Biogen Idec Submits Application to FDA for Approval of Oral BG-12 to Treat Multiple Sclerosis

February 28, 2012

- EMA Submission Anticipated within the Coming Days -

WESTON, Mass.--(BUSINESS WIRE)--Today Biogen Idec (NASDAQ: BIIB) announced the company has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for marketing approval of BG-12 (dimethyl fumarate), the company's oral therapeutic candidate for the treatment of multiple sclerosis (MS). The regulatory submission was based on BG-12's comprehensive development program, in which BG-12 demonstrated significant reductions in MS disease activity coupled with favorable safety and tolerability in the Phase 3 DEFINE and CONFIRM studies.

"While there have been important therapeutic advances in MS over the last 15 years, there is still a significant unmet need for new and innovative therapies that target the disease in different ways," said Douglas E. Williams, Ph.D., Biogen Idec's executive vice president of Research and Development. "Based on the robust clinical efficacy and safety data seen in our Phase 3 studies, we believe BG-12 has the potential to become an important oral treatment option for MS patients."

Biogen Idec plans to submit a Marketing Authorisation Application (MAA) for BG-12 to the European Medicines Agency (EMA) within the coming days.

"The rapid submissions of our BG-12 regulatory packages, which integrated one of the largest placebo-controlled data sets for a filing in MS, reflect our commitment to bringing additional therapies to patients in need as quickly as possible," concluded Dr. Williams. "We anticipate hearing from regulatory authorities regarding the status and acceptance of our submissions within the next couple of months."

About BG-12

BG-12 (dimethyl fumarate) is an investigational oral therapy in late-stage clinical development for the treatment of relapsing-remitting multiple sclerosis (RRMS), the most common form of MS. BG-12 is the only currently known investigational compound for the treatment of RRMS 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.

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.

Safe Harbor

This press release includes forward-looking statements, including statements about regulatory actions and the development and commercialization of BG-12 in MS. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "estimate," "expect," "forecast," "intend," "may," "plan," "will," and other words and terms of similar meaning. You should not place undue reliance on these statements. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including obtaining regulatory approval, the occurrence of adverse safety events, product competition, the availability of reimbursement for our products, adverse market and economic conditions, problems with our manufacturing processes and our reliance on third parties, failure to comply with government regulation and possible adverse impact of changes in such regulation, our ability to protect our intellectual property rights and the cost of doing so, and the other risks and uncertainties that are described in the Risk Factors section of our most recent annual or quarterly report and in other reports we have filed with the SEC. These statements are based on our current beliefs and expectations and speak only as of the date of this press release. We do not undertake any obligation to publicly update any forward-looking statements.

Contact:

MEDIA CONTACT:
Biogen Idec
Kate Niazi-Sai, +1 781-464-3260
or
INVESTOR CONTACT:
Biogen Idec
Kia Khaleghpour, +1 781-464-2442