



Large Body of Data on TYSABRI® to Be Presented at Annual Meeting of the American Academy of Neurology

April 13, 2010

– Data suggests improvement across broad range of functional and quality of life measures –

TORONTO--([BUSINESS WIRE](#))--[Biogen Idec](#) (NASDAQ: BIIB) and [Elan Corporation, plc](#) (NYSE: ELN) today announced 15 company-sponsored platform and poster presentations at the American Academy of Neurology's (AAN) 62nd Annual Meeting in Toronto, April 10 – 17, 2010. The AAN Annual Meeting is the world's largest gathering of neurologists. The presented data, based on post-hoc analyses and patient-reported outcomes studies, highlights the ability of [TYSABRI](#) (natalizumab), in some multiple sclerosis (MS) patients, to improve sustained visual function, disability, overall quality of life (QoL), cognition and fatigue.

"TYSABRI continues to change the way neurologists and patients define success in the treatment of MS," said Alfred Sandrock, M.D., Ph.D., Senior Vice President of Neurology Research and Development at Biogen Idec. "The data presented at AAN contribute to the growing body of scientific evidence supporting TYSABRI's strong efficacy profile."

Multiple sclerosis is one of the most common neurological disorders, affecting more than 400,000 people in the United States each year. Physical disabilities such as the loss of vision and difficulty walking are among the common symptoms associated with the disease and can have a devastating impact on quality of life for many MS patients. TYSABRI's strong efficacy profile in treating MS demonstrated in clinical trials continues to be enhanced further with data such as those being presented at AAN.

Data from the 15 company-sponsored presentations at the conference show that TYSABRI, in some patients, improves sustained visual function, disability, overall QoL, cognition and fatigue. The presentations also include results from two studies related to the JC virus (JCV) and a follow-up study in pregnant women.

TYSABRI associated with sustained visual function improvement

Results of a post-hoc analysis of Phase III AFFIRM data demonstrated that TYSABRI is associated with sustained visual function improvement in some patients with MS. Vision impairment is one of the first symptoms experienced by many people with MS and can have a significant impact on daily life.

"Visual problems are often the first symptom of MS, and for many patients, the knowledge that vision may be compromised adds a level of anxiety about future quality of life and activities of daily living," said Steven L. Galetta, M.D., University of Pennsylvania School of Medicine and an author on the study. "Fortunately, we have the suggestion from this study that natalizumab treatment may be associated with sustained improvement in visual function in some patients."

In this post-hoc analysis, investigators examined whether TYSABRI caused improvement in visual function, as well as the capacity of low-contrast letter acuity (LCA), gray letters against a white background, and high-contrast letter acuity (HCA), standard black-on-white vision testing, to detect treatment-related improvement in visual function.

Visual improvement was measured by the number of letters a patient identified correctly at each visit. Cumulative probability of visual function improvement sustained over 12 weeks was determined for increases in score by seven letters, as well as by five letters and 10 letters.

Results showed that visual improvement, defined as ≥ 7 -letter score increase from baseline, sustained for 12 weeks, was greater for TYSABRI (n=627) vs. placebo (n=314). This result was observed for LCA, where improvement in visual function at the 2.5 percent and 1.25 percent contrast levels was 57 percent (21.1% vs. 13.4%; HR=1.6, p=0.012) and 39 percent (31.6% vs. 23.9%; HR=1.4, p=0.014, Cox proportional hazards models), respectively. There were no significant differences between the treatment groups at the five-letter and 10-letter thresholds or the HCA.

The poster, *Low-Contrast Letter Acuity Detects Visual Function Improvement in Phase 3 Relapsing MS Trials of Natalizumab* (P05.060), will be available for viewing on April 15 from 7:30 a.m. - 12 p.m. EDT.

Dr. Galetta serves as a paid consultant for Biogen Idec.

Sustained improvement in physical function, as measured on the EDSS scale, was associated with improved quality of life for patients with relapsing MS taking TYSABRI

This study evaluated the relationship between sustained changes in disability, as measured by the Expanded Disability Status Scale (EDSS), and changes in patient-reported quality of life in TYSABRI patients. Disability improvement may be associated with improvements in patient-reported outcomes.

This analysis showed that sustained improvement in physician-rated EDSS scores was associated with sustained improvement in patient-reported QoL, including physical and mental components of QoL (as measured by Physical Component Summary, PCS, [p<0.0001] and Mental Component Summary, MCS, [p=0.0250] scores) and overall well-being (as measured by Visual Analogue Scale, VAS, [p<0.0001]). The association between sustained improvement in physician-measured EDSS and patient-reported measures of QoL suggests that EDSS is a meaningful outcome for assessing the impact of MS therapies on patients.

The poster, *Improvement in EDSS Corresponds with Improvement in Quality of Life in Patients with Multiple Sclerosis* (P02.169), will be available for viewing on April 13 from 3 - 7:30 p.m. EDT.

MS patients report improvements in quality of life, including physical and psychological well-being, as well as reduced fatigue and improved cognitive function after one year of treatment with TYSABRI

In this ongoing one-year longitudinal study, patients with MS were asked to assess their outcomes using validated patient-reported outcome measures prior to treatment initiation and after the third, sixth and 12th infusions with TYSABRI. The posters presented at AAN show that patients reported significant improvements in quality of life, including physical and psychological well-being, as well as reduced fatigue and improved cognitive function after one year of treatment with TYSABRI.

One of the posters on this study, *Effect of Natalizumab on Disease-Specific Quality of Life after One Year of Natalizumab Treatment* (P02.164), will be available for viewing on April 13 from 3 - 7:30 p.m. EDT. Another titled *Improvement in Health-Related Quality of Life in Multiple Sclerosis Patients Receiving Natalizumab in the United States* (P02.166) will be available for viewing on April 13 from 3 - 7:30 p.m. EDT. A third titled *Improvement in Patient-Reported Fatigue and Cognitive Function over Time with Natalizumab Treatment* (P06.167) will be available for viewing on April 15 from 3 - 7:30 p.m. EDT.

AAN platform presentation shows MS patients treated with TYSABRI experienced no substantial changes in the presence of JCV DNA, and second platform shows that patients who developed progressive multifocal leukoencephalopathy (PML) had evidence of antibodies to JCV that suggests prior infection

One platform presents data suggesting that treatment with TYSABRI does not have a substantial effect on the presence of JCV DNA in MS patients. In the Dose Suspension Safety Assessment (n=1397) and STRATA (n=1094), JCV DNA was detected in less than 1 percent of all patients, approximately 50 percent of whom were TYSABRI naïve.

The second platform presents data indicating that patients who developed PML had evidence of prior infection with JCV, as measured by the presence of anti-JCV antibodies. Investigators evaluated serum samples from TYSABRI patients who developed PML where blood samples had been collected at least one year prior to the diagnosis of PML. Most of these samples were collected prior to beginning treatment with TYSABRI. In all of these patients, serum samples were positive for JCV antibodies prior to onset of PML, suggesting pre-existing JCV infection in these patients. Additional analyses are needed to determine whether anti-JCV antibodies are useful in stratifying for PML risk.

The first platform presentation, *Effects of Natalizumab Treatment on the Presence of JC Virus DNA in Blood or Urine in Multiple Sclerosis Patients* (S31.002), is on April 14 during the session from 4:15 - 5:30 p.m. EDT, and the second, *Evaluation of the Incidence of Anti-JCV Antibodies in a Cohort of Natalizumab-Treated MS Patients* (S31.003), is on April 14 during the session from 4:15 - 5:30 p.m. EDT.

Preliminary pregnancy outcomes among women exposed to TYSABRI

The TYSABRI Pregnancy Exposure Registry (TPER) is an observational, exposure-registration, follow-up study of pregnant women with MS or Crohn's disease who were exposed to TYSABRI within three months prior to conception or at any time during pregnancy. The study is being conducted in the United States, Canada and the rest of the world. Information on TYSABRI exposure, potential confounding factors and pregnancy outcomes is being collected. Enrollment in the TPER is ongoing.

The poster, *Preliminary Evaluation of Pregnancy Outcomes from the TYSABRI® (Natalizumab) Pregnancy Exposure Registry* (P01.185), will be available for viewing on April 13 from 7:30 a.m. - 12 p.m. EDT.

About TYSABRI

TYSABRI is approved in more than 45 countries. In the U.S., it is approved for relapsing forms of MS and in the European Union for relapsing-remitting MS.

Data from the Phase III AFFIRM trial highlights TYSABRI's powerful efficacy. According to that data, which was 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 ($p<0.001$). 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, based on MRI and clinical measures, compared to seven percent of placebo-treated patients.

TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain. The risk of PML increases with increasing duration of use. 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 worldwide 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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