



Biogen Idec and Elan Submit Applications to Update TYSABRI Labeling That May Help Stratify Risk of PML with Anti-JC Virus Antibody Status

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WESTON, Mass. & DUBLIN--(BUSINESS WIRE)--[Biogen Idec](#) (NASDAQ: BIIB) and [Elan Corporation, plc](#) (NYSE: ELN) announced that the companies have submitted a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) and a Type II Variation to the European Medicines Agency (EMA) to request review and approval to update the respective TYSABRI Prescribing Information and Summary of Product Characteristics. The companies are proposing updated product labeling to include anti-JC Virus antibody status as one potential factor to help stratify the risk of progressive multifocal leukoencephalopathy (PML), a rare but serious brain infection, in the TYSABRI-treated population.

These filings are part of the companies' ongoing commitment to actively identify and address potential risk factors for PML in TYSABRI-treated patients.

About TYSABRI

TYSABRI is approved in more than 45 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 and powerful 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 ($p < 0.001$). At the end of a separate two-year study, approximately seven out of 10 patients on TYSABRI had no flare-ups at all. In the same study, nearly 9 out of 10 TYSABRI patients were free from sustained disability progression.

TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. The risk of PML increases with longer treatment duration and in patients treated with an immunosuppressant prior to receiving TYSABRI; these risks appear to be independent of each other. Data beyond four years are limited. 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. 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 biological products for the treatment of serious diseases with a focus on neurological disorders. 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.

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