Biogen Idec and Elan Submit Applications for First-Line Use of TYSABRI in anti-JCV Antibody Negative Patients with MS

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- Marketing Applications Supported by Risk Stratification Data -

WESTON, Mass. & DUBLIN--(BUSINESS WIRE)--Today Biogen Idec (NASDAQ: BIIB) and Elan Corporation, plc (NYSE: ELN) announced that they have submitted applications to the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) requesting updates to the TYSABRI® (natalizumab) labels. The applications request an expanded indication that would include first-line use for people living with certain relapsing forms of multiple sclerosis (MS) who have tested negative for antibodies to the JC virus (JCV). A formal assessment of both applications is ongoing.

These submissions are supported by risk stratification data and a risk algorithm that enables physicians and individuals living with MS to make informed decisions when considering treatment with TYSABRI. If approved, a first-line label will allow all appropriate anti-JCV antibody negative patients to consider TYSABRI early in the course of treatment, regardless of the level of disease activity or prior treatment history. TYSABRI is a highly efficacious treatment that has been shown to slow disability progression by 42 – 54 percent and reduce annualized relapse rates by 68 percent.

“Our anti-JCV antibody test, STRATIFY JCV®, helps to determine the most appropriate patients for TYSABRI and the data collected to date supports our recent filing for first-line use,” said Alfred Sandrock, M.D., Ph.D., senior vice president, Development Sciences and Chief Medical Officer, Biogen Idec. “Many appropriate patients are already benefiting from TYSABRI. A first line approval would allow people with MS access to a highly efficacious treatment earlier in the course of the disease, potentially leading to better outcomes. This is an important consideration for people with MS who may want or need more efficacy.”

Currently in the U.S., due to an increased risk of an opportunistic viral infection, progressive multifocal leukoencephalopathy (PML), TYSABRI is generally recommended for people living with relapsing forms of MS whose disease is not responding to, or who are unable to tolerate, an alternative therapy regardless of JCV status. In the EU, TYSABRI is approved for highly active relapsing-remitting MS (RRMS) in adult patients who have failed to respond to beta interferons or have rapidly evolving, severe RRMS.

“TYSABRI is an important treatment option for thousands of people living with MS,” said Hans Peter Hasler, chief operating officer, Elan Corporation, plc. “We are excited about these filings and the potential to make TYSABRI available as a treatment option for more individuals early in the course of their disease.”

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 interferons or have rapidly evolving, severe RRMS.

TYSABRI has advanced the treatment of MS 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 the 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.

Safe Harbor
This press release includes forward-looking statements, including statements about regulatory actions and the development and commercialization of TYSABRI in MS. 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 obtaining regulatory approval, the occurrence of adverse safety events, product competition, the availability of reimbursement for our products, adverse market and economic conditions, problems with our manufacturing processes and our reliance on third parties, failure to comply with

government regulation and possible adverse impact of changes in such regulation, our ability to protect our intellectual property rights and the cost of doing so, and the other risks and uncertainties that are described in the Risk Factors section of our most recent annual or quarterly report and in other reports we have filed 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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