Biogen Idec Announces Positive Top-Line Results from the First Phase 3 Trial Investigating Oral BG-12 (DIMETHYL FUMARATE) in Multiple Sclerosis

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- DEFINE Study Achieves Primary and All Secondary Endpoints for Both Study Doses -

- Full Data to Be Presented at a Future Medical Meeting -

WESTON, Mass.--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) announced today positive top-line results from DEFINE, the first of two pivotal Phase 3 clinical trials designed to evaluate the investigational oral compound BG-12 (dimethyl fumarate) as a monotherapy in people with relapsing-remitting multiple sclerosis (RRMS). Results showed that 240 mg of BG-12, administered either twice or three times a day, met the primary study endpoint, demonstrating a highly statistically significant reduction ($p<0.0001$) in the proportion of patients with RRMS who relapsed at two years compared with placebo. Both doses of BG-12 also met all of the secondary study endpoints, providing a statistically significant reduction in annualized relapse rate, in the number of new or newly enlarging T2 hyperintense lesions, in new gadolinium-enhancing (Gd+) lesions, and in the rate of disability progression as measured by the Expanded Disability Severity Scale (EDSS) at two years.

DEFINE was a global, randomized, double-blind, placebo-controlled, dose-comparison study to determine the efficacy and safety of BG-12 in people with RRMS. In addition to meeting the primary and all secondary endpoints, initial data from the trial showed that BG-12 demonstrated a favorable safety and tolerability profile. The overall incidence of adverse events and serious adverse events was similar among the placebo group and both BG-12 treatment groups. The safety profile was consistent with what was seen in the published Phase 2 study of BG-12. Further analyses of the DEFINE study are ongoing, and the company anticipates presenting detailed data at a future medical meeting.

“The significant clinical responses seen in the DEFINE study represent an important step forward in the development of BG-12 for multiple sclerosis (MS),” said Douglas Williams, Ph.D., Biogen Idec’s Executive Vice President of Research and Development. “We are very pleased with these data and believe that BG-12 has the potential to offer MS patients a highly effective oral treatment option with a strong safety profile.”

Data from scientific studies indicate that BG-12 has the potential to be distinctive by reducing the entry into and the action of inflammatory cells on the Central Nervous System (CNS), as well as potentially protecting CNS cells from oxidative stress and death by activation of the Nrf-2 pathway.

BG-12 received Fast Track designation from the U.S. Food and Drug Administration (FDA) in 2008. In addition to DEFINE, another Phase 3 RRMS clinical trial, CONFIRM, is currently underway. This study is evaluating BG-12 and an active reference comparator, glatiramer acetate, against placebo on clinical relapse, magnetic resonance imaging (MRI) measures of MS, progression of disability, and safety. Results from CONFIRM are expected in the second half of 2011.

About the DEFINE Trial

DEFINE (**D**etermination of the **E**fficacy and safety of oral **F**umarate **IN** r**E**lapsing-remitting MS) was a global, randomized, double-blind, placebo-controlled, dose-comparison study to determine the efficacy and safety of BG-12 in more than 1,200 people with RRMS. The study evaluated two doses of BG-12: 240 mg twice a day and 240 mg three times a day. The primary objective was to determine if BG-12 is effective in reducing the proportion of relapsing patients at two years. Secondary endpoints included reduction in the number of new or newly enlarging T2 hyperintense lesions and new Gd+ lesions as measured by MRI, reduction in annualized relapse rate, and reduction of disability progression as measured by EDSS. Additional endpoints included the safety and tolerability of BG-12.

About Biogen Idec

Biogen Idec uses cutting-edge science to discover, develop, manufacture, and market therapeutic products for the treatment of serious diseases with a focus on neurological 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 $4 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 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 meeting endpoints in clinical trials, 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.

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