Biogen Idec Makes Statement About U.S. FDA Approval of Gilenya™

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WESTON, Mass.--(BUSINESS WIRE)--Biogen Idec is committed to improving the lives of people with multiple sclerosis (MS), and no company is doing more for these patients. There has been a desire within the MS community for an oral treatment for a long time, and the approval of Gilenya has made this a reality.

MS impacts each person differently and, until we have a cure, there should be multiple treatments available to address the individual needs of patients. Today, Biogen Idec is pleased to provide leading MS therapies AVONEX® (interferon beta-1a) and TYSABRI® (natalizumab), both of which have been used in a broad range of patients worldwide.

Biogen Idec also has the most robust pipeline in the industry, with three late-stage clinical candidates that target multiple pathways thought to be critical in treating MS. BG-12, our Phase 3 investigational oral therapy, has demonstrated promising safety and efficacy data in clinical studies, which supported its further investigation. Prior clinical evidence suggests that BG-12 may have the potential to both reduce inflammation and promote neuroprotection. We look forward to seeing the Phase 3 data in 2011.

As with any treatment, patients and physicians should consider not only efficacy, but safety, tolerability and long-term experience when choosing a treatment option. The long-term safety profile of Gilenya has yet to be established and there is limited data for it in patients with certain common comorbidities. We agree with the FDA that there is a need for safety monitoring for Gilenya through a comprehensive Risk Evaluation and Mitigation Strategy (REMS). As we enter an era where new therapies may have important safety concerns, we believe it is the responsibility of all companies bringing MS drugs to market to be rigorous in monitoring for these issues.

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 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.

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 ($p<0.001$).

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 increasing duration of treatment. The risk of PML also increases with immunosuppressant use prior to TYSABRI therapy, and this increased risk is independent of treatment duration. 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,www.biogenidec.com or 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 140,000 patients on therapy. 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.

About BG-12

BG-12 (BG00012, dimethyl fumarate) is an investigational oral therapy in Phase III clinical development as a monotherapy 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 U.S. 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 as a monotherapy 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.

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