



Elan and Biogen Idec Initiate First Clinical Trial of TYSABRI(R) in Oncology

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First Multiple Myeloma Patient Treated

CAMBRIDGE, Mass. & DUBLIN, Ireland--([BUSINESS WIRE](#))--Elan Corporation, plc (NYSE: ELN) and Biogen Idec (NASDAQ: BII.B) today announced the initiation of the first clinical trial of TYSABRI® (natalizumab) in oncology. The first dose of TYSABRI was administered yesterday in the trial. The objectives of this Phase I/II study are to evaluate the safety and potential anti-tumor activity of TYSABRI in patients with relapsed or refractory multiple myeloma. TYSABRI is a recombinant, humanized monoclonal antibody that targets the adhesion molecule VLA4 (also known as alpha-4 integrin) that is expressed on the surface of many types of immune cells. VLA4 is also found on the surface of multiple myeloma cells and may be involved in their survival.

"We are excited to initiate the oncology clinical trial program for TYSABRI," said Wayne Saville, MD, Director, Oncology Medical Research at Biogen Idec. "TYSABRI has potential in multiple myeloma and a number of other cancers through its action as a blocker of VLA4. It is a meaningful addition to Biogen Idec's robust oncology pipeline."

"This clinical trial in oncology represents an opportunity for TYSABRI to continue to address unmet medical needs, potentially bringing new therapeutic options to patients and their oncologists," said Gordon Francis, MD, Senior Vice President, Global Clinical Development at Elan Pharmaceuticals, Inc.

About the Trial

This Phase I/II, open-label, two-arm study is designed to evaluate the safety and anti-tumor activity of TYSABRI in patients with relapsed or refractory multiple myeloma. In the Phase I portion of the trial, a standard dose-escalation design will be used to assess the safety and tolerability of TYSABRI in up to 12 patients. In the Phase II portion of the study, up to 30 patients will be randomized to the tolerated doses identified in Phase I of the study.

Treatment cycles will consist of intravenous infusions of TYSABRI once every 28 days for 6 months. After 6 months, if the patient has achieved a partial or a complete response, he or she may continue to receive TYSABRI once every 28 days until progression of disease occurs.

Patients eligible for the study must be at least 18 years of age with relapsed or refractory multiple myeloma who have failed or cannot tolerate therapy with bortezomib and thalidomide or lenalidomide.

About Multiple Myeloma

Multiple myeloma is a cancer of the plasma cell, an important part of the immune system that produces antibodies to help fight infection and disease. Certain immune cells, called B cells, change into plasma cells when they respond to an antigen, producing antibodies to attack bacteria and viruses. However, when plasma cells multiply in an uncontrolled way, they can produce tumors, which generally develop in the bone marrow. These plasma cells produce excessive amounts of antibodies and can interfere with normal blood-forming functions of the bone marrow, crowding out healthy cells and leaving patients susceptible to anemia, hemorrhage, infection and severe osteoporosis.

Multiple myeloma is the second most common blood cancer in the United States (US). More than 50,000 people in the US are living with multiple myeloma, and about 20,000 new cases are expected to be diagnosed this year. Nearly 11,000 Americans are expected to die from the disease this year. Men are 50 percent more likely to develop the disease than women. Other risk factors include race, radiation exposure, family history, occupational exposure to petroleum, obesity and other plasma cell disorders.

About TYSABRI

TYSABRI is a treatment 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% ($p < 0.001$).

TYSABRI was recently approved to induce and maintain 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 increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. Cases of PML have been reported in patients taking TYSABRI who were recently or concomitantly treated with immunomodulators or immunosuppressants, as well as in patients receiving TYSABRI as monotherapy. 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 is approved in more than 35 countries.

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 the potential use of TYSABRI. These statements are based on the companies' current beliefs and expectations. The development of TYSABRI in new indications and its commercial potential are subject to a number of risks and uncertainties. Factors which could cause actual results to differ materially from the companies' current expectations include but are not limited to 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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