European Commission Approves Inclusion of Anti-JC Virus Antibody Status as a PML Risk Factor in TYSABRI Labeling

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--Five Year Marketing Authorization for TYSABRI Also Renewed --

WESTON, Mass. & DUBLIN--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) and Elan Corporation, plc (NYSE: ELN) announced today that the European Commission (EC) has approved the inclusion of anti-JC virus (JCV) antibody status as an additional factor to aid in stratifying patients at risk for developing progressive multifocal leukoencephalopathy (PML) in the Summary of Product Characteristics (SmPC) for TYSABRI® (natalizumab) in the European Union (EU). In addition, as part of a standard review process, the EC concluded the quality, safety and efficacy of TYSABRI continue to be adequately demonstrated and renewed the EU five-year Marketing Authorisation.

The new SmPC language states that patients who are anti-JCV antibody positive are at an increased risk of developing PML compared to patients who are anti-JCV antibody negative. Recent studies suggest that irrespective of MS treatment, approximately 55% of MS patients are anti-JCV antibody positive. The SmPC language also states that 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. The addition of anti-JCV antibody status to previously-established risk factors further stratifies the potential risk of developing PML.

"This label change can help give confidence to physicians and patients by providing additional guidance on stratifying the potential risk for developing PML in TYSABRI-treated patients," said Tomas Olsson, Professor of Neurology in the Department of Clinical Neurosciences at the Karolinska Institute in Stockholm, Sweden. "Understanding all factors, including anti-JCV antibody status, is essential, and the Swedish MS Society has established guidelines recommending how this can be put into practice."

“For half a decade, TYSABRI has benefited thousands of patients worldwide, offering hope for those in need of a powerful therapy to treat their MS,” said Douglas E. Williams, Ph.D., Executive Vice President, Research and Development at Biogen Idec. “In addition, now that STRATIFY JCV, the Biogen Idec and Elan-developed anti-JCV antibody assay, is commercially available in Europe, these established risk factors can be used to help inform treatment choices. This empowers physicians and patients to make better informed decisions about treatment with TYSABRI.”

This update to the SmPC was based on analysis of data from Biogen Idec and Elan’s quantitative risk stratification algorithm, which was presented at a number of recent major, international medical meetings. In the analysis, patients who were anti-JCV antibody negative were at a lower risk for developing PML. Patients who were anti-JCV antibody positive had varying degrees of risk for developing PML depending on prior IS use and TYSABRI treatment duration.

"With its proven efficacy, TYSABRI is an important therapy in the treatment of MS, which can be a devastating disease affecting patients in the prime of their lives," said Eliseo Salinas, MD, M.Sc., Chief Medical Officer at Elan. "The demonstration that these three risk factors confer different levels of PML risk allows for a more personalized benefit-risk discussion for each patient on or considering TYSABRI."

About TYSABRI

TYSABRI is approved in more than 60 countries. In the U.S., it is approved for relapsing forms of multiple sclerosis (MS) and in the European Union for relapsing-remitting MS.

TYSABRI has advanced the treatment of MS patients with its established efficacy. It has been proven to reduce flare-ups and slow physical disability progression. Data from the Phase III 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 that usually leads to death or severe disability. 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 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 Corporation, plc. 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 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-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 and Irish Stock Exchanges. For additional information about the Company, please visit www.elan.com.

Safe Harbor

This press release contains forward-looking statements, including statements about TYSABRI labeling and our efforts to improve the benefit-risk profile of TYSABRI. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "estimate," "expect," "forecast," "intend," "may," "plan," "will" and other words and terms of similar meaning. You should not place undue reliance on these statements. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including the occurrence of adverse safety events with TYSABRI, whether the recent studies that indicate that approximately 55% of MS patients are anti-JCV antibody positive prove to be accurate, failure to comply with government regulation and possible adverse impact of changes in such regulation, and our ability to protect our intellectual property rights and the cost of doing so. Additional risks and uncertainties are described in the Risk Factors section of our reports on Form 10-K and Form 10-Q for Biogen Idec, and Form 20-F and Form 6-K for Elan, and in other reports we file with the SEC. These statements are based on our current beliefs and expectations and speak only as of the date of this press release. We do not undertake any obligation to publicly update any forward-looking statements.

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