# FDA Updates TYSABRI® (natalizumab) Label to Include Anti-JC Virus Antibody Status as a PML Risk Factor

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WESTON, Mass. & DUBLIN--(BUSINESS WIRE)--Today Biogen Idec (NASDAQ: BIIB) and Elan Corporation, plc (NYSE: ELN) announced that the U.S. Food and Drug Administration (FDA) has approved a product label change for TYSABRI that will help enable individual benefit risk assessment for patients with multiple sclerosis (MS). The new label identifies anti-JCV antibody status as a risk factor for developing an infrequent but serious brain infection known as progressive multifocal leukoencephalopathy (PML). This marks the third risk factor identified to help physicians and people with MS have more confidence in their treatment decisions when considering TYSABRI, a highly effective treatment for relapsing forms of MS.

“This label change marks an important advance in assisting people with MS and their physicians to make better-informed decisions concerning the challenges of balancing effectiveness with safety,” said Dr. Nicholas LaRocca, Vice President Heath Care Delivery and Policy Research at the National MS Society. “We are encouraged by the proactive role that Biogen Idec and Elan are taking in addressing PML risk stratification.”

Infection with the JC virus (JCV) is required for the development of PML and the new label states that anti-JCV antibody negative status indicates that exposure to the JC virus has not been detected. Patients who are anti-JCV antibody positive have a higher risk of developing PML. Patients who are anti-JCV antibody positive, have received prior immunosuppressant (IS) therapy and received treatment with TYSABRI for more than two years have the highest risk of developing PML.

“TYSABRI has benefited thousands of patients worldwide who are living with multiple sclerosis, an often devastating disease affecting people in the prime of their lives,” said George Scangos, Ph.D., Chief Executive Officer, Biogen Idec. “Biogen Idec and Elan’s use of novel research and scientific expertise has allowed us to gain a better understanding of the benefit-risk profile for TYSABRI. Our development of the risk stratification algorithm and subsequent efforts to support the commercial availability of anti-JCV antibody testing reflect our commitment to providing patients and their physicians with additional guidance to help them make more personalized treatment decisions.”

The label update was based on analysis of data from Biogen Idec’s and Elan's quantitative risk stratification algorithm, which was presented at a number of major international medical meetings, including the American Academy of Neurology's annual meeting in April, 2011. In the analysis, patients who were anti-JCV antibody positive were at an increased risk for developing PML with varying degrees of risk depending on prior IS use and TYSABRI treatment duration. Irrespective of MS treatment, approximately 55 percent of MS patients are anti-JCV positive.

“We welcome the inclusion of PML risk stratification in the U.S. label as it significantly supports our aim to provide the information patients and physicians need to make a more informed treatment decision,” said Kelly Martin, Chief Executive Officer, Elan. “This further confirms the utility of the anti-JCV antibody status, which along with prior IS use and treatment duration enables the identification of differing levels of risk.”

The FDA has granted Quest Diagnostics (NYSE: DGX), the world’s leading diagnostic company, a *de novo* classification petition for the STRATIFY JCV Antibody ELISA testing service. STRATIFY JCV allows neurologists to determine their MS patients’ anti-JCV antibody status and is the first blood test to be FDA authorized for the qualitative detection of antibodies to the polyomavirus JC virus.

The U.S. label update follows the European Commission approval of anti-JCV antibody status as an additional factor to aid in stratifying patients at risk for developing PML in the Summary of Product Characteristics for TYSABRI in the European Union. Through the third quarter of 2011, globally there have been approximately 59,000 anti-JCV antibody tests administered commercially and through clinical trials.

**About TYSABRI**

TYSABRI is approved in more than 65 countries. TYSABRI is approved in the United States as a monotherapy for relapsing forms of MS, generally for patients who have had an inadequate response to, or are unable to tolerate, an alternative MS therapy. In the European Union, it is approved for highly active relapsing-remitting MS (RRMS) in adult patients who have failed to respond to beta interferon or have rapidly evolving, severe RRMS.

TYSABRI has advanced the treatment of MS patients with its established efficacy. Data from the Phase 3 AFFIRM trial, which was published in the New England Journal of Medicine, showed that 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 increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain which usually leads to death or severe disability. Infection by the JC virus (JCV) is required for the development of PML and patients who are anti-JCV antibody positive have a higher risk of developing PML. Factors that increase the risk of PML are presence of anti-JCV antibodies, prior immunosuppressant use, and longer TYSABRI treatment duration. Patients who have all three risk factors have the highest risk of developing PML. 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 also been reported in the post-marketing setting. A list of adverse events can be found in the full TYSABRI product labeling for each country where it is approved.

TYSABRI is marketed and distributed by Biogen Idec Inc. and Elan Corporation, plc. For full prescribing information and more information about TYSABRI, please visit www.biogenidec.com or www.elan.com.

**About Biogen Idec**

Biogen Idec uses cutting-edge science to discover, develop, manufacture and market therapies for serious diseases with a focus on neurology, immunology and hemophilia. Founded in 1978, Biogen Idec is the world's oldest independent biotechnology company. Patients worldwide benefit from its leading multiple sclerosis therapies and the company generates more than $4 billion in annual revenues. For product labeling, press releases and additional information about the company, please visit www.biogenidec.com.

**About Elan**

Elan Corporation, plc is a neuroscience-focused 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 and Irish Stock Exchanges. For additional information about Elan, please visit www.elan.com.

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