Subset Data from Two Randomized Phase 3 Trials Show TYSABRI Significantly Reduces Rates of Hospitalization in Patients with Moderate-to-Severe Crohn's Disease

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DUBLIN & SAN DIEGO--(BUSINESS WIRE)--Elan Corporation, plc (NYSE: ELN) and Biogen Idec (NASDAQ: BIIB) today announced data showing that treatment with TYSABRI® (natalizumab) significantly reduced the rate of hospitalization compared with placebo in patients with moderate–to–severe Crohn's disease during both induction and maintenance treatment. These results were obtained from retrospective subset analyses of three registrational Phase 3 trials (ENACT-1 [Efficacy of Natalizumab as Active Crohn's Therapy]), (ENACT-2 [Evaluation of Natalizumab as Continuous Therapy] and ENCORE [Efficacy of Natalizumab in Crohn's Disease Response and Remission]), and one open-label study (ENABLE [Evaluation of the Natalizumab Antibody for Long-term Efficacy]). The data were presented for the first time in an oral session at the American College of Gastroenterology Annual Scientific Meeting in San Diego.

"Hospitalization accounts for a large proportion of the cost of Crohn's disease management," said Corey A. Siegel, M.D., director, Inflammatory Bowel Disease Center, Dartmouth-Hitchcock Medical Center in Lebanon, N.H., and lead author of the subset analysis. "Therefore, we were encouraged to see that TYSABRI reduced hospitalization rates, particularly in the more difficult-to-treat subsets of patients previously treated with anti-TNFα therapy."

The retrospective subset analysis evaluated the effect of TYSABRI on the rate of hospitalization during induction and maintenance treatment using pooled data from the ENACT-1 and ENCORE trials. In those trials, patients with Crohn's disease were randomized to intravenous TYSABRI 300 mg or placebo every four weeks for three doses. The maintenance analysis was conducted on TYSABRI responders in ENACT-1 who were re-randomized and followed for an additional 48 weeks of therapy in ENACT-2. Data on patients losing response in ENACT-2 who rolled over to an open-label study (ENABLE) supplemented the ENACT-2 data. Rates of all-cause hospitalization and Crohn's disease-related hospitalization per 100 patients over the 84-day induction period and the 336-day maintenance periods were evaluated.

Results of the subset analysis showed that hospitalization rates were significantly lower in patients treated with TYSABRI when compared with placebo. Two physicians, blinded to treatment, reviewed all data to determine hospitalizations and surgeries and whether they were, or were not, related to Crohn's disease. Out of the approximately 1500 patients involved in these trials, the total number of all-cause hospitalizations was (n=136). In those patients treated with TYSABRI, the rate of all-cause hospitalizations was reduced by 35% (*p=0.009*) during the induction period and 44% (*p=0.044*) during the maintenance period. The total number of Crohn's disease-related hospitalizations was (n=109). In these Tysabri-treated patients, the rate was reduced by 31% (*p<0.001)* during the induction period and 58% (*p=0.027*) during the maintenance period.

In patients who had received prior anti-TNF therapy, a more difficult-to-treat patient population, the benefit of TYSABRI was higher. During the induction period, the total number of all-cause hospitalizations was (n=57). In these patients, the rate was reduced by 56% (*p=0.031*) and Crohn's disease-related hospitalization (n=46) the rate was reduced by 55% (*p=0.052)*. During the maintenance period, all-cause hospitalization rate was reduced by 60% (*p=0.034*) and the Crohn's disease-related hospitalization rate was reduced by 75% (*p=0.029*).

"The results of this analysis showing reduced hospitalization rates, together with subset data previously announced at Digestive Disease Week in May, provide additional support that TYSABRI is an important treatment option for patients with this chronic and debilitating disease who have failed anti-TNFα therapies," said Elan President Carlos V. Paya, M.D., Ph.D. "TYSABRI continues to show benefits in improving quality of life, in CD patients, as well as in multiple sclerosis patients who also exhibit benefits across clinical and radiological measures."

Natalizumab Reduces the Rate of Hospitalization in Moderate to Severe Crohn's Patients: Data from the ENACT and ENCORE Trials, Siegel, CA, Sands BE, Feagan B, et al. Presented at the American College of Gastroenterology Annual Scientific Meeting, October 27, 2009. Abstract #41.

About ENACT-1, ENACT-2, ENCORE, and ENABLE

ENACT-1 involved patients with moderately to severely active Crohn's disease who received either TYSABRI 300 mg or placebo for 3 infusions. The primary endpoint was clinical response at week 10. Patients who responded to therapy were eligible to enroll into ENACT-2.

ENACT-2 presented maintenance data for an additional year of TYSABRI therapy 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 maintained 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 at 6 months). Among the patients that had previously failed anti-TNFα therapy, response and remission was sustained at every visit through an additional 6 months of TYSABRI in 52% and 30% of patients, respectively. Given the requirement to discontinue chronic steroids, among the subset of patients (n=65) 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. Although permitted in the clinical trials, combination therapy with immunosuppressants is not recommended.

Data from the second induction trial, ENCORE, 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 showed a 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 TNFα, 38% achieved a response at weeks 8 and 12.

ENABLE was an open-label extension study, which treated over 1000 patients with TYSABRI, for up to an additional 12 months.

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®

In early 2008, TYSABRI was approved in the U.S. 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. According to the U.S. full prescribing information, among patients who responded to TYSABRI in a clinical trial, 54 percent sustained their response through the one year visit compared to 20 percent of patients receiving placebo ($p<0.001$), for a treatment difference of 34 percent.

In the U.S., TYSABRI is approved for relapsing forms of multiple sclerosis (MS) and in the European Union for relapsing-remitting MS. TYSABRI is approved for MS in more than 40 countries. According to data from the Phase III AFFIRM trial 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. 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 Elan

Elan Corporation, plc is a neuroscience-based biotechnology company committed to making a difference in the lives of patients and their families by bringing innovations in science to fill significant unmet medical needs. Elan shares trade on the New York 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 the 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, that the companies may encounter other unexpected hurdles, or that new therapies for MS with better efficacy or safety profiles or more convenient methods of administration are introduced into the market. 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 Elan has 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.

Contact:

INVESTOR:
Elan
Chris Burns, 800-252-3526
David Marshall, 353-1-709-4444
or
Biogen Idec
Eric Hoffman, 617-679-2812
or
MEDIA:
Elan
Miriam Mason, 650-278-7113
Mary Stutts, 650-823-5255 (on-site)
or
Biogen Idec
Jennifer Neiman, 617-914-1201