New TYSABRI® Data Show Earlier Treatment and Longer-Term Use Result in Significant Reductions in MS Disease Activity

October 3, 2013

– Earlier Treatment with TYSABRI Demonstrated Reduction in Relapse Severity, Accelerated Relapse Recovery and Greater Potential for No Clinical or MRI Activity –

– TYSABRI Use Beyond Two Years Continued to Reduce Disability Progression and Maintained Very Low Relapse Rates –

WESTON, Mass.--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) today announced results from several new analyses of TYSABRI® (natalizumab) data that demonstrate its effectiveness in reducing multiple sclerosis (MS) disease activity. This effect was particularly significant in people with relapsing MS who initiated treatment when they had lower Expanded Disability Status Scale (EDSS) scores as well as in those who have been treated for more than two years. These data will be presented at the 29th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Copenhagen, Denmark from 2-5 October.

"These analyses build upon a growing body of evidence that demonstrates greater clinical benefits for people with MS when TYSABRI is initiated earlier in the course of the disease, as well as when TYSABRI is used for a longer duration in appropriate patients," said Alfred Sandrock, M.D., Ph.D., group senior vice president, Development Sciences and Chief Medical Officer, Biogen Idec.

More Patients Demonstrated No Evidence of Clinical or MRI Disease Activity with Earlier TYSABRI Use

AFFIRM was a two-year, randomized, multi-center, placebo-controlled, double-blind study of 942 patients evaluating the effect of TYSABRI on the rate of clinical relapses and the progression of disability as measured by at least a one-point worsening in EDSS score sustained for three months.

A post-hoc analysis of AFFIRM was undertaken to determine which baseline characteristics were associated with patients showing no evidence of clinical or MRI disease activity (defined as no relapse, no 12-week sustained EDSS progression, and no gadolinium-enhancing [Gd+] or new/enlarging T2-hyperintense lesions) at two years. A greater proportion of TYSABRI patients were found to have no evidence of clinical or MRI disease activity compared to those on placebo in all sub-groups analyzed with the beneficial effect being significantly greater in patients with an EDSS score of <3.0 versus ≥ 3.0 at baseline.

Fewer and Less-Severe Relapses with TYSABRI

An additional sub-analysis of AFFIRM assessed the effectiveness of TYSABRI on reducing relapse severity and recovery from relapse compared to placebo. Observations from this sub-analysis showed that patients treated with TYSABRI experienced less-severe relapses, as measured by EDSS score changes during the relapse and residual deficits following relapse.

These data will be presented in the poster session titled, "Immunomodulation/Immunosuppression," on Friday, 4 October at 3:45 p.m. – 5:00 p.m. CET:

- *Effects of natalizumab treatment on freedom from disease activity by baseline characteristics in AFFIRM* (poster 519)
- *Natalizumab reduces the disabling amplitude of multiple sclerosis relapses and improves post-relapse residual disability* (poster 524)

Clinical Benefit of TYSABRI Improves Beyond Two Years of Treatment

An analysis of data from the TYSABRI Observational Program (TOP), an ongoing observational, open-label, 10-year prospective study of relapsing-remitting MS (RRMS) patients, assessed patients who have been treated with TYSABRI for at least four years. The analysis found that patients with less disability at baseline (EDSS score of <3.0 at baseline) had a significantly greater reduction in 12 month sustained disability progression in months 25-48 compared with months 0-24. Additionally, annualized relapse rates (ARR) in patients treated with TYSABRI decreased from 2.03 at baseline to 0.19 during months 0-24 and 0.18 during months 25-48 ($p<0.0001$).

"TYSABRI has advanced the treatment of RRMS patients with its established efficacy," Sandrock added. "This analysis is encouraging because it provides new insight into the use of TYSABRI beyond two years and suggests that effects of treatment are even better with longer use in appropriate patients."

These data will be presented in the poster session titled, "Long-Term Treatment Monitoring," on Friday, 4 October at 3:30 p.m. – 5:00 p.m. CET:

- *Disease activity and disability progression decrease beyond 2 years on natalizumab in relapsing MS patients in the TYSABRI® (natalizumab) Observational Program* (poster 1050)

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 glatiramer acetate 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 ($p<0.001$).

Important Information about TYSABRI

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. For full prescribing information, including boxed warning and important safety information, and more information about TYSABRI, please visit www.biogenidec.com.

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

Safe Harbor

This press release contains forward-looking statements, including statements about the potential therapeutic effect of TYSABRI in certain patients. These statements may be identified by words such as "believe," "expect," "may," "plan," "potential," "will" and similar expressions, and are based on our current beliefs and expectations. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including the occurrence of adverse safety events, failure to comply with government regulation, product liability claims 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.

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