Oral BG-12 (Dimethyl Fumarate) Significantly Reduced Multiple Sclerosis (MS) Relapses and Disability Progression in Define Phase 3 Clinical Trial

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--240 mg of BG-12 Administered Either Twice or Three Times Daily Demonstrated Significant Clinical Effects--

WESTON, Mass.--(BUSINESS WIRE)--Today Biogen Idec (NASDAQ: BIIB) announced positive data from the Phase 3 DEFINE clinical trial of oral BG-12 (dimethyl fumarate) in people with relapsing-remitting multiple sclerosis (RRMS). Results showed that 240 mg of BG-12, administered either twice a day (BID) or three times a day (TID), significantly reduced the proportion of patients who relapsed by 49 percent and 50 percent, respectively, at two years compared with placebo. Detailed data from DEFINE will be presented at the 5th Joint Triennial Congress of the European and Americas Committees on Treatment and Research in Multiple Sclerosis (ECTRIMS and ACTRIMS) in Amsterdam, including a platform presentation on Friday, October 21, 2011 at 9:30 a.m. CEST.

“The significant clinical and radiological responses in DEFINE are further evidence that BG-12 may become an oral therapy of choice for MS patients,” said Doug Williams, Ph.D., Biogen Idec’s Executive Vice President of Research and Development. “Results from our second Phase 3 trial, CONFIRM, will provide additional insight into BG-12’s profile, as well as a comprehensive data set to further discussions with regulatory authorities. We anticipate releasing top-line data from CONFIRM later this year.”

DEFINE was the first of two Phase 3 clinical trials designed to determine the efficacy and safety of BG-12 in people with RRMS. Both BG-12 BID and TID met the primary and all secondary endpoints in the study. In addition to demonstrating a significant reduction in the proportion of patients who relapsed, BG-12 significantly reduced the annualized relapse rate (ARR) and the risk of disability progression as measured by the Expanded Disability Status Scale (EDSS) at two years compared to patients on placebo.

- BG-12 reduced the risk of relapse by 49 percent in the BID group (HR 0.51; 95% confidence interval [CI] 0.40, 0.66; p<0.0001) and by 50 percent in the TID group (HR 0.50; 95% CI 0.39, 0.65; p<0.0001).
- BG-12 BID reduced the ARR by 53 percent, while BG-12 TID reduced the ARR by 48 percent (p<0.0001 for both).
- BG-12 BID reduced the risk of disability progression by 38 percent (HR 0.62; 95% CI 0.44, 0.87; p=0.0050), while BG-12 TID reduced this risk by 34 percent (HR 0.66; 95% CI 0.48, 0.92; p=0.0128).

“BG-12 may be a valuable treatment option for MS patients, combining strong efficacy, a favorable safety profile and oral administration,” said Ralf Gold, M.D., Professor and Chair, Department of Neurology, St. Josef-Hospital/Ruhr-University, Bochum, Germany. “Preclinical research has shown that BG-12 has anti-inflammatory and neuroprotective effects. If the clinical responses seen in DEFINE are replicated in its second Phase 3 trial, BG-12 has the potential to provide a new approach to treating MS and be an important step forward for patients.”

Magnetic resonance imaging (MRI) scans were performed at baseline, 24 weeks, one year and two years to determine the number of T2 hyperintense lesions, gadolinium-enhancing (Gd+) lesions and T1 hypointense lesions (a tertiary endpoint). At two years, results demonstrated that RRMS patients receiving BG-12 experienced significant reductions in the number of brain lesions compared to patients on placebo.

- BG-12 BID and TID reduced the mean number of new or newly enlarging T2 hyperintense lesions by 85 percent and 74 percent (p<0.0001), respectively.
- BG-12 BID and TID reduced the mean number of Gd+ lesions by 90 percent and 73 percent (p<0.0001), respectively.
- BG-12 BID and TID reduced the mean number of new T1 hypointense lesions by 72 percent and 63 percent (p<0.0001), respectively.

“The BG-12 program further demonstrates Biogen Idec’s commitment to developing innovative therapies to address unmet needs in the MS community,” continued Dr. Williams. “BG-12’s distinct mechanism of action, combined with strong efficacy and safety data, position it as a potentially valuable option for MS patients and a further growth driver for Biogen Idec.”

In DEFINE, the safety profile for the two BG-12 treatment groups was similar. The overall incidence of adverse events (AEs), serious adverse events (SAEs) and AEs leading to study discontinuation was similar among the BG-12 and placebo groups. AEs were reported by 95 to 96 percent of patients, irrespective of study group. The most frequently reported AEs across the three study groups were flushing, MS relapse, nasopharyngitis, headache, diarrhea and fatigue. Flushing (35% BG-12; 5% placebo), gastrointestinal AEs such as diarrhea (17% BG-12; 13% placebo), nausea (13% BG-12; 9% placebo), upper abdominal pain (11% BG-12; 7% placebo) and abdominal pain (10% BG-12; 5% placebo) were higher in the BG-12-combined group than the placebo group, with the highest incidence in the first month of treatment, which decreased thereafter.

SAEs were reported in 21 percent of patients receiving placebo and 17 percent of patients receiving BG-12. The most frequently reported SAE across all treatment groups was MS relapse (15% placebo; 9% BG-12). There were no deaths related to study treatment. There was no increase in infections, serious infections, opportunistic infections or malignancies.

These data will be presented in two posters and a platform presentation at ECTRIMS/ACTRIMS:

- *Clinical Efficacy of BG-12, An Oral Therapy, In Relapsing-Remitting Multiple Sclerosis: Data from the Phase 3 DEFINE Trial* (#95) will be presented by Professor Ralf Gold on Friday, October 21, 2011 from 9:30 to 9:45 a.m. CEST.

- *Efficacy on MRI Endpoints of BG-12, An Oral Therapy, In Relapsing-Remitting Multiple Sclerosis: Data from the Phase 3 DEFINE Trial* (P#831) will be available for viewing on Friday, October 21, 2011 from 3:30 to 5:00 p.m. CEST.
- *Safety and Tolerability of BG-12 in the Phase 3 DEFINE Trial in Patients with Relapsing-Remitting Multiple Sclerosis* (P#994) will be available for viewing on Friday, October 21, 2011 from 3:30 to 5:00 p.m. CEST.

About DEFINE

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 people with RRMS. The primary objective was to determine if BG-12 is effective in reducing the proportion of relapsing patients at two years. Secondary endpoints included ARR, disability progression as measured by EDSS, and, in a cohort of sites, the number of new or newly enlarging T2 hyperintense lesions and the number of Gd+ lesions as measured by brain MRI. Additional endpoints included the safety and tolerability of BG-12.

DEFINE enrolled 1,237 patients, 18 to 55 years of age, at 198 sites in 28 countries. Patients participating in the study were required to have RRMS per McDonald criteria 1-4, a baseline EDSS score between 0.0 and 5.0 (inclusive), and at least one MS relapse in the 12 months prior to randomization or a Gd+ lesion on brain MRI scans within six weeks of randomization. Patients were randomized in a ratio of 1:1:1 to: 240 mg of BG-12 BID, 240 mg of BG-12 TID or placebo. All patients underwent clinical assessments at screening, baseline and every four weeks for up to two years.

About BG-12

BG-12 (dimethyl fumarate) is an investigational oral therapy in late-stage clinical development for the treatment of RRMS, the most common form of MS. BG-12 is the only compound in clinical trials for the treatment of MS known to activate the Nrf-2 pathway. Research suggests that BG-12 has the potential to reduce the activity and impact of inflammatory cells on the Central Nervous System (CNS) and induce direct cytoprotective responses in CNS cells. These effects may enhance the CNS cells' ability to mitigate the toxic inflammatory and oxidative stress that plays a role in MS pathophysiology.

Top-line data from the second Phase 3 trial of BG-12, CONFIRM, is anticipated in the second half of 2011.

About Biogen Idec

Biogen Idec uses cutting-edge science to discover, develop, manufacture and market therapies for serious diseases with a focus on neurology, immunology and hemophilia. 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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