TYSABRI® (natalizumab) Data at ECTRIMS Reaffirm Positive Effects of Treatment for People with Relapsing Forms of MS

October 11, 2012

-- Data demonstrate TYSABRI effect on Annualized Relapse Rates and EDSS scores over 4 years--

-- A pooled analysis report TYSABRI effect on fatigue at 12 months --

-- Long-term safety data presented are consistent with current TYSABRI labeling --

WESTON, Mass. & DUBLIN--(BUSINESS WIRE)--Today, Biogen Idec (NASDAQ: BIIB) and Elan Corporation, plc (NYSE: ELN) announced that results from 11 company-sponsored TYSABRI presentations, including 10 posters and one platform, will be available for viewing at the 28TH Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Lyon, France, October 10 – 13.

Key data highlights from ECTRIMS 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
- *Imaging findings for PML in natalizumab-treated MS patients* – Platform 99

“These data further establish the benefits of TYSABRI in reducing relapse rates and slowing disease progression,” said Alfred Sandrock, M.D., Ph.D., senior vice president, Development Sciences and Chief Medical Officer, Biogen Idec. “Data from TOP demonstrate that patients who began TYSABRI earlier had better outcomes than patients in the study who were switched to TYSABRI at two years, further demonstrating the positive effect TYSABRI can make for those living with MS.”

Multiple sclerosis (MS) is an often debilitating disease of the brain and spinal cord that affects nearly 2.1 million people worldwide. While a number of disease modifying therapies are currently available, an unmet need remains for effective treatment options.

“Common symptoms of MS, such as cognitive difficulties, fatigue and visual function can have a tremendous impact on people living with MS.” said Hans Peter Hasler, Chief Operating Officer, Elan Corporation, plc. “The encouraging outcomes from the data presented at ECTRIMS, together with TYSABRI’s proven efficacy, continue to support its strength as a valuable treatment for MS patients around the world.”

SELECT TYSABRI PRESENTATIONS AT ECTRIMS:

- *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 available for viewing on Thursday, October 11, 2012 from 15:30 to 17:00 GMT

  The objective of the TYSABRI Observational Program (TOP) is to evaluate long-term safety, efficacy, associations between baseline treatment history and post baseline annualized relapse rate (ARR), and overall two-year clinical disease-activity–free status in RRMS patients treated with TYSABRI. As of June 1, 2012, 4434 patients were enrolled.

  Results from TOP demonstrate that in the post marketing setting TYSABRI treatment has an effect on ARR, which is also accompanied by stable EDSS over four years. ARRs were lower in treatment-naïve patients than in previously treated patients, and lower in patients with EDSS score <3.0 at baseline. Overall, the incidence of serious adverse events, including infections, reported in TOP are consistent with the known safety profile of TYSABRI.

- *Improvement of MS-related fatigue also significantly improves quality of life in patients treated with natalizumab: results from the TYNERGY trial* – Poster 445 available for viewing on Thursday, October 11, 2012 from 15:30 to 17:00 GMT

  The objective of the TYNERGY trial was to evaluate whether improvement in MS-related fatigue during TYSABRI treatment is associated with significant improvement of health-related quality of life (HRQoL) in a multicenter, single-arm, non-randomized, open-label, prospective, observational study (TYNERGY) in patients with RRMS who are TYSABRI treatment naïve at baseline.

  After 12 months of natalizumab treatment in TYNERGY, a significant reduction in fatigue, as measured by the FSMC total

score, was associated with improvements in mental and physical components of HRQoL. Reduced cognitive fatigue was associated with improved mental components of HRQoL, while reduced motor fatigue was associated with improved physical components of HRQoL.

- *Relation of disease activity-free status to visual function in the AFFIRM trial* – Poster 557 available for viewing on Thursday, October 11, 2012 from 15:30 to 17:00 GMT.

  The objective of this post-hoc analysis was to determine the relation of changes in visual function and disease activity-free (DAF) status among patients with relapsing-remitting MS in AFFIRM. Low-contrast letter acuity is a visual function measure that captures treatment effects as well as overall disability in MS.

  In the AFFIRM trial, 37 percent of TYSABRI-treated patients were free of clinical and radiological disease activity over the two-year study period. Patients with lower relapse rates, fewer MRI lesions, and better EDSS scores at treatment initiation were more likely to achieve DAF.

  Among all patients in AFFIRM (n=942), mean changes from baseline in VFT were greater and in the direction of increased (better) scores over time in the DAF compared with the non-DAF group. Sustained visual function test (VFT) worsening was less likely in the group that remained free of disease activity than in the group that had disease activity. In the post-hoc analysis, a relationship between visual function and clinical or radiological disease activity was also observed.

- *Utilization of JC-virus antibody testing in clinical practice* – Poster 546 available for viewing on Thursday, October 11, 2012 from 15:30 to 17:00 GMT

  The objective of this study was to explore how the JC-virus (JCV) antibody assay is utilized and whether test results impact treatment decision making in clinical practice. In January 2012, a questionnaire was distributed to 18 MS centers in central Europe in order to evaluate the extent to which JCV antibody testing was used in daily clinical practice, thus exploring its relevance to routine treatment decisions.

  Seventeen of 18 MS centers have provided data so far, representing a total of 7,757 RRMS patients. In total, 828 RRMS patients were measured for JCV antibodies, with 443 testing positive for JCV antibodies. Of those patients testing positive for JCV antibodies, 76% have either started or continued (> = 2 years) TYSABRI treatment. Scores for the test were ranked as follows: 1= very important, 2 = important, 3 = less important, 4 = not important. The JCV antibody status was judged as “important” for making decision to start (mean score 2.1) or to continue at two years TYSABRI treatment (mean score 1.8).

- *Imaging findings for PML in natalizumab-treated MS patients* – Platform 99 on Thursday, October 11, 2012 at 17:30 GMT

  The objective of this platform presentation is to describe how MRI can aid in early detection of PML. Topics to be addressed during the presentation include how MRI sequences, lesion location, lesion appearance and patterns of contrast enhancement are useful for early detection.

About TYSABRI

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 is approved in more than 65 countries.

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. and Elan Corporation, plc. 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 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 $4 billion in annual revenues. For product labeling, press releases and additional information about the company, please visit www.biogenidec.com.

About Elan

Elan Corporation, plc is a neuroscience-focused biotechnology company 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. Elan shares trade on the New York and Irish Stock Exchanges. For additional information about Elan, please visit www.elan.com.

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