MRI Data Showing TYSABRI® Promoted Remyelination Presented at the 61st Annual Meeting of the American Academy of Neurology

April 28, 2009

-- Additional data suggests improvement in TYSABRI patients across clinical and patient-reported outcomes --

SEATTLE--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) and Elan Corporation, plc (NYSE: ELN) today announced results of a study demonstrating that TYSABRI® (natalizumab) promoted regeneration and stabilization of damage done to the myelin sheath, as measured by advanced MRI technology. Damage to the myelin sheath causes the symptoms of multiple sclerosis (MS). Additional posters will also be presented during the Congress highlighting the ability of TYSABRI, in some patients, to improve physical function and patient reported outcomes on cognition, quality of life, and fatigue. TYSABRI is the first approved MS therapy with reported data suggesting that some of the signs of disease progression can be stopped. The strong efficacy profile demonstrated in clinical trials is enhanced further from these data and may help redefine success in MS.

“What we have seen in these MRI data suggest that TYSABRI may have the capacity to repair and possibly restore some of the damaged myelin sheath that protects nerve fibers. Results from this study support the continued investigation of the potential effects of TYSABRI on this process,” said Robert Zivadinov, M.D., of the Jacobs Neurological Institute in Buffalo, N.Y., the lead investigator for the remyelination study.

“TYSABRI is changing the way neurologists and patients define success in the treatment of MS,” said Michael Panzara, M.D., M.P.H., vice president and chief medical officer of neurology, Biogen Idec. “These MRI data presented at AAN provide early evidence that TYSABRI may not just slow the progress of MS, but may also be able to reverse the damage inflicted by the disease.”

”Everyday, more patients understand that TYSABRI can represent a new way of looking at – and managing – their disease,” stated Carlos Paya, M.D., Ph.D., president, Elan Corporation. “These latest analyses further build on the impressive data we have seen to date with TYSABRI.”

TYSABRI helped stabilize and restore damage to the myelin sheath

The imaging study, which included a total of 110 subjects, used an advanced MRI technology called the Voxel-Wise MTR to measure lesions and normal brain tissue. The study showed that TYSABRI promoted remyelination when compared to those receiving interferon beta-1a IM and normal controls.

The effect of TYSABRI on lesions and NABT in relapsing MS was evaluated with a Voxel-Wise (VW) imaging method using magnetization transfer ratio (MTR). VWMTR is recognized as a powerful instrument for monitoring MS disease activity and effectiveness of therapeutic interventions in patients with MS.

In the study, 62 MS patients who received TYSABRI were followed for 12 months together with 26 MS patients who received interferon beta-1a IM and 22 age-matched and sex-matched normal controls. For each subject, baseline and follow-up MTR volume maps were placed in a common halfway-space. The resulting VW subtraction map was then enhanced via threshold-free cluster enhancement (TFCE) algorithm, and a significance threshold was determined based on subject-specific Monte Carlo simulation. Supra-threshold volumes (95th percentile) were quantified for both areas of increasing (remyelinating) and decreasing (demyelinating) MTR voxels, which represent a volume value.

There was no significant difference in decreasing VWMTR NABT volume over the follow-up between TYSABRI-treated and normal control groups. Relapsing-remitting patients on both therapies showed higher remyelination potential and less evident demyelination than relapsing secondary progressive patients. The volume of VWMTR changes in NABT (decreasing or increasing) was almost 3-5 times higher than the amount of changes observed for T2-lesion volume. This indicates that the VWMTR method might be a much more sensitive approach to capture demyelination/remyelination changes over time than the lesion-based volume measures.

The poster describing the study *Natalizumab (Tysabri®) Promotes Remyelination in Patients with Multiple Sclerosis. A Voxel-Wise Magnetization Transfer Imaging Case-Control Study (P03.071)* is available for viewing on Tuesday, April 28, 2009, at 4:00 p.m. PDT.

TYSABRI significantly increased the cumulative probability of achieving sustained improvement in disability in patients with relapsing MS

The poster describing the study *Sustained Improvement in Physical Disability with Natalizumab in Patients with Relapsing Multiple Sclerosis (P06.131)* will be available for viewing on Wednesday, April 29, 2009, at 4:00 p.m. PDT.

Data from this post-hoc analysis was previously presented at the 2008 World Congress on Treatment and Research in Multiple Sclerosis. The data showed TYSABRI produced significant results on the cumulative probability of sustained improvement in physical disability in those treated over two years compared with placebo. In patients with a baseline expanded disability status scale (EDSS) score ≥ 2.0, treatment with natalizumab significantly increased the probability of sustained improvement in disability by 69 percent relative to placebo. In the same patients, the probability of achieving sustained improvement was 29.6 percent with TYSABRI (*n=417*) compared with 18.7 percent with placebo (*n=203*) (*p=0.006*). In patients with an EDSS score ≥ 2.0 and highly active disease at baseline, the difference between groups was even greater, 35.5 percent for TYSABRI (*n=103*) and 15.4 percent for placebo (*n=40*) (*p=0.045*).

Patient-Reported Outcomes Study

In this study, patients with relapsing-remitting MS were asked after three months of treatment to rate their improvement, using validated outcomes tools. The posters presented at AAN show that overall, patients reported significant improvement in cognitive function, general and disease-specific health-related quality of life, and lower-levels of fatigue after the third infusion of TYSABRI. The ongoing one-year longitudinal study assesses health outcomes from the perspective of the patient before starting TYSABRI and at predetermined timepoints thereafter.

One of the posters, *Early Effects of Natalizumab on Patient Reported Fatigue and Cognitive Function (P02.142)* was made available for viewing on

Tuesday, April 28 at 11:30 a.m. PDT and a second poster, *Change in Health-Related Quality of Life in Multiple Sclerosis Patients Receiving Natalizumab (P05.144)* will be available for viewing on Wednesday, April 29, 2009, at 11:30 a.m. PDT.

About TYSABRI

TYSABRI is a treatment approved for relapsing forms of MS in the U.S. and relapsing-remitting MS in the European Union. According to data that have been 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 compared to placebo and reduced the relative risk of disability progression by 42-54 percent (*p<0.001*).

In early 2008, TYSABRI was approved in the U.S. to induce and maintain clinical response and remission in adult patients with moderately to severely active Crohn's disease (CD) with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-alpha. According to the US full prescribing information, among patients who responded to TYSABRI, 54 percent sustain their response through every visit for one year compared to 20 percent of patients receiving placebo (*p<0.001*), for a treatment difference of 34 percent.

TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. Cases of PML have been reported in patients taking TYSABRI who were recently or concomitantly treated with immunomodulators or immunosuppressants, as well as in patients receiving TYSABRI as monotherapy. Other serious adverse events that have occurred in TYSABRI-treated patients included hypersensitivity reactions (e.g., anaphylaxis) and infections. Serious opportunistic and other atypical infections have been observed in TYSABRI-treated patients, some of whom were receiving concurrent immunosuppressants. Herpes infections were slightly more common in patients treated with TYSABRI. In MS and CD clinical trials, the incidence and rate of other serious adverse events, including serious infections, were similar in patients receiving TYSABRI and those receiving placebo. Common adverse events reported in TYSABRI-treated MS patients include headache, fatigue, infusion reactions, urinary tract infections, joint and limb pain and rash. Other common adverse events reported in TYSABRI-treated CD patients include respiratory tract infections and nausea. Clinically significant liver injury has been reported in patients treated with TYSABRI in the post-marketing setting.

TYSABRI is approved in more than 40 countries.

For more information about TYSABRI please visit www.tysabri.com, www.biogenidec.com or www.elan.com or call 1-800-456-2255.

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 in more than 90 countries 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 Elan

Elan Corporation, plc is a neuroscience-based 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, London and Dublin Stock Exchanges. For additional information about the company, please visit http://www.elan.com.

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