



TYSABRI(R) Demonstrates Sustained Improvement in Functional Outcomes in Multiple Sclerosis Patients According to New Post-Hoc Analysis

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MONTREAL--([BUSINESS WIRE](#))--Biogen Idec (NASDAQ: BIIB) and Elan Corporation, plc (NYSE: ELN) announced that a post-hoc analysis showed **TYSABRI®** (natalizumab) treatment increases the probability of achieving sustained improvement in physical disability over two years when compared to placebo. This post-hoc analysis provides the first evidence that **TYSABRI** is associated with a significant improvement in functional outcome, rather than only slowing or preventing progression of disability, in those living with relapsing multiple sclerosis (MS). These findings were derived from a subset analysis of the Phase III AFFIRM trial and were presented today as a poster presentation at the World Congress on Treatment and Research in Multiple Sclerosis in Montreal, Canada. This is the first joint meeting of the Americas Committee on Treatment and Research in Multiple Sclerosis (ACTRIMS) and its counterparts in Europe and Latin America: ECTRIMS and LACTRIMS.

"These results show that **TYSABRI** treated patients are significantly more likely to experience a sustained improvement in disability compared to placebo patients. This finding from a post-hoc analysis of the pivotal AFFIRM trial supports both the earlier findings from the AFFIRM trial that **TYSABRI** is associated with an improvement in quality of life as well as anecdotal evidence of recovery of function in some patients," said Frederick E. Munschauer, MD, Smith Professor and Chair, Department of Neurology, State University of New York at Buffalo. "While, like **TYSABRI**, other therapies have shown a slowing of progression in disability, this analysis represents the first evidence supporting a sustained improvement in function associated with an approved disease modifying therapy."

Post-hoc Disability Analysis of Phase III AFFIRM Study

The proportion of patients exhibiting sustained improvements in physical disability in the AFFIRM study was determined based upon the Expanded Disability Status Scale (EDSS) over two years in patients with relapsing MS. EDSS is one of the oldest and most widely utilized methods of quantifying disability in MS.

Post-hoc analysis of AFFIRM patients assessed sustained improvement in disability among patients with a baseline EDSS score ≥ 2.0 . Improvement in disability was defined as a one-point decrease in EDSS score sustained for 12 weeks. The cumulative probabilities of 12-week sustained improvement in disability at two years were estimated using the Kaplan-Meier method. Treatment effects were analyzed using the Cox proportional hazards model adjusted for baseline EDSS score. The distribution of sustained improvement by baseline EDSS score for each treatment group was also examined.

TYSABRI produced significant results on the cumulative probability of sustained improvement in disability in those treated over two years compared with placebo. In patients with a baseline EDSS score ≥ 2.0 , the probability of achieving sustained improvement was 29.6% with **TYSABRI** (n=417) compared with 18.7% 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% for **TYSABRI** (n=103) and 15.4% for placebo (n=40) ($p=0.045$).

The submitted abstract for this study, entitled "Natalizumab significantly increases the cumulative probability of sustained improvement in physical disability" (ID #P474), is available on the World Congress' website.

About **TYSABRI**

TYSABRI is a treatment approved for relapsing forms of MS in the US 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% relative reduction ($p<0.001$) in the annualized relapse rate compared to placebo and reduced the relative risk of disability progression by 42-54% ($p<0.001$).

TYSABRI was approved in early 2008 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% sustain their response through every visit for one year compared to 20% of patients receiving placebo ($p<0.001$), for a treatment difference of 34%.

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 35 countries. At the end of June 2008, more than 31,800 patients were on commercial and clinical **TYSABRI** therapy worldwide. Patients on **TYSABRI** therapy have continued to increase. An update will be provided in October in conjunction with Biogen Idec's third quarter earnings release.

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

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 www.elan.com.

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.

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