ASCEND Study to Evaluate the Effectiveness of TYSABRI® (natalizumab) as a Treatment for Secondary-Progressive Multiple Sclerosis

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WESTON, Mass. & DUBLIN--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) and Elan Corporation, plc (NYSE: ELN) today announced a global Phase 3b study, ASCEND, that is being conducted to evaluate the effectiveness of TYSABRI as a treatment for secondary-progressive multiple sclerosis (SPMS). According to the National Multiple Sclerosis Society, approximately half of all people initially diagnosed with relapsing-remitting multiple sclerosis (RRMS) - the most common form of multiple sclerosis (MS) - will transition to SPMS within 19 years.

Patients with RRMS typically experience unpredictable relapses; the time between relapses is characterized by full or partial recovery and a lack of disease progression. SPMS is characterized by a steady progression of nerve damage, symptoms and disability, but the exact reasons for the progression are unknown. The potential for greater disease burden in SPMS typically includes decreased mobility, impaired activities of daily living, loss of independence and reduced quality of life.

"There are limited treatment options available to people living with SPMS and there is a high unmet need for effective therapies," said Aaron Miller, M.D., member of the ASCEND advisory board; Medical Director, Corinne Goldsmith Dickinson Center for Multiple Sclerosis; and Co-Director of the Multiple Sclerosis Care Center at Maimonides Medical Center in Brooklyn, New York. "The ASCEND trial is investigating whether treatment with TYSABRI may prevent worsening in walking, hand movement and daily functioning in these patients."

"One hypothesis behind the development of SPMS is that disease progression is a result of chronic inflammation in the brain tissue trapped behind the blood-brain-barrier. This causes destruction of the myelin sheath which protects the coating around nerve fibers, as well as the progressive loss of nerve cells, which can lead to disability in MS patients," said Professor Richard Reynolds, Professor of Cellular Neuroscience, Imperial College, London; and Scientific Director of the UK Multiple Sclerosis Society Tissue Bank. "Preliminary data suggest that TYSABRI may hinder this inflammation in the brain and reduce SPMS-related disease progression; therefore, further investigation of this hypothesis is warranted."

The ASCEND study is part of the ongoing commitment of both Biogen Idec and Elan to find ways to improve the well-being of patients with multiple sclerosis.

About the ASCEND Study

ASCEND (**A** **S**tudy to **C**haracterize the **E**fficacy of **N**atalizumab on **D**isability in SPMS) is a double-blind, placebo-controlled study with SPMS patients being randomized to receive either TYSABRI 300 mg or placebo intravenously every four weeks for 96 weeks. A global study, ASCEND is expected to enroll approximately 850 patients in 15 countries.

Study participants will be between the ages of 18 and 58, inclusive, with a diagnosis of SPMS for at least two years; an Expanded Disability Status Scale (EDSS) score between 3.0 and 6.5, inclusive; MS Severity Score of 4 or higher; documented, confirmed evidence of disease progression, independent of clinical relapses during the one-year prior to enrollment; and naïve to TYSABRI treatment.

The primary endpoint is to investigate whether treatment with TYSABRI slows the accumulation of disability not related to relapses in subjects with SPMS.

Secondary endpoints are:

- The proportion of subjects with consistent improvement in Timed 25-foot Walk (T25FW);
- The change in subject-reported ambulatory status as measured by the 12-Item MS Walking Scale (MSWS-12);
- The change in manual ability based on the ABILHAND questionnaire;
- The impact of TYSABRI on subject-reported quality of life using the Multiple Sclerosis Impact Scale-29 Physical (MSIS-29 Physical);
- The change in whole brain volume between the end of study and week 24 using MRI; and
- The proportion of subjects experiencing progression of disability as measured by individual physical EDSS system scores.

ASCEND is ongoing and actively enrolling patients. Patients interested in learning more about the study may speak with their physician or e-mail neurologyclinicaltrials@biogenidec.com.

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 interferon or have rapidly evolving, severe RRMS.

TYSABRI has advanced the treatment of MS patients 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 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

Through cutting-edge science and medicine, Biogen Idec discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hemophilia and autoimmune 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 nearly $5 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 contains forward-looking statements, including statements about the development of TYSABRI in SPMS. 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 we may not fully enroll our planned clinical trials, the occurrence of adverse safety events, regulatory authorities may require additional information, further studies, or may fail to grant the desired drug approval, or we may encounter other unexpected hurdles. 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.

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