CHMP Recommends Updating TYSABRI Labeling with anti-JC Virus Antibody Status as a Third Factor to Further Stratify Risk of PML

April 18, 2011

-- Positive opinion for five-year renewal also recommended from the CHMP --

WESTON, Mass. & DUBLIN--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) and Elan Corporation, plc (NYSE: ELN) today announced that the Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for inclusion of an additional risk factor, anti-JC virus (JCV) antibody status, to the product label for TYSABRI® (natalizumab) in the European Union (EU). The CHMP has also adopted a positive opinion for the five year renewal of the Marketing Authorisation for TYSABRI.

The addition of anti-JCV antibody status as a risk factor allows for a three-factor approach to risk stratification. Prior immunosuppressant therapy and TYSABRI treatment duration are established risk factors previously included in the product labeling. This provides an opportunity to identify patients at lower or higher risk for the development of progressive multifocal leukoencephalopathy (PML), an infrequent but serious brain infection.

“We are pleased the CHMP has recommended adding anti-JCV antibody status as a third important risk factor for PML to the TYSABRI product label. By identifying and understanding the multiple factors that are part of the benefit-risk equation, patients can be informed and empowered to engage in a discussion with their physician about choosing the right therapy for their MS. We are working diligently to make our CE-marked assay broadly available to European physicians at the time of the product label change,” said Douglas E. Williams, Ph.D., executive vice president, research and development at Biogen Idec. “Patient safety is our utmost concern. We are dedicated to better understanding PML and have several ongoing initiatives designed to identify additional factors that may further mitigate the risk.”

“The decision to prescribe TYSABRI requires consideration of an individual’s expected or observed benefit, as well as the risk of potential adverse events associated with treatment,” added Eliseo Salinas, M.D., M.Sc., chief medical officer at Elan. “All potential risk factors should be considered when making a decision about the appropriate treatment.”

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. The risk of PML increases with longer treatment duration and in patients treated with an immunosuppressant prior to receiving TYSABRI. 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 therapeutic 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.

Safe Harbor

This press release contains forward-looking statements, including statements about TYSABRI labeling and marketing renewal, 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 risk that the European Commission will not follow the CHMP’s recommendations, we may be unable to adequately address concerns or questions raised by regulatory authorities, the occurrence of adverse safety events with our products, our dependence on collaborations and other third parties over which we may not always have full control, 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, Form 10-Q, Form 20-F and Form 6-K 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.

Contact:

Media Contacts:
Biogen Idec
Shannon Altimari, +41 (0) 79 732 14 11
or
Elan
Niamh Lyons, +353 1 663 3600
or
US Media Relations
866-964-8256
or
Investor Contacts:
Biogen Idec
Kia Khaleghpour, +1 781-464-2442
or
Elan
Chris Burns, + 353 1 709 4444 / +1 800-252-3526
or
David Marshall, +353 1 709 4444