New TYSABRI Data Reaffirm Substantial Efficacy in Treatment of People with MS and Demonstrate Stability of Anti-JCV Antibody Status

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– Continued Research into Risk Stratification and PML Early Detection Provides Additional Insights for Physicians –

WESTON, Mass.--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) and Elan Corporation, plc (NYSE: ELN) announced results from several studies of TYSABRI® (natalizumab) that demonstrate its efficacy compared to other multiple sclerosis (MS) treatments, provide additional data supporting anti-JC virus (JCV) antibody status stability, and suggest better outcomes when progressive multifocal leukoencephalopathy (PML) is detected early. These data will be presented at the 65th Annual Meeting of the American Academy of Neurology (AAN) in San Diego.

"These new data reinforce our belief in the substantial efficacy TYSABRI has demonstrated at both the early and advanced stages of relapsing forms of MS," said Alfred Sandrock, M.D., Ph.D., senior vice president, Development Sciences and chief medical officer, Biogen Idec. "We are also encouraged by the consistency in anti-JCV antibody status demonstrated over 18 months, as well as results from our pursuit of additional paths to help mitigate the impact of PML. These combined efforts may allow a more individualized approach when selecting TYSABRI treatment, while helping physicians better understand a patient's benefit-risk profile."

Substantial TYSABRI Efficacy Demonstrated Against First-Line Therapies

In an independent statistical analysis led by Timothy Spelman and Helmut Butzkueven, M.D. at the University of Melbourne, with contribution by Fabio Pellegrini and Annie Zhang, TYSABRI demonstrated a significantly lower rate of first relapse compared to interferon beta (IFN) and glatiramer acetate (GA). This propensity-matched analysis was conducted using data from two MS patient registries: TYSABRI Observational Program (TOP) and MSCOMET. The results indicate that relapses were not only more likely to occur in patients taking IFN and GA, but that they occurred more quickly, when compared to patients taking TYSABRI (hazard ratio 2.73, 95 percent confidence interval 2.10-3.55, p<0.001).

- *Comparison of Patients Treated with Natalizumab and Interferon-Beta/Glatiramer Using Propensity-Matched Multiple Sclerosis Registry Data (P01.211)* will be available for viewing on Monday, March 18, 2013 from 2:00 to 6:30 p.m. PDT

Anti-JCV Antibody Stability Data Support Risk Stratification Approach

To help physicians better identify the most appropriate patients for TYSABRI treatment, Biogen Idec developed a risk stratification approach. This approach assesses each patient's personal benefit-risk profile based on several factors, including anti-JCV antibody status, which was added to the TYSABRI EU label in 2011 and the U.S. label in 2012.

An analysis of data from the longitudinal, observational U.S. study of TYSABRI-treated patients, STRATIFY-1, demonstrates that anti-JCV antibody status remained consistent in 90 percent of the study population when tested every six months over an 18-month period. Approximately 38 percent of patients tested consistently negative and 52 percent tested consistently positive.

- *Longitudinal Stability of Anti-JC Virus Antibody Status in Multiple Sclerosis Patients: Results of STRATIFY-1 (S30.001)* will be presented on Wednesday, March 20, 2013 from 2:00 to 3:45 p.m. PDT

Early PML Detection May Improve Survival

Results from Biogen Idec's ongoing research into PML, an infrequent but serious brain infection, suggest that TYSABRI-treated patients who develop PML and are asymptomatic at time of diagnosis may have improved survival and less functional disability compared with patients who are diagnosed when symptomatic.

This analysis includes preliminary data from four years of case reports and evaluates outcomes in 319 TYSABRI-treated patients who developed PML, 21 of whom had no clinical symptoms of PML but were diagnosed based on magnetic resonance imaging (MRI) findings that were consistent with PML and spinal fluid that was positive for the presence of JCV. It shows that survival following PML was 100 percent in the patients without symptoms at diagnosis, compared to 77 percent in the patients with symptoms at diagnosis. Functional outcomes and disability were also better in the asymptomatic group one year after PML diagnosis: the average score on the Karnofsky Performance Scale, which measures functional outcomes, was 70 for asymptomatic patients (meaning the person can care for him/herself), compared to 47 for those with symptoms at diagnosis (meaning the person may be disabled and requires considerable assistance and frequent medical care; p=0.021); and scores on the Expanded Disability Status Scale, which measures disability, were numerically better for asymptomatic patients (3.7 vs. 6.5 p=0.066).

- *Natalizumab–associated Progressive Multifocal Leukoencephalopathy (PML) in Multiple Sclerosis Patients: Survival and Functional Outcome when Asymptomatic at Diagnosis (P04.271)* will be available for viewing on Wednesday, March 20, 2013 from 7:30 a.m. – 12:00 p.m. PDT

For members of the media interested in more information and additional resources, please visit www.biogenidec.com/us_media_corner.

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. For full prescribing information and more information about TYSABRI, please visit www.biogenidec.com.

About Multiple Sclerosis

Multiple sclerosis (MS) is a chronic, often disabling disease that attacks the central nervous system (CNS), which is made up of the brain, spinal cord and optic nerves. Symptoms may be mild or severe, ranging from numbness in the limbs to paralysis or loss of vision. The progression, severity and specific symptoms of MS are unpredictable and vary from one person to another. MS affects more than 2.5 million people worldwide,[1] with approximately 400,000 sufferers in the United States.[2] Relapsing-remitting MS is the most common form of the disease, accounting for 85 percent of cases, and is characterized by clearly defined acute attacks with full recovery or with residual deficit upon recovery.[3]

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 Elan

Elan is a biotechnology company, headquartered in Ireland, committed to making a difference in the lives of patients and their families by dedicating itself to bringing innovations in science to fill significant unmet medical needs that continue to exist around the world. For additional information about Elan, please visit http://www.elan.com.

Safe Harbor

This press release contains forward-looking statements, including statements regarding risk-stratification and the therapeutic impact of TYSABRI in MS. 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. 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 and possible adverse impact of changes in such 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.

[1] Multiple Sclerosis International Federation. *About MS – What is MS.* Date Accessed: March 6, 2013. http://www.msif.org/en/about_ms/what_is_ms.html

[2] Multiple Sclerosis Association of America (MSAA). *About MS.* Date accessed: March 6, 2013. http://mymsaa.org/about-ms/overview/

[3] National Multiple Sclerosis Society (NMSS). *For People with Relapsing MS*. Date accessed: March 6, 2013. http://www.nationalmssociety.org/about-multiple-sclerosis/relapsing-ms/index.aspx

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