



MS Patients Treated with TYSABRI® Remain Free of Disease Activity for Two Years, According to Data Published in the Lancet Neurology

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TYSABRI is the first product approved for the treatment of MS to show that significantly more patients are living a life free of disease activity

CAMBRIDGE, Mass. & DUBLIN--([BUSINESS WIRE](#))--Biogen Idec (NASDAQ: BIIB) and Elan Corporation, plc (NYSE: ELN) today announced five-times as many multiple sclerosis (MS) patients taking TYSABRI® (natalizumab) were free from disease activity versus placebo in the overall patient population. Results from this retrospective analysis showed that two years after beginning treatment with TYSABRI, 37 percent of patients remained free of disease activity, compared to seven percent of placebo-treated patients. Sixty-four percent of patients showed no sign of relapse or sustained disability progression and 58 percent were free of radiological disease activity. Both of these measures were used to define freedom from disease activity in this analysis of the AFFIRM clinical trial. These data were published online today and in the March 2009 issue of *The Lancet Neurology*.

The analysis also suggests that the efficacy of TYSABRI may increase over time. The data show the proportion of MS patients who were free of disease activity in the TYSABRI group were greater in the second year than in the first year, while the number of MS patients in a placebo group free of disease activity stayed about the same in the second year.

"Natalizumab is the first therapy to show a robust effect on a composite of disease measures for a two-year time period. These data are encouraging because they suggest that disease remission might become an increasingly attainable goal in MS treatment," said one of the study's authors, Steven Galetta, M.D., professor of neurology, University of Pennsylvania School of Medicine. "The ultimate treatment goal in MS, as with many other autoimmune diseases, is to help patients remain symptom free for as long as possible."

MS is a disease that attacks the central nervous system. In the United States, there are approximately 400,000 people with MS; 200 people are diagnosed with the disease each week.

"The significant efficacy of TYSABRI allows us for the first time to describe response to an MS therapy in terms of freedom from disease activity, as opposed to simply a reduction in relapse rate or change in a disability scale," said Michael Panzara, MD, MPH, vice president, chief medical officer of neurology, Biogen Idec. "It is a change in thinking that raises the bar on what should be considered successful treatment of this devastating disease."

"Since we first discovered TYSABRI in our labs, we have been confident in the product's efficacy and the impact it can have on improving the lives of patients," said Carlos V. Paya, MD, PhD, president of Elan.

About the Study

The retrospective analysis examined the results of the phase III Natalizumab Safety and Efficacy in Relapsing-Remitting Multiple Sclerosis (AFFIRM) study at two years to determine the effects of TYSABRI in increasing the proportion of patients who were free of disease activity over two years, when compared with patients receiving placebo. AFFIRM was a multicenter, randomized, double-blind, placebo-controlled study. The primary endpoints were rate of clinical relapse at one year and the cumulative probability of sustained disability progression at two years. In the study, patients were randomly assigned, two to one, to receive TYSABRI 300 mg or placebo by intravenous infusion once every four weeks for up to 116 weeks.

The analysis showed that 383 of 596 patients (64 percent) taking TYSABRI were free of clinical disease activity over two years compared to 117 of 311 taking placebo (39 percent). Additionally, the proportion of patients who were free of disease activity based on the composite of clinical and radiological measures in the TYSABRI group was greater in the second year than in the first year (68 percent vs. 47 percent) but was similar for placebo (13 percent vs. 15 percent). Absence of disease activity was defined as no activity in clinical measures (no relapses and no sustained disability progression as defined by $> \text{ or } = 1.0$ -point increase in Expanded Disability Status Scale (EDSS) score from a baseline score of $> \text{ or } = 1.0$, or a $> \text{ or } = 1.5$ -point increase from a baseline score of 0.0, sustained for 12 weeks), radiological measures (no gadolinium-enhancing lesions and no new or enlarging T2-hyperintense lesions), or a composite of both measures.

Steven Galetta, M.D., professor of neurology, University of Pennsylvania School of Medicine is a co-author of the study. He has served as a consultant for Biogen Idec and has received research support from the company.

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% ($p < 0.001$).

In early 2008, TYSABRI was approved in the US 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 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 www.elan.com.

Safe Harbor/Forward-Looking Statements

This press release contains forward-looking statements regarding TYSABRI. These statements are based on the companies' current beliefs and expectations. The commercial potential of TYSABRI is subject to a number of risks and uncertainties. Factors which could cause actual results to differ materially from the companies' current expectations include the risk that we may be unable to adequately address concerns or questions raised by the FDA or other regulatory authorities, that concerns may arise from additional data, that the incidence and/or risk of PML or other opportunistic infections in patients treated with TYSABRI may be higher than observed in clinical trials, that the companies may encounter other unexpected hurdles, or that new therapies for MS with better efficacy or safety profiles or more convenient methods of administration are introduced into the market. Drug development and commercialization involves a high degree of risk.

For more detailed information on the risks and uncertainties associated with the companies' drug development and other activities, see the periodic and current reports that Biogen Idec and Elan have filed with the Securities and Exchange Commission. The companies assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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