New TYSABRI Data Presented at 64th Annual AAN Meeting Highlight Biogen Idec & Elan Commitment to Improving Outcomes in Multiple Sclerosis

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-- Preliminary Results from TYNERGY Study Measure Impact of TYSABRI on MS-related Fatigue; Data from Observational TOP Study Evaluate Long-term Safety and Efficacy in Clinical Setting –

-- Updates to the First Risk Stratification Algorithm That Uses Safety Biomarker to Inform Treatment Decisions in MS --

WESTON, Mass. & DUBLIN--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) and Elan Corporation, plc (NYSE: ELN) today announced findings from several studies of TYSABRI® (natalizumab) evaluating its long-term safety and efficacy in the treatment of multiple sclerosis (MS) across the course of disease and impact on MS-related symptoms such as fatigue. These data, as well as data relating to the companies' risk stratification algorithm as a way to help enable individual benefit risk assessment for patients with MS, were accepted for presentation at the 64th Annual Meeting of the American Academy of Neurology (AAN).

"We continue to build on the extensive data we have for TYSABRI and are committed to studying its long-term use and potential effect on symptoms like fatigue, which MS patients struggle with every day," said Douglas E. Williams, Ph.D., executive vice president of Research and Development at Biogen Idec. "Our research is aimed at discovering additional ways TYSABRI can help physicians and patients best manage the symptoms of MS and make informed and personalized treatment choices."

Long-Term Observational Study of TYSABRI

Initial results from the TYSABRI Observational Program (TOP) indicate that post-baseline annualized relapse rates (ARR) after four years for patients receiving TYSABRI therapy decreased from 1.99 at baseline to 0.28 ($p<0.0001$); disability, as measured by the Expanded Disability Status Scale (EDSS), remained stable over time. TOP is an ongoing open-label, multicenter, observational study designed to assess long-term outcomes in patients with relapsing-remitting MS (RRMS) in Europe, Australia, and Canada. TOP is expected to enroll more than 4,500 patients who will be followed for 10 years.

Neither reduction in ARR nor stabilization of a patient's EDSS was affected by the type of treatment they were using before initiating TYSABRI therapy. However, ARR were lowest in immunosuppressant (IS) therapy-naïve patients and highest in patients who had used IS therapy ($p<0.0001$).

The incidence and type of serious adverse events (SAEs) seen in these patients after long-term use was consistent with TYSABRI's known safety profile. There were no significant differences by baseline treatment history in the incidence of SAEs, infection-related SAEs, or progressive multifocal leukoencephalopathy (PML) during TYSABRI therapy, although there was a trend of higher incidence of PML in patients with prior IS use.

"TOP may help provide insight into the potential impact current treatment may have on long term efficacy and safety outcomes with TYSABRI," said Professor Ludwig Kappos, MD, chair of Neurology, Research Group Leader Clinical Neuroimmunology and Neurobiology, Department of Biomedicine, University Hospital, Basel, Switzerland. "The reduction of MS relapse and stable disability progression that we observed with TYSABRI in the TOP study across naive and previously treated patients was sustained after four years of treatment."

Risk-Stratification Initiatives

Biogen Idec and Elan developed a quantitative risk stratification algorithm to help physicians and people with MS have more confidence in their treatment decisions when considering TYSABRI. The algorithm provides guidance for physicians and patients about the varying degrees of PML risk associated with TYSABRI treatment. The variables impacting PML risk are: anti-JCV antibody status, prior IS use, and TYSABRI treatment duration.

"We are pleased to be able to offer MS patients and their physicians an approach for assessing the potential benefit-risk with TYSABRI," said Ted Yednock, executive vice president and head of Global Research, Elan. "A significant advancement in this area is the inclusion of anti-JCV antibody status in the TYSABRI label as a risk factor for developing PML, as well as the commercial availability of the STRATIFY JCV™ blood test. Use of this approach for risk stratification is supported by data presented at AAN."

PML risk was quantified by assessing more than 92,000 MS patients from TYSABRI post-marketing sources and clinical studies; through September 2011 there were 159 cases of PML among this patient population and data show PML risk was lowest in anti-JCV antibody negative patients (no PML cases occurred in anti-JCV antibody negative patients; with the inclusion of one hypothetical anti-JCV antibody negative case, the risk is ≤0.10 cases per 1,000 patients treated). PML risk was highest in patients with all three risk factors: anti-JCV antibody positive status; prior immunosuppressant use; and 25-48 months of TYSABRI treatment (10.6 cases per 1,000 patients treated). The use of anti-JCV antibody status in this algorithm marks the first time a safety biomarker for risk stratification has been used to inform treatment decisions in MS and these data will be updated during the AAN presentation.

A separate study, STRATIFY-2, an ongoing, longitudinal, observational U.S. study, is the largest data set to date to analyze anti-JCV antibody seroprevalence among MS patients. Baseline anti-JCV antibody testing results from more than 35,000 MS patients who were either receiving or considering treatment with TYSABRI showed that the overall prevalence of anti-JCV antibodies was 53.5 percent (95% confidence interval [CI]: 53.0%–54.0%), which is consistent with the prevalence of anti-JCV antibodies observed in MS patients in other clinical research. Interim results from STRATIFY-2 demonstrated prospectively that the PML incidence in TYSABRI-treated anti-JCV antibody negative patients was significantly lower than that in anti-JCV antibody positive patients (anti-JCV negative = 0, CI: 0–0.34; anti-JCV positive=1.02, CI: 0.53–1.78 [p=0.0004]). Final data from STRATIFY-2 will further characterize PML risk in anti-JCV antibody negative and positive patients.

TYSABRI Impact on MS-related Fatigue

Initial findings from the TYNERGY study (Effects of TYSABRI Over 12 Months on MS Related Fatigue in Patients with RRMS) show that TYSABRI

treatment was associated with improved MS-related fatigue. TYNERGY was a multicenter, 12-month clinical follow-up study conducted to evaluate the effect of TYSABRI on MS-related fatigue in patients with RRMS. Fatigue is considered the most common symptom of MS, impacting 75-95 percent of patients. Further, 50-60 percent of MS patients report fatigue as one of their most disabling symptoms, which can contribute to cognitive and physical difficulties.

In the study, researchers measured MS-related fatigue at 0 and 12 months via the Fatigue Scale for Motor and Cognitive Functions (FSMC). Results indicate that treatment with TYSABRI impacted fatigue in patients with RRMS as evidenced by a median reduction of the FSMC score by 9.0 points ($p<0.0001$), which corresponds to an improvement from severe to moderate fatigue. Both the motor and the cognitive components of the FSMC showed similar improvement ($p<0.0001$). Researchers noted that these first results are promising but need further validation.

Data highlighted in this press release is featured in the following poster and platform presentations at the AAN annual meeting:

- *Long-Term Safety and Efficacy and Association between Baseline Treatment History and Postbaseline Relapses in Multiple Sclerosis Patients Treated with Natalizumab in the TYSABRI Observational Program (TOP)* (P04.134) was presented on Wednesday, April 25, 2012
- *Updated Incidence of Progressive Multifocal Leukoencephalopathy in Natalizumab-Treated Multiple Sclerosis Patients Stratified by Established Risk Factors (S41.001)* –presented by Dr. Gary Bloomgren on Thursday, April 26, 2012 from 1:00 to 1:15 p.m. CDT
- *Anti-JCV Antibody Prevalence in Patients with Relapsing Multiple Sclerosis Receiving or Considering Treatment with Natalizumab: Baseline Results of STRATIFY-2 (S41.002)* – presented by Dr. Sandra Richman on Thursday, April 26, 2012 from 1:15 to 1:30 p.m. CDT
- *Natalizumab Reduces Fatigue as Measured by the Fatigue Scale for Motor and Cognitive Functions (FSMC)—First Results from the TYNERGY trial (P07.081)* – available for viewing on Thursday, April 26, 2012 from 2:00 to 6:30 p.m. CDT

Full session details and additional TYSABRI data presentation listings for the 2012 AAN Annual Meeting can be found through the AAN website (www.aan.com/go/am12).

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, 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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