



Preliminary Data in Support of Investigational Anti-JCV Antibody Assay Published in the *Annals of Neurology*

August 24, 2010

-- Clinical studies underway to further evaluate assay's potential to stratify risk in TYSABRI-treated patients --

WESTON, Mass.--(BUSINESS WIRE)--[Biogen Idec](#) (NASDAQ: BIIB) and [Elan Corporation plc](#) (NYSE: ELN) today announced data has been published in the *Annals of Neurology* on an investigational, two-step assay to detect anti-JC virus (JCV) antibodies in human serum and plasma. This assay is currently being evaluated in clinical studies as a potential tool for risk stratification in [TYSABRI®](#) (natalizumab)-treated patients. Data from this preliminary analysis have been released online and will be published in the journal's September issue.

Detection of anti-JCV antibodies may provide a means to segment patients into groups at higher risk or lower risk for developing progressive multifocal leukoencephalopathy (PML), a rare but serious brain infection. In order to develop PML, it is believed that a person must experience a convergence of viral and environmental factors, one of which is being anti-JCV antibody positive. The publication describes the development and validation efforts undertaken to date, as well as preliminary findings on the prevalence of anti-JCV antibodies in multiple sclerosis (MS) patients from the Safety of TYSABRI Redosing and Treatment (STRATA) study. Plasma and serum samples were also analyzed from 17 TYSABRI-treated patients who were later diagnosed with PML. These data showed that all 17 patients were anti-JCV antibody positive prior to the onset of PML.

"We believe an assay with the ability to detect anti-JCV antibodies will be useful in our efforts to stratify patients for the risk of developing PML. It also has the potential to change the clinical management of MS patients," said Alfred Sandrock, M.D., Ph.D., senior vice president of neurology research and development at Biogen Idec. "These data support our ongoing clinical studies to assess the clinical utility of this assay and our commitment to further mitigating the rare risk of PML in TYSABRI-treated patients."

About the study

The study was undertaken to develop an enzyme-linked immunosorbent assay (ELISA) to detect JCV-specific antibodies in MS patients and to evaluate its potential utility in identifying patients at higher or lower risk of developing PML.

A two-step assay for detecting and confirming the presence of anti-JCV antibodies in human serum and plasma was developed and demonstrated to be both sensitive and specific. ELISA cutpoints were statistically established using plasma and serum samples obtained from a total of 831 patients with relapsing MS from the STRATA study. STRATA is an open-label, single-arm, multinational study in which all patients receive TYSABRI every four weeks for 48 weeks. Subsequently, the assay was used to determine the presence of anti-JCV antibodies in TYSABRI-treated PML patients where serum samples were collected 16-180 months prior to the diagnosis of PML.

In the evaluation, 53.6 percent of MS patients in the STRATA study tested positive for anti-JCV antibodies, with a 95 percent confidence interval of 49.9 to 57.3 percent. The false-negative rate was calculated as 2.5 percent. Notably, all pre-PML serum samples from 17 TYSABRI-treated patients who were later diagnosed with PML were anti-JCV antibody positive. This was significantly different from the 53.6 percent seropositivity observed in the analysis of the STRATA study ($p < 0.001$).

The article, entitled "Anti-JC Virus Antibodies: Implications for PML Risk Stratification," can be found online and will be published in the *Annals of Neurology* September print issue, Volume 68, Issue 3.

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.

Data from the Phase III AFFIRM trial highlights TYSABRI's powerful efficacy. According to that data, which was published in the *New England Journal of Medicine*, 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 increasing duration of treatment. The risk of PML also increases with immunosuppressant use prior to TYSABRI therapy, and this increased risk is independent of treatment duration. 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 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 Pharmaceuticals, Inc. 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 all of our products are 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 our products, that concerns may arise from additional data, that we may not be able to get the drugs in development approved and that the incidence and/or risk of any safety issues with respect to our products may be higher than observed in clinical trials. The company may also encounter other unexpected hurdles. Additional risks and uncertainties are described in the Risk Factors section of our reports on Form 10-K and Form 10-Q 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.

Contact:

Media Contacts:

Biogen Idec

Kate Weiss, 781-464-3260

or

Elan

Miriam Mason, 650-877-7616

or

Investor Contacts:

Biogen Idec

John Applegate, 617-679-2812

or

Kia Khaleghpour, 617-679-2812

or

Elan

Chris Burns, + 353 1 709 4444 / 800-252-3526

or

David Marshall, +353 1 709 4444