TECFIDERA® (Dimethyl Fumarate) Approved in the European Union as a First-Line Oral Treatment for Multiple Sclerosis

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- Biogen Idec to Begin Launching TECFIDERA in Initial EU Countries in the Coming Weeks -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--TECFIDERA® (dimethyl fumarate) has been approved by the European Commission (EC) as a first-line oral treatment for people with relapsing-remitting multiple sclerosis (RRMS), the most common form of multiple sclerosis (MS). Biogen Idec (NASDAQ: BIIB) will begin to introduce TECFIDERA in initial European Union (EU) countries in the coming weeks.

TECFIDERA was first approved in the United States in March 2013 and became the country's number one prescribed oral therapy for relapsing forms of MS after six months.[1] TECFIDERA was also approved in Canada and in Australia in 2013.

"TECFIDERA exemplifies our commitment to deliver innovative therapies that help people living with serious diseases," said George A. Scangos, Ph.D., chief executive officer of Biogen Idec. "We already have seen TECFIDERAs significant impact on transforming the standard of care for MS where it is available and are excited to quickly bring its benefits to patients in the EU as well."

The EC approval is based on a robust clinical development program that included two global Phase 3 clinical trials, DEFINE and CONFIRM, as well as an ongoing extension study, ENDORSE, in which some patients have been followed for up to six and a half years. TECFIDERA has been clinically shown to significantly reduce important measures of disease activity, including relapses and the development of brain lesions, as well as to slow disability progression, while demonstrating a favorable safety and tolerability profile.

"As a physician, I am all too familiar with the challenges my patients experience while managing their MS. TECFIDERA may lower this burden for many because it is an oral therapy that has been proven to lessen disease activity effectively while maintaining a favorable safety profile," said Ralf Gold, M.D., professor and chair of the Department of Neurology, St. Josef-Hospital/Ruhr-University Bochum and lead investigator of DEFINE. "Moreover, the positive experience we have had with TECFIDERA throughout its extensive clinical program gives me confidence about the benefits this oral therapy may offer my patients in the EU."

TECFIDERA is the fourth therapy Biogen Idec offers to people living with MS.

About the TECFIDERA Phase 3 Clinical Program

The efficacy and safety of TECFIDERA were evaluated in two large, global Phase 3 clinical studies, DEFINE and CONFIRM.

In DEFINE, TECFIDERA administered twice daily significantly reduced the proportion of patients who relapsed by 49 percent ($p<0.0001$), the annualized relapse rate (ARR) by 53 percent ($p<0.0001$), and the risk of 12-week confirmed disability progression, as measured by the Expanded Disability Status Scale (EDSS), by 38 percent ($p=0.0050$) compared to placebo at two years. In CONFIRM, which also included an active reference comparator of glatiramer acetate (GA) compared to placebo, twice-daily TECFIDERA significantly reduced ARR by 44 percent ($p<0.0001$) and the proportion of patients who relapsed by 34 percent ($p=0.0020$) compared to placebo at two years. While not statistically significant, TECFIDERA showed a 21 percent reduction in the risk of 12-week confirmed disability progression in CONFIRM compared to placebo at two years.

In both DEFINE and CONFIRM,TECFIDERA also significantly reduced lesions in the brain compared to placebo, as measured by magnetic resonance imaging (MRI). Glatiramer acetate data in CONFIRM, compared to placebo, was consistent with EU product labeling.

The most common adverse events (AEs) associated with TECFIDERA were flushing and gastrointestinal (GI) events (i.e., diarrhea, nausea, abdominal pain, upper abdominal pain). Overall, clinical trial discontinuations due to flushing (3%) and GI events (4%) were low.

Mean lymphocyte counts decreased during the first year of treatment and then remained stable. There were no opportunistic infections in TECFIDERA-treated patients and no overall increased risk of serious infections.

About TECFIDERA®

TECFIDERA (dimethyl fumarate) gastro-resistant hard capsules are indicated for the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS). TECFIDERA has been shown to reduce multiple sclerosis (MS) relapses and MS brain lesions, as well as to slow the progression of disability, while demonstrating a favorable safety and tolerability profile. The efficacy and safety of TECFIDERA has been studied in a large, global clinical program, which includes an ongoing long-term extension study. As of September 2013, approximately 35,000 patients were being treated with TECFIDERA globally.[2]

It is believed that TECFIDERA provides a new approach to treating MS by activating the Nrf2 pathway, although its exact mechanism of action is not fully understood. This pathway provides a way for cells in the body to defend themselves against inflammation and oxidative stress caused by conditions like MS.

According to the EU Summary of Product Characteristics (SmPC), the starting dose of TECFIDERA is 120 mg twice a day orally. After seven days, the recommended dose should be increased to 240 mg twice a day.

The most common adverse reactions for TECFIDERA are flushing and gastrointestinal (GI) events (i.e., diarrhea, nausea, abdominal pain, upper abdominal pain), which were mostly mild or moderate in patients experiencing these reactions in clinical trials. For patients who experience these side effects, they tend to begin primarily during the first month of treatment and may continue to occur intermittently throughout treatment with TECFIDERA.

TECFIDERA may decrease lymphocyte counts. TECFIDERA has not been studied in patients with pre-existing low lymphocyte counts. A complete

blood count (CBC) is recommended prior to initiating treatment. A follow up CBC is also recommended after six months of treatment, every six to 12 months thereafter and at the discretion of the physician.

Changes in renal and hepatic laboratory tests have been seen in clinical trials in patients treated with TECFIDERA. The clinical implications of these changes are unknown. Liver and kidney function tests are recommended prior to starting treatment, after three and six months of treatment, every six to 12 months thereafter and at the discretion of the physician.

TECFIDERA is not recommended during pregnancy or in women of child bearing potential not using appropriate contraception.

Additional resources on TECFIDERA are available to the media upon request.

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 and therapeutic impact of TECFIDERA. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "project," "target," "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 uncertainty of success in commercialization of TECFIDERA, unexpected hurdles or difficulties in launching TECFIDERA in EU countries, difficulties obtaining or changes in the availability of reimbursement for TECFIDERA, problems with our manufacturing processes and our reliance on third parties to manufacture and supply TECFIDERA, the occurrence of adverse safety events, failure to comply with government regulation, our ability to protect our intellectual property and other proprietary rights, product liability claims 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 U.S. Securities and Exchange Commission (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] *Based on number of prescriptions from IMS NPA™ Weekly Data (27 September 2013) and Biogen Idec data on file.*

[2] *Biogen Idec data on file.*

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