



Data Presented at the 60th Annual Meeting of the American Academy of Neurology Offers Additional Support for Plasma Exchange as a Potential Tool to Accelerate TYSABRI(R) Removal

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CHICAGO--([BUSINESS WIRE](#))--Biogen Idec (NASDAQ: BIIB) and Elan Corporation, plc (NYSE: ELN) today announced additional findings from the PLEX study which shows that plasma exchange accelerates the removal of TYSABRI® (natalizumab) from blood serum in patients and may help improve central nervous system immune response based on an *in vitro* model. The data was presented today at the 60th Annual Meeting of the American Academy of Neurology (AAN). Plasma exchange is one of several research efforts the companies have underway to learn more about potential interventions or treatments for progressive multifocal leukoencephalopathy (PML).

"The goal of these studies is to evaluate the value of plasma exchange in patients who may develop PML. The data are encouraging as they show that removal of TYSABRI through plasma exchange may be a potential intervention to rapidly clear TYSABRI and restore immune function when clinically appropriate," said the study's lead author, Bhupendra O. Khatri, MD, Medical Director of the Regional MS Center, Aurora St. Luke's Medical Center, Milwaukee, WI.

PLEX is an open-label, single-arm, multicenter exploratory study involving 12 patients with relapsing-remitting multiple sclerosis (MS), designed to explore whether plasma exchange could significantly reduce the concentration of TYSABRI in blood serum and alpha 4-integrin receptor saturation. Plasma exchange is an established method of removing large molecules from the body's blood circulation. Based on the PLEX findings, plasma exchange was effective at accelerating the normal decline of TYSABRI serum concentrations.

A sub-study of PLEX, also presented today at the meeting, evaluated the effect of plasma exchange on the migration of certain immune cells, called leukocytes, across an *in vitro* model of the blood-brain barrier. TYSABRI was shown to reduce the migration of these cells across the blood-brain barrier. The results showed that plasma exchange improved the ability of these cells to migrate across the blood brain barrier, potentially reestablishing normal central nervous system immune response.

Plasma exchange was generally well tolerated with no increase in MS disease activity. There were no study discontinuations due to adverse events and all patients returned to TYSABRI treatment without complications. While further studies are being conducted, plasma exchange has been shown to hold potential as an intervention in the setting of PML.

Abstracts from the larger PLEX study, "Plasma Exchange Accelerates the Decline of Serum Natalizumab Concentration in Patients with Multiple Sclerosis: Results of the Natalizumab PLEX Study" (Presentation #S22.005) and the sub-analysis, "Plasma Exchange Augments Leukocyte Transmigration Across an *In Vitro* Blood-Brain Barrier In Natalizumab-Treated Patients with Multiple Sclerosis" (Presentation #S27.005) are available on-line at the AAN's website.

About TYSABRI

TYSABRI is a treatment approved for relapsing forms of MS in the United States 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 recently approved 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.

TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. 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 30 countries including the United States and many countries throughout the European Union, as well as Switzerland, Canada, Australia, New Zealand and Israel.

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 and the PLEX study. 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 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, or that the companies may encounter other unexpected hurdles. 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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