Biogen Idec and Elan Receive Notification of PDUFA Date Extension

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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 extended the initial PDUFA date for its review of the supplemental Biologics License Application (sBLA) for TYSABRI® (natalizumab). The sBLA was submitted in December 2010 to update the Prescribing Information for TYSABRI to include anti-JC virus antibody status as a factor to help stratify the risk of progressive multifocal leukoencephalopathy (PML) in the TYSABRI-treated population. The 3 month extension is a standard extension period.

The FDA has indicated that the extension of the PDUFA date is needed to allow time for review of the changes being incorporated into the Risk Evaluation and Mitigation Strategies (REMS) program for TYSABRI, to be consistent with the anticipated Prescribing Information.

Biogen Idec and Elan are working with the FDA to help facilitate a timely review of the REMS changes and the sBLA.

About TYSABRI

TYSABRI is approved in more than 60 countries. As a monotherapy, it is approved in the U.S. 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 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. 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.

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