



Biogen Idec Receives Approval for TYSABRI® High Titer Production

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CAMBRIDGE, Mass.--([BUSINESS WIRE](#))--Biogen Idec (NASDAQ: BIIB) today announced that the U.S. Food and Drug Administration (FDA) has approved the company's high titer process for the production of its multiple sclerosis (MS) drug TYSABRI® (natalizumab). Biogen Idec received similar approval from the European Medicines Agency (EMA) for the high titer process in December 2008. The new, higher-yield process will be used to manufacture TYSABRI at the company's plant in Research Triangle Park (RTP).

"Developing this high titer process is another example of our world-class expertise and leadership in biologics manufacturing," said Biogen Idec Chief Operating Officer Bob Hamm. "We expect this new process to result in about a four-fold increase in yield."

Biogen Idec is a global leader in biologics manufacturing with capabilities and capacity for protein production that are world-class in quality and scale. Biogen Idec is one of a handful of biotechnology companies that has two licensed and dedicated biological bulk-manufacturing facilities, including its large-scale manufacturing plant in RTP, which is one of the world's largest cell culture facilities.

TYSABRI, which is co-marketed with Elan Corporation, plc (NYSE: ELN), is approved in more than 40 countries. TYSABRI is approved in the United States for relapsing forms of MS and moderately-to-severely active Crohn's disease. It is approved in the European Union for relapsing-remitting MS.

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.

About TYSABRI

TYSABRI is a treatment approved for relapsing forms of MS in the US 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 is also approved in the US to induce and maintain clinical response and remission in adult patients with moderately-to-severely active Crohn's disease (CD) with evidence of inflammation in those patients 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 TYSABRI, 54% sustain their response through every visit for one year compared to 20% of patients receiving placebo ($p < 0.001$), 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 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 40 countries. Biogen Idec and Elan Corporation, plc (NYSE: ELN) are in a 50-50 partnership for the development and promotion of TYSABRI.

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

Safe Harbor

This press release contains forward-looking statements about our manufacturing capacity and gross margins. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those that we expect, including the occurrence of adverse safety events, competitive pressures, possible adverse impact of government regulation, product liability claims and the other risks and uncertainties that are described in Item 1.A. Risk Factors in our annual report on Form 10-K and in other reports we file with the SEC. These forward-looking statements speak only as of the date of this presentation, 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.

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