



Biogen Idec's Commitment to MS Demonstrated Through Significant Scientific Data Being Presented at the 28th ECTRIMS

October 10, 2012

– More than 50 Company- and Partner-Sponsored Presentations from the Biogen Idec MS Franchise and Pipeline to be Presented at the MS Community's Largest Medical Meeting –

WESTON, Mass.--(BUSINESS WIRE)--[Biogen Idec](#) (NASDAQ: BIIB) will have extensive data from the company's leading multiple sclerosis (MS) franchise presented during the 28th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Lyon, France, October 10 – 13. Fifty-three poster and platform presentations will further showcase Biogen Idec's commitment to advancing the treatment of MS and improving the lives of people living with the disease around the world.

"For nearly 20 years, Biogen Idec has had a steadfast commitment to the MS community. This began with the approval of AVONEX and then TYSABRI, and continues today with the global regulatory submissions for oral dimethyl fumarate," said Alfred Sandrock, M.D., Ph.D., senior vice president, development sciences and chief medical officer, Biogen Idec. "Our continued dedication to the advancement of MS treatment is evident in our pipeline, which is the deepest in the industry. Though significant advances have been made, we will not rest while there is so much more we can do to improve the lives of those living with MS."

Data from the Biogen Idec MS Pipeline

Key scientific highlights being presented during ECTRIMS from the company's pipeline will include analyses of pooled data from the Phase 3 DEFINE and CONFIRM clinical trials of oral dimethyl fumarate (BG-12), primary results from the daclizumab high-yield process (DAC HYP) SELECTION study, and early-stage research showing the results of a study of anti-LINGO 1 (BIIB033) in optic nerve damage in animal models.

Dimethyl Fumarate

Dimethyl fumarate has been studied as an oral agent for MS and is currently under regulatory review in the United States, European Union, Switzerland, Australia and Canada for the treatment of MS. Detailed data from the program's two Phase 3 clinical trials, DEFINE and CONFIRM, were recently published in *The New England Journal of Medicine*. There will be 14 posters, one platform presentation and one late breaking news poster presented. Highlights include:

- Clinical efficacy of BG-12 in relapsing-remitting multiple sclerosis: an integrated analysis of the Phase 3 DEFINE and CONFIRM studies – Platform 151
- Safety and tolerability of BG-12 in patients with relapsing-remitting multiple sclerosis: an integrated analysis of the placebo-controlled studies – Poster 484
- Effects of BG-12 on magnetic resonance imaging outcomes in relapsing-remitting multiple sclerosis: an integrated analysis of the Phase 3 DEFINE and CONFIRM studies – Poster 920
- Long-term safety and tolerability of oral BG-12 (dimethyl fumarate) in relapsing-remitting multiple sclerosis: interim results from ENDORSE – Late Breaker Poster 1103

DAC HYP

DAC HYP is an investigational, once-monthly subcutaneous therapy that is in Phase 3 clinical development for the treatment of RRMS. Five DAC HYP posters will be presented, along with one late breaking news platform presentation of the primary results from the SELECTION study, a randomized, double-blind extension study designed to assess sustained efficacy and safety of DAC HYP in the second year of treatment. Highlights include:

- The effect of daclizumab HYP on sustained disability progression in the SELECT trial – Poster 949
- Effect of daclizumab HYP treatment in highly active relapsing-remitting multiple sclerosis: results from the SELECT study – Poster 463
- Primary results of the SELECTION trial of daclizumab HYP in relapsing multiple sclerosis – Late Breaker Presentation 169

Anti-LINGO 1

Anti-LINGO 1 is a monoclonal antibody in early stage clinical trials. Previous data from animal models have shown that it promotes remyelination and axon survival. Proof of concept studies in optic neuritis are expected to start in the fourth quarter of this year, and during the second half of 2013 for MS. Two company-sponsored anti-LINGO 1 posters will be presented at the Congress:

- BIIB033 Anti-LINGO-1 antibody reduces optic nerve axonal degeneration in MOG- EAE rodent models – Poster 785
- Technical feasibility of implementing multifocal VEP for multicentre clinical trials – Poster 281

Data from the Biogen Idec MS Franchise

TYSABRI

TYSABRI is approved in the United States for relapsing forms of MS and in the European Union for RRMS. There will be 10 company- and partner-sponsored TYSABRI posters and one platform presentation. Highlights include:

- Long-term safety and efficacy of natalizumab and assessment of 2-year freedom from clinical disease activity in patients with multiple sclerosis in the TYSABRI Observational Program (TOP) – Poster 519
- Improvement of MS-related fatigue also significantly improves quality of life in patients treated with natalizumab: results from the TYNERGY trial – Poster 445
- Relation of disease activity-free status to visual function in the AFFIRM trial – Poster 557
- Utilization of JC-virus antibody testing in clinical practice – Poster 546

AVONEX

AVONEX is one of the most prescribed treatments for relapsing forms of MS worldwide. AVONEX PEN, the first intramuscular autoinjector approved for MS, is available in the United States and European Union for those choosing AVONEX to treat their MS. Ten AVONEX posters will be presented. Highlights include:

- Interim analysis of AMETYST: a Phase 4 observational study of the impact of intramuscular interferon beta-1a on quality of life, disability, and cognition in patients with clinically isolated syndrome/clinically definite multiple sclerosis – Poster 1047
- Interferon beta-1a (AVONEX) as treatment option for untreated MS patients (AXIOM) – Poster 1007

FAMPYRA

FAMPYRA is a novel MS treatment approved in the European Union to improve walking in adult patients with MS who have walking disability (EDSS between 4.0 and 7.0). There will be seven company- and partner-sponsored posters focusing on FAMPYRA. Highlights include:

- Dalfampridine extended release tablets: safety profile after 2 years of post-marketing experience in the United States – Poster 1026, sponsored by Acorda Therapeutics
- An alternative approach to estimate the health economic value of a non-disease modifying therapy for patients with multiple sclerosis: a Swedish application – Poster 1032

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 generates more than \$5 billion in annual revenues. For product labeling, press releases and additional information about the company, please visit www.biogenidec.com.

About Dimethyl Fumarate

Dimethyl fumarate, also known as BG-12, is an investigational oral therapy in late-stage clinical development for the treatment of relapsing-remitting multiple sclerosis (RRMS), the most common form of MS. Dimethyl fumarate is the only currently known investigational compound for the treatment of RRMS that has experimentally demonstrated activation of the Nrf-2 pathway.

Dimethyl fumarate is currently under review by regulatory authorities in the United States, European Union, Australia, Canada and Switzerland.

About DAC HYP

Daclizumab high-yield process (DAC HYP) is a subcutaneous formulation of daclizumab 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 CD56^{bright} 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 1-a therapy.

Biogen Idec is developing DAC HYP in collaboration with Abbott.

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. 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 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 progressive multifocal leukoencephalopathy (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.

TYSABRI is marketed and distributed by Biogen Idec Inc. and Elan Corporation, plc (NYSE: ELN). For full prescribing information, including boxed warning and important safety information, and more information about TYSABRI, please visit www.biogenidec.com or www.elan.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.

Two AVONEX dosing innovations were recently approved by regulators in the United States and European Union. The first is a clinically-supported schedule for gradually escalating the dose of AVONEX at the start of therapy, which has been shown to reduce the incidence and severity of flu-like symptoms that can occur with AVONEX treatment. The second, AVONEX PEN, is the first single-use, once-a-week, fully integrated intramuscular autoinjector for MS. It is designed for use with AVONEX treatment in patients with relapsing forms of MS. AVONEX PEN integrates the currently approved AVONEX Prefilled Syringe and incorporates a smaller needle (25 gauge, 5/8 inch), which is thinner and 50 percent shorter than the standard AVONEX Prefilled Syringe needle.

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. There are no adequate and well-controlled studies in pregnant women. 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 complete United States full prescribing information, please visit 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 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 Safe Harbor Statement

This press release contains forward-looking statements, including statements about product development and commercialization. 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. Drug development and commercialization involve a high degree of risk. Factors which could cause actual results to differ materially from current expectations include the risk that we may not fully enroll our planned clinical trials, adverse safety events may occur, regulatory authorities may require additional information or may fail to approve any potential new therapy, product reimbursement may be limited or unavailable, there may be problems with manufacturing processes, intellectual property rights may not be adequately protected, and the other risks and uncertainties that are described in the Risk Factors section of Biogen Idec Inc.'s most recent annual or quarterly report and in other reports Biogen Idec Inc. has filed with the SEC. These statements are based on current beliefs and expectations and speak only as of the date of this press release. Biogen Idec Inc. does not undertake any obligation to publicly update any forward-looking statements.

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