New Data from ENDORSE Show Positive Results Continued over Five Years with TECFIDERA® (Dimethyl Fumarate) in a Wide Range of Multiple Sclerosis Patients

September 11, 2014

– Long-term Favorable Safety Profile Sustained in Patients Treated with TECFIDERA –

– Positive Clinical and MRI Outcomes in Newly Diagnosed Patients –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Today Biogen Idec (NASDAQ: BIIB) announced that five-year results from the ENDORSE Phase 3 extension study show TECFIDERA® (dimethyl fumarate) provides strong and sustained efficacy in a broad range of people living with relapsing-remitting multiple sclerosis (RRMS). These data will be presented at the Sixth Triennial Joint Meeting of the Americas Committee for Treatment and Research in Multiple Sclerosis and the European Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS-ECTRIMS).

Across all patients in the ENDORSE study who received TECFIDERA, including some patients who were treated for up to seven and a half years, the safety profile remained consistent with no new or worsening safety signals. Additional analyses in patients who were newly diagnosed with multiple sclerosis (MS) when the parent studies DEFINE and CONFIRM began indicate that TECFIDERA had a robust long-term effect on MS relapse rates, disability progression and MRI measures in these patients.

“TECFIDERA continues to provide patients with effective oral treatment for MS that is supported by a growing body of data reinforcing its benefits and favorable safety profile,” said Alfred Sandrock, M.D., Ph.D., group senior vice president and chief medical officer at Biogen Idec. “These new ENDORSE results provide further insight into the positive impact of using TECFIDERA early in the course of MS and for long-term treatment of this chronic disease.”

ENDORSE Clinical Efficacy and MRI Outcomes

ENDORSE is a global, dose-blind extension study evaluating the long-term safety and efficacy of TECFIDERA (240 mg, dosed twice a day [BID] or three times a day [TID]). Patients who received up to two years of TECFIDERA in the pivotal Phase 3 DEFINE and CONFIRM studies 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 and CONFIRM were randomized 1:1 to TECFIDERA BID or TID.

At five years (two years in DEFINE or CONFIRM and three years in ENDORSE), interim results show that patients who continued on TECFIDERA BID treatment experienced sustained clinical efficacy on relapse and disability progression endpoints as measured by annualized relapse rate (ARR) and 24-week Expanded Disability Status Scale (EDSS), similar to what was observed after two years in DEFINE and CONFIRM. These patients also maintained a low frequency of brain lesions over five years as measured by new or enlarging T2-hyperintense lesions, new non-enhancing T1-hypointense lesions and gadolinium-enhanced [Gd+] lesions.

These data will be presented in poster presentations on Thursday, Sept.11 at 3:30 p.m. ET:

- *Five-Year Follow-up of Delayed-Release Dimethyl Fumarate in RRMS: Integrated Clinical Efficacy Data from the DEFINE, CONFIRM, and ENDORSE Studies (P110)*
- *Five-Year Follow-up of Delayed-Release Dimethyl Fumarate in Relapsing-Remitting Multiple Sclerosis: MRI Outcomes from DEFINE, CONFIRM, and ENDORSE (P059)*

Clinical Efficacy in Newly Diagnosed Patients

An analysis of data from ENDORSE evaluated the long-term efficacy of TECFIDERA in newly diagnosed patients, defined as those diagnosed within one year prior to enrolling in DEFINE or CONFIRM and either disease modifying treatment-naïve or previously treated with corticosteroids alone.

Over the five-year observation period, newly diagnosed patients taking TECFIDERA BID experienced sustained reductions in relapses (measured by ARR and proportion of patients who relapsed), disability progression (measured by 24-week EDSS) and number of brain lesions. These effects are similar to the results reported for the overall ENDORSE study population, supporting the consistent efficacy of TECFIDERA in this subpopulation.

These data will be presented in a poster presentation on Thursday, Sept. 11 at 3:30 p.m. ET:

- *Long-Term Efficacy of Delayed-Release Dimethyl Fumarate in Newly Diagnosed Patients With RRMS: An Integrated Analysis of DEFINE, CONFIRM and ENDORSE (P064)*

“As shown in the ENDORSE study, TECFIDERA provides consistent outcomes across a broad range of relapsing-remitting MS patients, including those who are newly diagnosed, highlighting its utility in the range of patients we see in practice,” said Ralf Gold, M.D., professor and chair of the Department of Neurology at St. Josef-Hospital, Ruhr-University in Bochum, Germany. “The long-term efficacy of TECFIDERA in reducing key measures of disease activity and its favorable safety profile help support its role as an important therapeutic option for people living with MS.”

Effect of TECFIDERA on No Evidence of Disease Activity

Another analysis from ENDORSE evaluated the long-term effects of TECFIDERA on the emerging measure of No Evidence of Disease Activity (NEDA) over five years. Patients were assessed annually and were considered to have NEDA if they had: no relapses, no 24-week confirmed disability progression, no Gd+ lesions, and no new or enlarging T2-hyperintense lesions.

Results over five years show that the proportion of patients achieving NEDA annually was maintained in patients who continued on TECFIDERA, and was improved in patients who switched from placebo to treatment with TECFIDERA BID in the ENDORSE study.

These data will be presented in a platform presentation on Friday, Sept. 12 at 9:00 a.m. ET:

- *Long-term Follow-up of the Effect of Delayed-Release Dimethyl Fumarate on No Evident Disease Activity in Patients with Multiple Sclerosis (FC3.5)*

ENDORSE Safety

The safety profile of TECFIDERA observed in ENDORSE was consistent with the favorable findings reported in the DEFINE and CONFIRM studies. There were no new or worsening safety findings observed in patients who continued treatment with TECFIDERA from DEFINE and CONFIRM or in patients who switched to TECFIDERA therapy after the conclusion of the pivotal studies.

All patients in ENDORSE had received treatment with TECFIDERA for at least five years if previously on TECFIDERA in DEFINE or CONFIRM, including some patients who had received TECFIDERA for up to seven and a half years cumulatively. Patients previously on placebo in DEFINE or CONFIRM had received TECFIDERA in ENDORSE for at least three 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, the most common adverse events were MS relapse and nasopharyngitis (common cold).

In patients continuing on, or new to, TECFIDERA treatment there was no overall increased risk of serious infections (including opportunistic infections) or malignancies. There was no overall increased risk of renal dysfunction, urinary events or hepatic adverse events in any treatment group; and mean white blood cell and lymphocyte counts remained stable.

These data will be presented in a poster presentation on Thursday, Sept. 11 at 3:30 p.m. ET:

- *Long-term Follow-up of the Safety of Delayed-Release Dimethyl Fumarate in RRMS: Interim Results From the ENDORSE Extension Study (P066)*

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 eight 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.

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 relapse at two years compared to the placebo group. 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 progression of disability as measured by EDSS. Safety and tolerability of TECFIDERA were also assessed.

About TECFIDERA®

TECFIDERA (delayed-release dimethyl fumarate [DMF; also known as gastro-resistant DMF]) is an oral therapy for relapsing forms of MS, including relapsing-remitting MS, the most common form of MS. TECFIDERA is currently approved in the United States, the European Union, Canada, Australia, and Switzerland. Through a robust clinical trial program and commercial launches starting with the United States in March 2013, more than 100,000 patients have been treated with TECFIDERA worldwide.[1]

TECFIDERA has been proven to reduce the rate of MS relapses, progression of disability, and MS brain lesions, while demonstrating a favorable safety and tolerability profile in a broad range of patients with relapsing forms of MS.[2] In clinical trials, the most common adverse events associated with TECFIDERA were flushing and gastrointestinal (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, 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 additional important safety information, and the United States full prescribing information, please visit www.tecfidera.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, hematologic conditions and autoimmune disorders. Founded in 1978, Biogen Idec is the world's oldest independent

biotechnology company and patients worldwide benefit from its leading multiple sclerosis and innovative hemophilia therapies. For product labeling, press releases and additional information about the Company, please visit http://www.biogenidec.com.

Biogen Idec Safe Harbor

This press release contains forward-looking statements, including statements about the potential benefits TECFIDERA may have in certain MS patients and statements about the results of certain clinical studies involving TECFIDERA. These statements may be identified by words such as "believe," "expect," "may," "plan," "potential," "will," “show,” “findings,” and similar expressions, and are based on our current beliefs and expectations and on results obtained from the studies described in this press release. These statements involve risks and uncertainties that could cause actual results or future results to differ materially from those reflected in such statements, including the occurrence of adverse safety events, unexpected results or concerns that may arise from additional data, clinical trials and studies, or analysis, unexpected regulatory actions or government regulation generally, 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.

[1] Biogen Idec, Data on file; includes commercial patients as of July 2014.

[2] TECFIDERA is approved in the European Union for relapsing-remitting multiple sclerosis.

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