



US and EU Regulatory Authorities Accept Oral BG-12 Marketing Applications for Review

May 9, 2012

WESTON, Mass.--([BUSINESS WIRE](#))--Today [Biogen Idec](#) (NASDAQ: BIIB) announced that U.S. and EU regulatory authorities have accepted the company's marketing applications for the review of BG-12 (dimethyl fumarate), an oral therapeutic candidate for the treatment of multiple sclerosis (MS). The U.S. Food and Drug Administration (FDA) has accepted Biogen Idec's New Drug Application (NDA) for marketing approval of BG-12 in the United States and granted the company a standard review timeline. In addition, the European Medicines Agency (EMA) has validated Biogen Idec's Marketing Authorisation Application (MAA) for review of BG-12 in the European Union.

Biogen Idec's regulatory applications for BG-12 were based on a comprehensive clinical development program in which BG-12 demonstrated significant reductions in MS disease activity coupled with favorable safety and tolerability in two pivotal Phase 3 clinical trials. Biogen Idec announced that it submitted an NDA to the FDA and an MAA to the EMA in the first quarter of 2012. The company also recently submitted regulatory applications in Canada and Switzerland.

About BG-12

BG-12 (dimethyl fumarate) is an investigational oral therapy under regulatory review for the treatment of MS. BG-12 is the only currently known investigational compound for the treatment of MS that has experimentally demonstrated activation of the Nrf-2 pathway. In 2011, Biogen Idec announced positive data from DEFINE and CONFIRM, two global, placebo-controlled Phase 3 clinical trials that evaluated 240 mg of BG-12, administered either twice a day or three times a day, for two years. BG-12 is currently being evaluated in a long-term extension study, ENDORSE.

About Biogen Idec

Through cutting-edge science and medicine, Biogen Idec discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hemophilia and autoimmune disorders. Founded in 1978, Biogen Idec is the world's oldest independent biotechnology company. Patients worldwide benefit from its leading multiple sclerosis therapies, and the company generates more than \$5 billion in annual revenues. For product labeling, press releases and additional information about the company, please visit www.biogenidec.com.

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