapy currently in the final stages of development. With two therapies already approved to treat MS, and four compounds in clinical trials, Biogen Idec continues to lead the field in developing MS treatments."

For the first time, the World Congress on Treatment and Research in Multiple Sclerosis will bring together the leading MS-focused professional organizations from around the world including ACTRIMS (the Americas Committee on Treatment and Research in Multiple Sclerosis), and its counterparts in Europe and Latin America: ECTRIMS and LACTRIMS. The meeting will be attended by over 3,500 clinicians, clinical researchers, and scientists from around the globe coming together for the largest international forum of MS clinicians and researchers in the world.

The following is a sampling of presentations that will be held during the World Congress:

## <u>TYSABRI</u>

TYSABRI is thought to inhibit the adhesion of certain molecules on the surface of immune cells. Research suggests TYSABRI works by preventing immune cells from migrating from the bloodstream into the brain where they can cause inflammation and potentially damage nerve fibers and their insulation.

- [P8] Effect of natalizumab on relapses in patients with relapsing multiple sclerosis who experience MRI activity during treatment - Thursday, September 18, 3:30 PM
- [P62] Natalizumab increases the proportion of disease-free patients in relapsing multiple sclerosis Thursday, September 18, 3:30 PM
- [P474] Natalizumab significantly increases the cumulative probability of sustained improvement in physical disability -Friday, September 19, 3:30 PM
- [P488] Natalizumab utilization and safety in patients with relapsing multiple sclerosis: updated results from TOUCH ™ and TYGRIS Friday, September 19, 3:30 PM
- [P494] Safety and effectiveness of natalizumab re-dosing and treatment in the STRATA study Friday, September 19, 3:30 PM
- [P516] Natalizumab utilization and safety in the TYGRIS program in the European Union Friday, September 19, 3:30 PM

## AVONEX

AVONEX is thought to limit the immune response seen in MS that causes the immune system to attack the nerve cells in the brain and spinal cord. By controlling the damage done to the nerve cells, AVONEX interacts with these immune cells to limit the "attack."

• [P14] AVONEX 15-year long-term follow-up study of patients with relapsing multiple sclerosis - Thursday, September 18, 3:30 PM

- [P39] A multi-centre, open label, non-comparative trial investigating the recovering of IFN-beta efficacy in breakthrough relapsing-remitting multiple sclerosis patients with neutralizing IFN-beta antibodies (RECOVER) Thursday, September 18, 3:30 PM
- [P56] Investigation of the effect of early initiation of therapy with interferon beta-1a (i.m.) on disease course, quality of life and cognition in patients with relapsing-remitting multiple sclerosis Thursday, September 18, 3:30 PM
- [P76] Magnetic resonance imaging activity predicts multiple sclerosis patients' response to treatment with interferon beta-1a Thursday, September 18, 3:30 PM
- [P410] Quality of life in 1,000 patients with relapsing-remitting multiple sclerosis and the impact of treatment initiation with intramuscular interferon beta-1a Thursday, September 18, 3:30 PM
- [P415] The relationship between baseline clinical measures and quality of life in patients with relapsing multiple sclerosis: analyses from the phase 3 trial of intramuscular interferon beta-1a Thursday, September 18, 3:30 PM
- [P504] Predictors of long-term disability in relapsing multiple sclerosis: 8- and 15-year analyses from the phase 3 clinical trial of intramuscular interferon beta-1a Friday, September 19, 3:30 PM
- [P523] A multivariate analysis of factors that influence adherence with disease-modifying therapy in multiple sclerosis -Friday, September 19, 3:30 PM

## <u>BG-12</u>

BG-12 is an oral formulation of dimethyl fumarate in development for MS. It is the first compound that has been shown to activate the Nrf2 pathway. Experimentally, this pathway has been associated with reduction in oxidative cell damage and inflammatory responses, which may provide cytoprotective and anti-inflammatory effects.

- [P50] Safety Profile of BG00012, an oral formulation of dimethyl fumarate for patients with relapsing MS Thursday, September 18, 3:30 PM
- [P459] The effect of BG00012 on conversion of gadolinium-enhancing lesions to T1-hypointense lesions Friday, September 19, 3:30 PM

## **Daclizumab**

Daclizumab is a humanized monoclonal antibody that binds to the alpha chain (CD25) of the interleukin-2 (IL-2) receptor on activated T cells, which are white blood cells that play a role in inflammatory and immune-mediated processes in the body. It is currently being tested in a Phase 2 study in patients with multiple sclerosis.

- [P479] Daclizumab exhibits efficacy in multiple sclerosis subjects positive for interferon-beta neutralizing antibodies -Friday, September 19, 2008, 3:30 PM
- [P521] Exposure-response relationship of daclizumab added to interferon-beta for treatment of multiple sclerosis during a phase 2 study Friday, September 19, 2008, 3:30 PM

## <u>RITUXAN</u>

RITUXAN is a therapeutic antibody that targets and selectively depletes CD20-positive B-cells.

• Efficacy and safety of rituximab in patients with primary progressive multiple sclerosis: results of a randomized, doubleblind, placebo-controlled, multicenter trial - Saturday, September 20, Late breaking news, 8:30 AM

#### About AVONEX

AVONEX is the most prescribed treatment for relapsing forms of MS worldwide, with more than 130,000 patients on therapy. It is used worldwide as a treatment for relapsing forms of MS to slow the progression of 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 <u>www.avonex.com</u>.

#### About TYSABRI

TYSABRI is a treatment approved for relapsing forms of MS in the US and relapsing-remitting MS in the European Union. According to data that have been published in the *New England Journal of Medicine*, after two years, TYSABRI treatment led to a 68% relative reduction (p<0.001) in the annualized relapse rate compared to placebo and reduced the relative risk of disability progression by 42-54% (p<0.001).

TYSABRI was recently approved to induce and maintain clinical response and remission in adult patients with moderately to severely active Crohn's disease (CD) with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-alpha. According to the US full prescribing information, among patients who responded to TYSABRI, 54% sustain their response through every visit for one year compared to 20% of patients receiving placebo (p<0.001), for a treatment difference of 34%

TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. Cases of PML have been reported in patients taking TYSABRI who were recently or concomitantly treated with immunomodulators or immunosuppressants, as well as in patients receiving TYSABRI as monotherapy. Other serious adverse events that have occurred in TYSABRI-treated patients included hypersensitivity reactions (e.g., anaphylaxis) and infections. Serious opportunistic and other atypical infections have been observed in TYSABRI-treated patients, some of whom were receiving concurrent immunosuppressants. Herpes infections were slightly more common in patients treated with TYSABRI. In MS and CD clinical trials, the incidence and rate of other serious adverse events, including serious infections, were similar in patients receiving TYSABRI and those receiving placebo. Common adverse events reported in TYSABRI-treated CD patients include respiratory tract infections, joint and limb pain and rash. Other common adverse events reported in TYSABRI-treated CD patients include respiratory tract infections and nausea. Clinically significant liver injury has been reported in patients treated with TYSABRI and those receiving and nausea. Clinically significant liver injury has been reported in patients treated with TYSABRI and the respiratory tract infections and nausea.

TYSABRI is approved in more than 35 countries. At the end of June 2008, more than 31,800 patients were on commercial and clinical TYSABRI therapy worldwide. Patients on TYSABRI therapy have continued to increase. An update will be provided in October in conjunction with Biogen Idec's third quarter earnings release.

For more information about TYSABRI please visit www.tysabri.com, www.biogenidec.com or www.elan.com or call 1-800-456-2255.

#### Daclizumab

Although daclizumab is currently marketed for other uses, it is not approved for use in patients with MS.

#### BG-12

Although BG-12 (dimethyl fumarate) is currently marketed for other uses, it is not approved for use in patients with MS.

#### RITUXAN

Although RITUXAN is currently marketed for other uses, it is not approved for use in patients with MS.

#### About Biogen Idec

Biogen Idec creates new standards of care in therapeutic areas with high unmet medical needs. Founded in 1978, Biogen Idec is a global leader in the discovery, development, manufacturing, and commercialization of innovative therapies. Patients in more than 90 countries 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 <u>www.biogenidec.com</u>.

For more information about TYSABRI, please visit <u>www.tysabri.com</u>. For more information about AVONEX, please visit <u>www.avonex.com</u>. For more information about RITUXAN, please visit <u>www.rituxan.com</u>.

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