



Data Supporting Unique Efficacy of TYSABRI Presented at the 25th Congress of the European Committee for Treatment and Research in Multiple Sclerosis

September 11, 2009

-- TYSABRI redefines expectations of multiple sclerosis therapy for some patients --

DUSSELDORF, Germany--([BUSINESS WIRE](#))--Biogen Idec (NASDAQ: BIIB) and Elan Corporation, plc (NYSE: ELN) today announced data presented at the 25th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) showing the potential of TYSABRI® (natalizumab) to redefine successful multiple sclerosis (MS) therapy. These data were from observational studies and retrospective analyses of the Phase III AFFIRM clinical trial, demonstrating that TYSABRI:

- Significantly improves measures of physical and cognitive disability using the Multiple Sclerosis Functional Composite (MSFC) in patients from the AFFIRM trial with baseline impairment;
- Promoted regeneration or stabilization of damage to the myelin sheath, which can cause some of the symptoms seen in MS patients, as measured by advanced MRI technology; and
- Shows improvement in quality of life as reported by patients.

"MS patients should expect more from an MS therapy and studies such as these demonstrate the potential for TYSABRI to satisfy their expectations," said Michael Panzara, M.D., M.P.H., vice president and chief medical officer of neurology, Biogen Idec. "These data presented at ECTRIMS show that, for many MS patients, TYSABRI may lead to improvement in a broad range of physical and cognitive symptoms."

"The strong efficacy profile demonstrated in clinical trials is enhanced further from these and other important TYSABRI data presented at ECTRIMS," said Carlos Paya, M.D., Ph.D., president, Elan Corporation. "TYSABRI is the first approved MS therapy with reported data suggesting some signs of the progression of MS can be stopped, whether measured by clinical, radiological or patient-reported measures."

TYSABRI significantly improves physical and cognitive function

This post-hoc analysis from the Phase III AFFIRM trial was conducted using the MSFC, a measure of disability that assesses aspects of neurologic dysfunction in MS not captured by Expanded Disability Status Scale (EDSS), to evaluate the effects of TYSABRI on disability improvement in patients with baseline impairment. Baseline impairment was defined when a patient experienced at least one of the following:

- Taking more than five seconds on the timed 25-foot walk (T25FW; ambulation);
- Taking more than 21 seconds on the 9-hole peg test (9-HPT; upper extremity function); or
- Providing fewer than 55 correct sums on the paced auditory serial addition test (PASAT-3; cognitive function).

The MSFC was administered to patients every 12 weeks; change from baseline to two years was a prespecified secondary endpoint. In the study, 460 patients received TYSABRI and 225 received placebo.

Results showed that TYSABRI significantly increased the proportion of patients who improved from baseline to two years on the T25FW ($p=.023$), 9-HPT ($p=.001$) and PASAT-3 ($p=.012$) compared with placebo. The effect of TYSABRI remained significant for the T25FW, 9-HPT and PASAT-3 compared with placebo when improvement was defined as an improved change from baseline sustained for at least six, seven, or eight out of ten planned study visits.

"This data showing the ability of TYSABRI to improve both physical and cognitive function represents a new paradigm for defining success in MS therapies," said Frederick E. Munschauer, III, M.D., Irvin and Rosemary Smith professor, University of New York, Buffalo, New York.

Natalizumab improves disability on the Multiple Sclerosis Functional Composite in a randomized, double-blind, placebo-controlled study of patients with relapsing multiple sclerosis (poster P434).

TYSABRI stabilizes and restores damage to the myelin sheath

Results from the study showed TYSABRI promoted regeneration and stabilization of damage done to the myelin sheath, as measured Voxel-Wise MTR (VWMTR), an advanced MRI technology, when compared with those receiving interferon beta-1a IM and healthy subjects.

In the study, 77 MS patients who received TYSABRI were followed for 12 months along with 21 MS patients who received interferon beta-1a IM and 17 age-matched and sex-matched healthy volunteers. TYSABRI significantly promoted remyelination when compared to patients treated with interferon beta-1a IM and healthy volunteers. There was no significant difference in decreasing VWMTR NABT volume over the follow-up between TYSABRI-treated patients and healthy volunteers. Relapsing-remitting patients on both therapies showed higher remyelination potential and less evident demyelination than relapsing secondary progressive MS patients.

Evolution of Voxel-Wise magnetization transfer ratio in natalizumab and interferon beta-1a IM treated patients with multiple sclerosis. A case-control study (poster P721).

TYSABRI patients report improvement in physical and psychological well-being

This ongoing, one-year longitudinal observational study assesses health outcomes from patients' perspectives before the start of TYSABRI treatment and after the third, sixth and 12th infusions. The Multiple Sclerosis Impact Scale-29 (MSIS-29) will be used to assess the impact of TYSABRI on disease-specific quality of life. Over a six-month period, the study showed patients receiving TYSABRI experienced a consistent improvement in both their physical and psychological well-being, suggesting that TYSABRI may improve overall quality of life of MS patients over time.

What do multiple sclerosis patients experience? Effect of natalizumab on disease-specific quality of life over time (poster P872).

About TYSABRI

TYSABRI is approved in more than 40 countries. In the U.S., it is approved for relapsing forms of MS and in the European Union for relapsing-remitting MS. According to data from the Phase III AFFIRM trial 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, when compared with placebo, and reduced the relative risk of disability progression by 42-54 percent ($p < 0.001$).

TYSABRI is redefining success in the treatment of MS. In post-hoc analyses of the Phase III AFFIRM trial and as published in *The Lancet Neurology*, 37 percent of TYSABRI-treated patients remained free of their MS activity, compared to seven percent of placebo-treated patients. In addition, data has been presented showing that treatment with TYSABRI significantly increased the probability of sustained improvement in disability in patients with a baseline expanded disability status scale (EDSS) score ≥ 2.0 by 69 percent relative to placebo.

TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain. 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 been reported in patients treated with TYSABRI in the post-marketing setting. Common adverse events reported in TYSABRI-treated MS patients include headache, fatigue, infusion reactions, urinary tract infections, joint and limb pain and rash.

TYSABRI is co-marketed by Biogen Idec Inc. and Elan Pharmaceuticals, Inc. 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 are listed on the New York and Irish Stock Exchanges. For additional information about the company, please visit <http://www.elan.com>.

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