Positive Results from Phase 3 CONFIRM Clinical Trial Show Efficacy and Safety of Oral BG-12 in Multiple Sclerosis

April 24, 2012

-- Detailed CONFIRM Data Presented at 2012 American Academy of Neurology Annual Meeting --

-- Regulatory Applications Submitted to the FDA and EMA --

WESTON, Mass.--(BUSINESS WIRE)--Today Biogen Idec (NASDAQ: BIIB) announced that detailed positive data from CONFIRM, the second Phase 3 clinical trial of oral BG-12 (dimethyl fumarate) in people with relapsing-remitting multiple sclerosis (RRMS), will be presented in three platform presentations at the 64th Annual Meeting of the American Academy of Neurology (AAN) in New Orleans. In CONFIRM, BG-12 demonstrated efficacy across a variety of clinical and radiological outcome measures, as well as favorable safety and tolerability profiles. These data, along with results from BG-12's first Phase 3 study, DEFINE, were included in regulatory applications that were submitted to U.S. and EU regulatory agencies early this year.

"Results from CONFIRM complement the profile we have seen for BG-12 throughout its clinical development program, which now includes robust data sets from two global, placebo-controlled Phase 3 pivotal studies with more than 2,600 multiple sclerosis (MS) patients," said Douglas E. Williams, Ph.D., Biogen Idec's executive vice president of Research and Development. "If approved by regulators, we believe BG-12 could be an important new oral therapeutic option for MS patients."

CONFIRM Efficacy Results

CONFIRM was a global, placebo-controlled clinical trial to determine the efficacy and safety of 240 mg of BG-12, administered either twice a day (BID) or three times a day (TID), in people with RRMS. The study included glatiramer acetate (GA; 20 mg subcutaneous daily injection) as a reference comparator. Both active treatments were compared to placebo.

BG-12 met the CONFIRM study's primary endpoint by significantly reducing annualized relapse rate (ARR) by 44 percent for BID and by 51 percent for TID ($p<0.0001$ for both) compared to placebo over two years. GA reduced ARR by 29 percent ($p=0.0128$) compared to placebo over two years.

BG-12 met the study's secondary relapse endpoint by significantly reducing the proportion of patients who relapsed at two years by 34 percent for BID ($p=0.0020$) and by 45 percent for TID ($p<0.0001$) compared to placebo. GA provided a 29 percent reduction ($p=0.0097$) in the proportion of relapsing patients compared to placebo over the same time period.

BG-12 also met magnetic resonance imaging (MRI) endpoints in a cohort of patients, demonstrating a significant effect on MS brain lesions. Reductions in new brain lesion counts were evident within the first year of treatment and were sustained throughout the study. At two years compared to placebo:

- BG-12 reduced the number of new or newly enlarging T2-hyperintense lesions (secondary endpoint) by 71 percent for BID ($p<0.0001$) and by 73 percent for TID ($p<0.0001$), while GA provided a 54 percent reduction ($p<0.0001$).
- BG-12 reduced the number of new non-enhancing T1-hypointense lesions (secondary endpoint) by 57 percent for BID ($p<0.0001$) and by 65 percent for TID ($p<0.0001$), while GA provided a 41 percent reduction ($p=0.0021$).
- BG-12 reduced the odds of having more gadolinium-enhancing (Gd+) lesions (tertiary endpoint) by 74 percent for BID ($p<0.0001$) and by 65 percent for TID ($p=0.0001$), while GA provided a 61 percent reduction ($p=0.0003$).

"Until we find a cure for MS, there is a need for new treatments that address this debilitating disease," said Robert J. Fox, M.D., medical director of the Mellen Center for Multiple Sclerosis at Cleveland Clinic and principal investigator of the CONFIRM clinical trial*. "The strong efficacy and safety results we have observed in the CONFIRM study suggest BG-12 may be a positive addition to the current MS treatment paradigm."

Results from CONFIRM also showed that BG-12 reduced the risk of 12-week confirmed disability progression, as measured by the Expanded Disability Status Scale (EDSS), by 21 percent for BID ($p=0.2536$) and by 24 percent for TID ($p=0.2041$) at two years compared to placebo, while GA reduced the risk of confirmed disability progression by 7 percent ($p=0.7036$).

** Dr. Robert Fox is a paid advisor for Biogen Idec for projects not related to BG-12 clinical development.*

CONFIRM Safety and Tolerability Results

In CONFIRM, both dose regimens of BG-12 showed favorable safety and tolerability profiles, which were consistent with those seen in DEFINE. Overall, the incidence of adverse events (AEs), serious adverse events (SAEs) and discontinuations due to AEs was similar across all study groups:

- Adverse events (placebo 92%; BG-12 BID 94%; BG-12 TID 92%; GA 87%)
- Serious adverse events (placebo 22%; BG-12 BID 17%; BG-12 TID 16%; GA 17%)
- Discontinuations due to AEs (placebo 10%; BG-12 BID 12%; BG-12 TID 12%; GA 10%)

The most common AEs reported with an increased incidence in the BG-12 groups were flushing (placebo 4%; BG-12 BID 31%; BG-12 TID 24%; GA 2%) and gastrointestinal (GI) events such as diarrhea (placebo 8%; BG-12 BID 13%; BG-12 TID 15%; GA 4%), nausea (placebo 8%; BG-12 BID 11%; BG-12 TID 15%; GA 4%) and upper abdominal pain (placebo 5%; BG-12 BID 10%; BG-12 TID 10%; GA 1%). The incidence of these events

decreased substantially in the BG-12 groups after the first month. The most frequently reported SAE was MS relapse, with no other events reported by more than two patients in any group.

Mean lymphocyte counts decreased during the first year of BG-12 treatment and then plateaued, staying within normal limits throughout the entire treatment period. The incidence of hepatic and renal events was comparable among all study groups. The incidence of serious infections was low and balanced across the study groups, and there were no opportunistic infections. In CONFIRM, there were no malignancies in the BG-12 groups, one malignancy in the placebo group and four malignancies in the GA group.

“Results from CONFIRM are similar to what was observed in DEFINE, providing favorable safety data from these two substantial global studies,” said J. Theodore Phillips, M.D., Ph.D., program director of the Multiple Sclerosis Program at the Baylor Institute for Immunology Research, clinical professor of Neurology at the University of Texas Southwestern Medical Center, and investigator in the CONFIRM study. “The most common BG-12 side effects were flushing and GI events, which decreased substantially in incidence after the first month and resulted in a low incidence of discontinuations.”

These data will be presented in three platform presentations at the AAN annual meeting:

- Clinical Efficacy of BG-12 in Relapsing-Remitting Multiple Sclerosis (RRMS): Data from the Phase 3 CONFIRM Study (S01.003) will be presented by Dr. Robert J. Fox on Tuesday, April 24, 2012 from 1:30-1:45 p.m. CDT
- Effects of BG-12 on Magnetic Resonance Imaging (MRI) Endpoints in Patients with Relapsing-Remitting Multiple Sclerosis (RRMS): Data from the Phase 3 CONFIRM Study (S11.001) will be presented by Dr. David Miller of the University College London’s Institute of Neurology, on Tuesday, April 24, 2012 from 3:00-3:15 p.m. CDT
- Safety and Tolerability of BG-12 in Patients with Relapsing-Remitting Multiple Sclerosis (RRMS): Analyses from the CONFIRM Study (S41.005) will be presented by Dr. J. Theodore Phillips on Thursday, April 26, 2012 from 2:00-2:15 p.m. CDT

BG-12 Regulatory Status

Earlier this year, Biogen Idec announced that it had submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for marketing approval of BG-12 in the United States and a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for review in the European Union. The EMA has validated Biogen Idec’s MAA and is reviewing the BG-12 data package. Biogen Idec is awaiting formal acceptance of its NDA for review by the FDA.

For members of the media interested in more information and additional resources, please visit www.biogenidec.com/us_media_corner.

About the CONFIRM Clinical Trial

The CONFIRM (**Co**mparator and a**n** Oral **F**umarate **i**n **RRM**S) clinical trial was a global, randomized, double-blind, placebo-controlled, dose-comparison study to determine the efficacy and safety of BG-12 and enrolled 1,430 people with RRMS. The study evaluated two dose regimens of BG-12, 240 mg BID and 240 mg TID, as well as a reference comparator of GA (20 mg subcutaneous daily injection). Both BG-12 and GA groups were evaluated versus placebo.

The primary objective was to determine whether BG-12 was effective in reducing the rate of clinical relapses at two years. Secondary objectives at two years included reduction in the number of new or newly enlarging T2-hyperintense lesions; in new non-enhancing T1-hypointense lesions; in the proportion of patients who relapsed; and in progression of disability as measured by EDSS. Safety and tolerability of BG-12 were also assessed.

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 and 2012, 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. Applications for marketing authorization for BG-12 were submitted by Biogen Idec by the FDA and the EMA in the first quarter of 2012.

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 the 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.

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