FDA Approves TYSABRI(R) for the Treatment of Moderate-to-Severe Crohn's Disease

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DUBLIN, Ireland & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Elan Corporation, plc (NYSE: ELN) and Biogen Idec (NASDAQ: BIIB) today announced the approval of a supplemental Biologics License Application (sBLA) by the U.S. Food and Drug Administration (FDA) for TYSABRI® (natalizumab). TYSABRI is now approved for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease (CD) with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-alpha. TYSABRI will be available for the treatment of CD upon the completion of key implementation activities related to the approved risk management plan. The companies anticipate TYSABRI will be available to Crohn's patients by the end of February 2008.

"The FDA's approval of TYSABRI is an important step forward in the treatment of Crohn's disease," said Dr. Stephen Hanauer, Professor of Medicine & Clinical Pharmacology & Chief of the Section of Gastroenterology at the University of Chicago Pritzker School of Medicine. "A significant number of patients either fail or cannot tolerate current therapies. The unique mechanism of action of TYSABRI affords us a new class of therapy in our fight against this debilitating disease."

The FDA granted approval based on its review of TYSABRI CD clinical trial data and overall safety data. The approval is accompanied by robust labeling with safety warnings; and a CD-specific risk management plan (including the mandatory TOUCH ™Prescribing Program) designed to inform prescribers, patients and infusion centers about the use of TYSABRI and to minimize potential risk of progressive multifocal leukoencephalopathy (PML) and other opportunistic infections.

"We are delighted that TYSABRI will be available for Crohn's patients and their physicians, who continue to need new therapeutic options with novel mechanisms of action," said Gordon Francis, MD, Senior Vice President, Global Clinical Development, Elan. "We are committed to providing therapeutic choice to those patients who can benefit from TYSABRI, and will continue to work with the FDA and the medical community to implement the TOUCH ™Prescribing Program for Crohn's patients."

"We are pleased with the FDA's decision to make TYSABRI available to Crohn's patients suffering from this chronic, debilitating disease," said Evan Beckman, MD, Senior Vice President, Immunology Research and Development, Biogen Idec. "Despite the therapeutic advances of the TNF-alpha inhibitors in CD, there remains a significant unmet need for Crohn's patients who have inadequate responses to, or are unable to tolerate, current CD therapies."

TOUCH ™Prescribing Program

The TOUCH ™(TYSABRI Outreach: Unified Commitment to Health) Prescribing Program was developed in conjunction with the FDA to facilitate appropriate use of TYSABRI and to assess, on an ongoing basis, the incidence and risk factors for PML and other serious opportunistic infections associated with TYSABRI treatment. This program represents Elan and Biogen Idec's commitment to making the unique benefits of TYSABRI available in a responsible manner. The program already has been implemented for patients receiving TYSABRI therapy for MS.

About Crohn's Disease

An estimated 500,000 people in the United States have Crohn's disease, a chronic and progressive inflammatory disease of the gastrointestinal tract, which commonly affects both men and women.

The disease usually causes diarrhea and crampy abdominal pain, often associated with fever, and at times rectal bleeding. Loss of appetite and weight loss also may occur. Complications include narrowing of the intestine, obstruction, abscesses, and fistulas (abnormal channels connecting the intestine and other organs, including the skin), and malnutrition. Most patients eventually require surgery, which has both risks and potential short- and long-term complications.

Crohn's disease can have a devastating impact on the lifestyle of patients, many of whom are young and active. Currently there is no medical or surgical cure for Crohn's disease. Many patients fail to respond to current therapies, including biological therapies such as agents that inhibit tumor necrosis factor alpha (TNF-alpha). Due to this failure of current therapies in CD, therapies that have alternate biological targets provide patients and physicians with therapeutic options.

About TYSABRI

Data from the ENCORE trial showed that TYSABRI induced response and remission among patients with moderately to severely active Crohn's disease, and objective evidence of inflammation, as measured by elevated C-reactive protein. After 12 weeks of therapy, 60% of TYSABRI-treated patients attained response, compared to 44% of placebo treated patients, and 48% of patients had sustained response at both weeks 8 and 12, compared to 32% of placebo treated patients ($p<0.005$ for both). Among the patients who had inadequate response to prior treatment with inhibitors of TNF-alpha, 38% achieved sustained response at weeks 8 and 12.

Data from the ENACT-2 showed that an additional year of TYSABRI therapy sustained response and remission among patients with an initial response to TYSABRI after 3 months in ENACT-1. Of patients with response in ENACT-1, sustained response during ENACT-2 was seen in 61% of patients treated with TYSABRI at every visit through an additional 6 months of therapy, compared to 29% for placebo. This treatment difference was also sustained through 12 months of additional therapy (54% vs. 20%). Remission was sustained at every visit with an additional 6 months or 12 months of TYSABRI in 45% and 40% of patients, respectively, compared to 26% and 15% of placebo treated patients ($p<0.005$ for all comparisons). Among the patients that had previously failed TNF-inhibitors, response and remission was sustained at every visit through an additional 6 months of TYSABRI in 52% and 30% of patients, respectively. Among patients on steroids and in whom a clinical response was achieved, approximately two-thirds were able to discontinue steroids within 10 weeks of beginning to taper steroids.

TYSABRI increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. Other serious adverse events that have occurred in TYSABRI-treated patients included hypersensitivity reactions (e.g., anaphylaxis) and infections. Serious opportunistic and other atypical infections have been observed in TYSABRI-treated patients, some of whom were receiving concurrent immunosuppressants. Herpes infections were slightly more common in patients treated with TYSABRI. In MS and CD clinical

trials, the incidence and rate of other serious adverse events, including serious infections, were similar in patients receiving TYSABRI and those receiving placebo. Common adverse events reported in TYSABRI-treated MS patients include headache, fatigue, infusion reactions, urinary tract infections, joint and limb pain, and rash. Other common adverse events reported in TYSABRI-treated CD patients include respiratory tract infections and nausea. Clinically significant liver injury has been reported in patients treated with TYSABRI in the post-marketing setting.

TYSABRI has previously been approved for relapsing forms of MS in the United States and relapsing-remitting MS in the European Union. According to data that have been published in the *New England Journal of Medicine*, after two years, TYSABRI treatment led to a 68% relative reduction ($p<0.001$) in the annualized relapse rate compared to placebo and reduced the relative risk of disability progression by 42-54% ($p<0.001$). In addition to the United States and European Union, TYSABRI is also approved for MS in Switzerland, Canada, Australia, New Zealand and Israel. TYSABRI was discovered by Elan and is co-developed with Biogen Idec.

For more information about TYSABRI please visit www.tysabri.com, www.biogenidec.com or www.elan.com, or call 1-800-456-2255.

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, London and Dublin Stock Exchanges. For additional information about the company, please visit www.elan.com.

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 in more than 90 countries 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.

Safe Harbor/Forward-Looking Statements

This press release contains forward-looking statements regarding TYSABRI. These statements are based on the companies' current beliefs and expectations. The commercial potential of TYSABRI is subject to a number of risks and uncertainties. Factors which could cause actual results to differ materially from the companies' current expectations include the risk that we may be unable to adequately address concerns or questions raised by FDA or other regulatory authorities, that concerns may arise from additional data, that the incidence and/or risk of PML or other opportunistic infections in patients treated with TYSABRI may be higher than observed in clinical trials, or that the companies may encounter other unexpected hurdles. Drug development and commercialization involves a high degree of risk.

For more detailed information on the risks and uncertainties associated with the companies' drug development and other activities, see the periodic and current reports that Biogen Idec and Elan have filed with the Securities and Exchange Commission. The companies assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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