



Subset Data from Two Randomized Phase 3 Trials Show TYSABRI® Significantly Improves Health-Related Quality of Life for Crohn's Disease Patients with Prior Exposure or Inadequate Response to Anti-TNF α Therapy

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DUBLIN, Ireland & CHICAGO, Ill.--([BUSINESS WIRE](#))--Elan Corporation, plc (NYSE: ELN) and Biogen Idec (NASDAQ: BIIB) shared data today that TYSABRI® (natalizumab) improved health related quality of life (QOL) in Crohn's Disease (CD) patients who had previously been exposed to or failed anti-TNF α therapy versus placebo. These results were obtained from subset analyses of the Phase 3 ENACT-2 (Evaluation of Natalizumab as Continuous Therapy) and ENCORE (Efficacy of Natalizumab in Crohn's Disease Response and Remission) trials and were presented today at Digestive Disease Week in Chicago.

QOL was measured using the patient-reported, disease-specific Inflammatory Bowel Disease Questionnaire (IBDQ), which measures bowel function, emotional function, systemic function, and social function. The Short-form 36 (SF-36), a general measure of QOL including physical function, bodily pain, general health, social function, mental health and vitality, was also used. In the 12-week ENCORE induction trial, patients receiving TYSABRI (n=89) who had failed previous anti-TNF α therapy achieved statistically significant improvements compared with those receiving placebo (n=83) on the total IBDQ scale and the two summary scales of the SF-36, the Physical Component Summary and the Mental Component Summary.

In the ENACT-2 maintenance trial, patients classified as responders to TYSABRI and who had an inadequate response to anti-TNF α therapy (n=32) had total IBDQ scores above 170, a level consistent with remission, throughout the length of the trial. These levels were significantly higher than placebo (n=40) at all measurements (P<0.05 at weeks 24, 36, 48, and 60). In addition, at week 60 of therapy, there was no clinically meaningful difference (i.e. <5 points) between patients receiving TYSABRI and the general population on seven of the eight individual scales of the SF-36. While the ability to improve the QOL of patients who have failed previous anti-TNF α therapy is important, a larger clinical question is whether these improvements can be sustained during long-term therapy.

Brian Feagan, M.D., of the Robarts Research Institute at the University of Western Ontario, and first author of a manuscript published in the *American Journal of Gastroenterology*¹ detailing the effects of TYSABRI on the full sample of patients in ENACT-2, said these data showed a similar impact. "In the more difficult-to-treat subsets of patients studied here, TYSABRI helped patients with moderate to severe CD achieve and maintain a considerably improved QOL as measured by the IBDQ and the SF-36 as compared with placebo," Dr. Feagan said.

"TYSABRI is an important treatment option for patients with this debilitating disease who have failed anti-TNF α therapies," stated Elan President Carlos V. Paya, MD, PhD.

"Quality of life is an important measure of how CD patients feel in their day-to-day lives," said Michael Panzara, MD, MPH, vice president, chief medical officer of neurology, Biogen Idec.

¹ Feagan BG, Sandborn WJ, Hass S, et al. (2007). Health-Related Quality of Life During Natalizumab Maintenance Therapy for Crohn's Disease. *Am J Gastroenterol*, 102:2737–2746. doi: 10.1111/j.1572-0241.2007.01508.x

About ENCORE and ENACT-2

Data from the ENCORE trial showed that TYSABRI induced response and remission among patients with moderately to severely active CD, 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 TNF α , 38% achieved a response at weeks 8 and 12.

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-TNF α 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.

About Crohn's Disease (CD)

An estimated 500,000 people in the United States have CD, a chronic and progressive inflammatory disease of the gastrointestinal tract, which commonly affects both men and women. CD 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 CD. Many patients fail to respond to current therapies, including biological therapies such as agents that inhibit tumor necrosis factor alpha (TNF α). Due to this failure of current therapies in CD, therapies that have alternate biological targets provide patients and physicians with therapeutic options.

The disease usually causes diarrhea and cramping 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.

About TYSABRI®

TYSABRI is a treatment approved for relapsing forms of MS in the U.S. 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, TYASABRI treatment led to a 68 percent relative reduction ($p < 0.001$) in the annualized relapse rate compared with placebo and reduced the relative risk of disability progression by 42-54 percent ($p < 0.001$).

In early 2008, TYASABRI 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 US full prescribing information, among patients who responded to TYASABRI in a clinical trial, 54 percent sustained their response through the one year visit compared to 20 percent of patients receiving placebo, for a treatment difference of 34%.

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 TYASABRI who were recently or concomitantly treated with immunomodulators or immunosuppressants, as well as in patients receiving TYASABRI as monotherapy. Other serious adverse events that have occurred in TYASABRI-treated patients included hypersensitivity reactions (e.g., anaphylaxis) and infections. Serious opportunistic and other atypical infections have been observed in TYASABRI-treated patients, some of whom were receiving concurrent immunosuppressants. Herpes infections were slightly more common in patients treated with TYASABRI. In MS and CD clinical trials, the incidence and rate of other serious adverse events, including serious infections, were similar in patients receiving TYASABRI and those receiving placebo. Common adverse events reported in TYASABRI-treated MS patients include headache, fatigue, infusion reactions, urinary tract infections, joint and limb pain and rash. Other common adverse events reported in TYASABRI-treated CD patients include respiratory tract infections and nausea. Clinically significant liver injury has been reported in patients treated with TYASABRI in the post-marketing setting.

TYSABRI is approved in more than 40 countries.

For more information about TYASABRI 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, 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 TYASABRI. These statements are based on the companies' current beliefs and expectations. The commercial potential of TYASABRI 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 TYASABRI 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.

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Contact:

Investors:

Elan

Chris Burns, 800-252-3526

David Marshall, 353-1-709-4444

or

Biogen Idec

Eric Hoffman, 617-679-2812

Media:

Elan

Miriam Mason, 650-278-7113 (onsite)

Mary Stutts, 650-794-4403

or

Biogen Idec

Shannon Altimari, 617-914-6524