Data Further Supporting Anti-JC Virus Antibody Assay Presented at the 26th Congress of the European Committee for Treatment and Research in Multiple Sclerosis

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- Studies support potential of assay to stratify risk of PML in TYSABRI-treated patients -

GOTHENBURG, Sweden--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) and Elan Corporation, plc (NYSE: ELN) today announced data further supporting the potential clinical utility of an investigational assay that detects anti-JC virus (JCV) antibodies in human plasma or serum. The detection of anti-JCV antibodies may provide a means to segment, or stratify, multiple sclerosis (MS) patients considering or receiving treatment with TYSABRI® (natalizumab) and assess their risk for developing progressive multifocal leukoencephalopathy (PML), a rare, but serious, brain infection. These data have been presented at the 26th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Gothenburg, Sweden.

This two-step, analytically-validated, enzyme-linked immunosorbant assay (ELISA) to detect anti-JCV antibodies is currently being evaluated in large-scale, prospective clinical studies (*>10,000 patients*) to determine the utility of the assay in stratifying the risk of PML in TYSABRI-treated patients. Infection with JCV is one of a number of factors required for the development of PML. Detection of anti-JCV antibodies may be a useful tool to identify prior or ongoing JCV infection, helping physicians better assess a patient's potential risk for developing PML.

"When treating a debilitating, chronic disease such as MS, patient safety is of the utmost importance. At Biogen Idec, we are committed to improving the lives of people with MS. Understanding and mitigating potential treatment risk factors further support our commitment," said Alfred Sandrock, M.D., Ph.D., Senior Vice President of Neurology Research and Development at Biogen Idec. "We are committed to better understanding PML and have embarked on a number of risk mitigation efforts. The anti-JCV antibody assay is one of our most advanced initiatives and has the potential to provide physicians a tool to help them assess patients' risk for developing PML."

Overview of Data

Late Breaking News – Factors associated with anti-JCV antibody prevalence in a large cohort of natalizumab-treated MS patients – Platform Presentation 138

The two-step ELISA was used to detect anti-JCV antibodies in blood from patients enrolled in the TYSABRI Global Observation Study (TYGRIS), Safety of TYSABRI Re-dosing and Treatment (STRATA) study, and JCV Antibody Program in Patients with Relapsing Multiple Sclerosis Receiving or Considering Treatment with TYSABRI (STRATIFY-1) study. A chi-square test was used to assess associations between factors and prevalence of anti-JCV antibodies. Together, these data represent one of the largest cohorts of MS patients evaluated for the presence of anti-JCV antibodies, demonstrating an overall prevalence of anti-JCV antibodies of approximately 50 to 60 percent and delineating the prevalence by factors such as age and gender. There was an increasing prevalence of anti-JCV antibodies in men compared to women. There was also an increasing prevalence with age, regardless of gender. TYSABRI use and prior treatment with immunosuppressants did not appear to affect the prevalence of anti-JCV antibodies in this cohort.

Assessment of the incidence of anti-JCV antibodies in a cohort of natalizumab-treated patients with multiple sclerosis – Poster P873

This study, which used the ELISA to evaluate more than 800 serum samples, was designed to assess the prevalence of anti-JCV antibodies in TYSABRI-treated MS patients and evaluate the possible utility of anti-JCV antibodies as a means to segment, or stratify, MS patients and assess their risk for developing PML. Of the more than 800 patients evaluated, 54 percent tested positive for anti-JCV antibodies.

Additionally, anti-JCV antibodies were detected in 20 out of 20 (100 percent) of TYSABRI-treated PML patients at least six months prior to the diagnosis of PML. Further clinical studies are being conducted to determine whether the presence or absence of anti-JCV antibodies may be useful to stratify PML risk.

Late Breaking News – Multi-site cross-validation of the assay to detect anti-JCV antibodies in human serum and plasma – Poster P992

In this study, cross-validation of the ELISA was performed by three laboratories (Focus Diagnostics, Quintiles Laboratories, and Biogen Idec) by evaluating intra- and inter-assay precision, including specificity, sensitivity, selectivity and matrix interference, robustness, and reagent stability. A panel of 100 serum and plasma samples was evaluated at each laboratory. The ability of the ELISA to detect anti-JCV antibodies in human serum and plasma was robust and cross-validated by all three laboratories. The assay is now being used in two global clinical trials to evaluate the potential clinical utility of anti-JCV antibody status for stratifying PML risk.

Late Breaking News – Anti-JCV antibody prevalence in a Swedish cohort of MS patients and non-MS controls – Poster P983

In this study from Sweden, the ELISA was used to detect anti-JCV antibodies in plasma from 2772 untreated or treated MS patients, as well as non-MS controls. A chi-square test was used to assess the association between demographic factors and prevalence of anti-JCV antibodies. Based on the data analyzed to date, it is estimated that the prevalence of anti-JCV antibodies in the Swedish MS population to be 61 percent, which is lower than the prevalence observed in the non-MS control population (67 percent) in the study.

About TYSABRI

TYSABRI is approved in more than 45 countries. In the U.S., it is approved for relapsing forms of 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. 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 creates new standards of care in therapeutic areas with high unmet medical needs. Founded in 1978, Biogen Idec is a global leader in the discovery, development, manufacturing, and commercialization of innovative therapies. Patients worldwide benefit from Biogen Idec's significant products that address diseases such as lymphoma, multiple sclerosis, and rheumatoid arthritis. 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 about our marketed products and our products in development. Drug development and commercialization involves a high degree of risk, and TYSABRI is subject to a number of risks and uncertainties. Important risk factors include the risk that we may be unable to adequately address concerns or questions raised by FDA or other regulatory authorities, the occurrence of adverse safety events with TYSABRI, that concerns may arise from additional data, that we may not be able to get the assay in development approved and that the incidence and/or risk of any safety issues with respect to the assay may be higher than observed to date. The companies may also 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 forward-looking statements speak only as of the date of this press release, and we do not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future events, or otherwise.

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