New TECFIDERA® (Dimethyl Fumarate) Data Show Sustained Efficacy and Long-Term Safety in a Broad Range of Multiple Sclerosis Patients

October 4, 2013

– Interim Results from ENDORSE Extension Study Reinforce Favorable Safety Profile in Patients Treated for Up to Six and a Half Years –

– Analysis of Treatment-Naïve MS Patients Shows Positive Treatment Effects on Relapses, Disability Progression and MRI Outcomes –

WESTON, Mass.--(BUSINESS WIRE)--Data presented today show that TECFIDERA® (dimethyl fumarate) continues to offer consistent and strong efficacy combined with a favorable safety profile in a broad range of patients with relapsing-remitting multiple sclerosis (RRMS), including those patients who are newly diagnosed with the disease. These data were presented by Biogen Idec (NASDAQ: BIIB) at the 29th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Copenhagen, Denmark from 2-5 October.

Interim analyses from the ENDORSE long-term extension study show that TECFIDERA maintained its effect in reducing disease activity in patients treated for four years. No new or worsening safety signals were observed in patients who had received TECFIDERA for up to six and a half years. In addition, a separate post-hoc analysis of the Phase 3 DEFINE and CONFIRM clinical trials shows that TECFIDERA significantly reduced multiple sclerosis (MS) relapses in treatment-naïve patients, while delaying the overall progression of the disease over time.

“Because MS is a chronic, life-long disease, physicians and patients need to know they are taking a treatment that will offer them sustained efficacy over the long-term with a consistent safety profile,” said Doug Williams, executive vice president, Research and Development, Biogen Idec. “These analyses provide important information on the benefits of TECFIDERA’s strong efficacy and favorable safety for a wide range of patients with RRMS – from those treating their MS for the first time to those who have been on TECFIDERA treatment for up to six and a half years.”

ENDORSE Interim Clinical Efficacy and MRI Outcomes
ENDORSE is a global, dose-blind extension study to determine the long-term safety and efficacy of TECFIDERA (240 mg, dosed twice a day (BID) or three times a day (TID)). Patients who received two years of TECFIDERA in DEFINE and CONFIRM continued on the same dose in ENDORSE. Patients who previously received placebo or glatiramer acetate (GA; 20 mg subcutaneous daily injection; CONFIRM only) in DEFINE or CONFIRM were randomized 1:1 to TECFIDERA BID or TID. All currently enrolled patients included in the interim analyses had completed four years in the TECFIDERA clinical program (two years in DEFINE or CONFIRM plus two years in ENDORSE). At present, some patients have received TECFIDERA treatment for up to six and a half years.

Interim efficacy results found that patients who continued on TECFIDERA treatment in ENDORSE for two years experienced sustained clinical efficacy (as measured by relapse and disability progression endpoints), similar to what was observed after two years in DEFINE and CONFIRM. These patients also experienced a similarly low frequency of MRI lesions over four years (as measured by new or enlarging T2-hyperintense lesions; new non-enhancing T1-hypointense lesions; and gadolinium-enhanced (Gd+) lesions).

Patients initially randomized to placebo or GA in DEFINE or CONFIRM who then received TECFIDERA in ENDORSE showed clinical and MRI outcomes similar to those observed with TECFIDERA treatment in the pivotal studies.

ENDORSE Interim Safety Outcomes
The safety profile of TECFIDERA observed in ENDORSE was consistent with favorable findings reported in the pivotal DEFINE and CONFIRM studies. There were no new safety findings observed in patients who continued treatment with TECFIDERA from DEFINE and CONFIRM. Safety follow-up was performed in patients who had received treatment for up to six and a half years.

The most common adverse events in patients who switched to TECFIDERA from placebo or GA were flushing and gastrointestinal (GI) events, the incidences of which were generally similar to what was observed in DEFINE and CONFIRM. In patients continuing on TECFIDERA therapy for up to six and a half years, the most common adverse events were MS relapse and nasopharyngitis (common cold).

Similar to what was seen with treatment with TECFIDERA in the pivotal studies, mean lymphocyte counts in patients who switched to TECFIDERA in ENDORSE decreased over the first year of treatment and then plateaued. For patients who continued treatment with TECFIDERA in ENDORSE, mean lymphocyte counts were generally stable and mean counts remained within normal limits at all time points.

Also consistent with data from the pivotal studies, there was no overall increased risk of serious infections (including opportunistic infections) or malignancies in patients continuing on, or new to, TECFIDERA treatment. There was no overall increased risk of renal dysfunction or hepatic adverse events in any treatment group.

“When making MS treatment decisions, we weigh efficacy and safety considerations, so it is encouraging to see that the positive profile of TECFIDERA observed in the DEFINE and CONFIRM studies has been maintained in the ENDORSE clinical trial to date,” said Ralf Gold, M.D., professor/chair of the Department of Neurology at St. Josef-Hospital/Ruhr-University in Bochum, Germany. “These interim ENDORSE findings reaffirm, over the longer term, the outcomes we have previously observed with TECFIDERA and provide important information for physicians and patients.”

DEFINE and CONFIRM Clinical Efficacy in Treatment-Naïve Patients
A post-hoc analysis from the Phase 3 DEFINE and CONFIRM studies evaluated the efficacy of TECFIDERA in disease-modifying therapy treatment-naïve patients who were diagnosed with RRMS within one year of enrolling in the studies.

Results show that at two years TECFIDERA BID reduced annualized relapse rate (ARR) compared to placebo by 56 percent ($p<0.0001$) and the risk of relapse by 54 percent ($p<0.0001$).

In addition, TECFIDERA BID reduced the risk of 12-week confirmed disability progression at two years, as measured by the Expanded Disability

Status Scale (EDSS), by 71 percent (p<0.0001) and had a significant positive effect on MRI outcomes in this patient population.

About ENDORSE
ENDORSE is an ongoing global, dose-blind, Phase 3 extension study to determine the long-term safety and efficacy of TECFIDERA (240 mg, BID or TID). The study has enrolled 1,738 patients with RRMS who completed the DEFINE or CONFIRM studies. Patients who received two years of TECFIDERA in DEFINE and CONFIRM continued on the same dose (BID or TID) in ENDORSE. Patients who previously received placebo or GA (CONFIRM only) were randomized 1:1 to TECFIDERA BID or TID. Patients participating in ENDORSE will be followed for up to five years.

The primary objective of the study is to evaluate the long-term safety profile of TECFIDERA. Secondary objectives include: long-term efficacy of TECFIDERA on clinical outcomes and MS brain lesions on MRI scans; and effects of TECFIDERA on quality of life measurements. It is estimated that the ENDORSE study will be completed in 2016.

About DEFINE and CONFIRM
DEFINE (**D**etermination of the **E**fficacy and safety of oral **F**umarate **IN** relapsing-r**E**mitting MS) was a global, two-year, randomized, multi-center, double-blind, placebo-controlled, dose-comparison Phase 3 clinical trial that enrolled more than 1,200 patients with RRMS at 198 sites in 28 countries. The study evaluated TECFIDERA (240 mg, BID or TID) compared to placebo.

The primary objective was to determine if TECFIDERA was 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 Gd+ lesions as measured by MRI, reduction in ARR, and reduction of disability progression as measured by EDSS. Safety and tolerability of TECFIDERA were also assessed.

CONFIRM (**CO**mparator and a**N** oral **F**umarate **I**n **R**elapsing-remitting **M**S) was a global, two-year, randomized, multi-center, placebo-controlled, double-blind, dose-comparison Phase 3 clinical trial that enrolled more than 1,400 patients with RRMS at 200 sites in 28 countries. The study investigated TECFIDERA (240 mg, BID or TID) compared to placebo and included a reference comparator arm of glatiramer acetate (GA; 20 mg subcutaneous daily injection) versus placebo.

The primary objective was to determine whether TECFIDERA was effective in reducing the rate of clinical relapses at two years. Secondary endpoints at two years included reduction in: the number of new or newly enlarging T2-hyperintense lesions and the number of new non-enhancing T1-hypointense lesions (MRI scans were obtained at a cohort of sites); the proportion of patients who relapsed; and in progression of disability as measured by EDSS. Safety and tolerability of TECFIDERA were also assessed.

About TECFIDERA®
TECFIDERA is an oral therapy for relapsing forms of MS, including RRMS, the most common form of MS. TECFIDERA is currently approved in the United States, Canada and Australia, and is under review by regulatory authorities in the European Union.

TECFIDERA has been proven to reduce MS relapses, progression of disability and MS brain lesions, while demonstrating a favorable safety and tolerability profile. In clinical trials, the most common adverse events associated with TECFIDERA were flushing and GI events. Other side effects included a decrease in mean lymphocyte counts during the first year of treatment, which then plateaued. The efficacy and safety of TECFIDERA has been studied in a large, global clinical program with more than 3,600 MS patients, which includes an ongoing long-term extension study. It is believed that TECFIDERA provides a new approach to treating MS by activating the Nrf2 pathway, although its exact mechanism of action is unknown. This pathway provides a way for cells in the body to defend themselves against inflammation and oxidative stress caused by conditions like MS.

For more information about TECFIDERA, please visit www.biogenidec.com.

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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