New Data Reinforce Efficacy of TECFIDERA® (Dimethyl Fumarate) in MS Patients with High Disease Activity

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– Additional Real-World Data Show Tolerability Profile Consistent with Pivotal Studies –

CAMBRIDGE, Mass.--(BUSINESS WIRE)--New data reinforce the efficacy of TECFIDERA in a wide range of patients with relapsing-remitting multiple sclerosis (RRMS), as well as support its favorable safety and tolerability profile in the real-world setting. These data were presented by Biogen Idec (NASDAQ: BIIB) at the 66th American Academy of Neurology (AAN) annual meeting in Philadelphia.

A new post-hoc analysis from the Phase 3 studies, DEFINE and CONFIRM, reinforce that TECFIDERA can be effective in RRMS patients with high disease activity. In addition, new data from the Phase 4 MANAGE study show that gastrointestinal (GI) events experienced by patients in the clinical practice setting were mostly mild to moderate and generally manageable, and significantly decreased in prevalence within the first two months of TECFIDERA treatment.

"These new data further reinforce the benefits TECFIDERA's strong efficacy may bring to a wide range of people with relapsing forms of multiple sclerosis (MS)," said Alfred Sandrock, M.D., Ph.D., group senior vice president and chief medical officer at Biogen Idec. "In addition, as we gain even more real-world experience with the therapy, it is encouraging to see that its tolerability profile remains manageable and that GI symptoms are largely transient."

Efficacy in Patients with High Disease Activity

A post-hoc analysis of pooled data from the Phase 3 DEFINE and CONFIRM studies evaluated the efficacy of TECFIDERA in RRMS patients with highly active disease. The findings are consistent with the data from the overall intent-to-treat patient populations in DEFINE and CONFIRM, which supported the regulatory submissions for TECFIDERA globally.

Patients with highly active disease were defined as those who experienced two or more relapses in the year prior to entering DEFINE or CONFIRM and had one or more gadolinium-enhancing (Gd+) lesions at baseline (n=136). Higher relapse frequency and the prevalence of more brain lesions are associated with an increased risk of disease progression.

Results show that at two years, TECFIDERA taken twice daily (BID; n=45) significantly reduced annualized relapse rate (ARR) by 60 percent (p=0.0018) and the proportion of patients who relapsed by 63 percent (p=0.0030). There was no significant effect of TECFIDERA on 12-week confirmed disability progression.

"MS has a spectrum of activity, from mild to very severe, and ranges significantly among patients," said Professor Michael Hutchinson, consultant neurologist, St. Vincent's University Hospital and Newman clinical research professor, University College Dublin, Ireland. "It is reassuring that TECFIDERA has demonstrated efficacy across a range of patient populations, including in those who have more active disease. This consistent benefit reinforces the importance of TECFIDERA as a powerful therapeutic agent in the MS treatment paradigm."

MANAGE Tolerability Results

The open-label, single-arm MANAGE study evaluated the incidence and prevalence of GI-related adverse events (AEs) experienced by U.S. patients with relapsing forms of MS who initiated TECFIDERA treatment in a clinical practice setting. The study also assessed the overall effect of symptomatic therapies on patients' GI symptoms. Patients were prompted twice a day to report GI-related AEs using an eDiary device and two numerical rating scales: the Modified Acute Gastrointestinal Symptom Scale (MAGISS) and the Modified Overall Gastrointestinal Symptom Scale (MOGISS).

Results show that GI events were largely transient, occurred most frequently in the first month of therapy and were mostly reported as mild to moderate in severity. By the 10th week of treatment, less than 10 percent of patients reported GI AEs. The incidence of discontinuation due to GI-related AEs was low (7.3 percent).

Of those who reported GI AEs, most patients (61.2 percent) used symptomatic therapies to manage the effects. By week 10, less than 10 percent of these patients were using symptomatic treatments.

The safety profile of TECFIDERA observed in MANAGE was consistent with that in the pivotal DEFINE and CONFIRM studies, with no new or worsening safety signals.

About MANAGE

MANAGE (A **M**ulti-center, Open-Label, Single-**A**rm Study of Gastroi**N**testinal Tolerability in Patients with Rel**A**psin**G** Forms of Multipl**E** Sclerosis Receiving Dimethyl Fumarate) was a Phase 4, multi-center, open-label, single-arm study (n=237) designed to evaluate the incidence and prevalence of GI-related AEs reported by patients with relapsing forms of MS initiating TECFIDERA in a clinical practice setting in the United States. The study also evaluated the overall effect of symptomatic therapies on those AEs. Patients received TECFIDERA twice daily (BID) for up to 12 weeks (120 mg BID for the first seven days and 240 mg BID thereafter) and recorded GI-related AEs on a daily basis using an eDiary device with the MOGISS and MAGISS numerical rating scales in which the severity of the event is rated from 0–10 as follows: 0=no event, 1–3=mild event, 4–6=moderate event, 7–9=severe event, and 10=extreme event.

The primary endpoint was the frequency, severity and duration of GI-related AEs. Secondary endpoints included the cumulative proportion of patients requiring symptomatic therapy, the type, frequency and duration of symptomatic therapies, and the incidence of discontinuation due to events requiring symptomatic therapy.

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 the Expanded Disability Status Scale (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. 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 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, the European Union, Canada and Australia. Through a robust clinical trial program and commercial launches starting with the United States in March 2013, more than 65,000 patients have been treated with TECFIDERA worldwide.[1]

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, 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. For product labeling, press releases and additional information about the Company, please visit www.biogenidec.com.

Safe Harbor

This press release contains forward-looking statements, including statements about the potential benefits TECFIDERA may have in certain MS patients. These statements may be identified by words such as "believe," "expect," "may," "plan," "potential," "will" and similar expressions, and are based on our current beliefs and expectations. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including the occurrence of adverse safety events, unexpected concerns that may arise from additional data 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.

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