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Interim data from long-term extension Tecfidera® (dimethyl fumarate) study

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Biogen (NASDAQ: BIIB) will, this week, present data at the 31st Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Barcelona, Spain, demonstrating the efficacy and safety of TECFIDERA® (dimethyl fumarate) across a broad range of people with relapsing-remitting multiple sclerosis (RRMS). The data includes important findings for people in the early stages of the disease (as determined by cognitive testing using paced auditory serial addition test 3), and coincides with recent recommendations on the importance of early treatment highlighted by the MS Society.(1)

A post-hoc analysis of the Phase 3 DEFINE and CONFIRM studies showed that dimethyl fumarate had significant effects on clinical outcomes in RRMS patients who initiated treatment early in their disease course, defined as those patients with a baseline Expanded Disability Status Scale (EDSS) score of ≤2.0 (indicating minimal to no disability). Compared to patients treated with placebo, dimethyl fumarate reduced the adjusted relapse rate (ARR) [95% confidence interval, CI]: 0.132 [0.102, 0.170] vs 0.357 [0.291, 0.438]; 63% reduction; p<.0001) and risk of 12-week confirmed disability progression (0.14 vs 0.24; 40% reduction; p=.0066) over a period of two years.(2)

In an interim analysis of newly diagnosed patients in the ENDORSE long-term extension study (two years in DEFINE or CONFIRM followed by four years in ENDORSE), the ARR for newly-diagnosed patients (diagnosis of multiple sclerosis within 1 year prior to study entry or previously treated with cortico-steroids alone) who started dimethyl fumarate treatment at the beginning of the study (n=144) remained low at 0.14 (0.10–0.19). In those patients who switched from placebo to dimethyl fumarate, the ARR was reduced from 0.26 (0.18–0.37) from the placebo period (years zero to two) to 0.10 (0.06–0.16) when dimethyl fumarate treatment was received (years three to six), representing a 61% reduction of risk; p<0.0001.3

The proportion of patients with 24-week confirmed disability after six years of dimethyl fumarate treatment was 15.7% (95% confidence interval 10.3% – 23.7%), compared to 24.3% (95% confidence interval 15.9% - 36.2%) in those who switched to dimethyl fumarate treatment in year three from placebo, representing a 49% reduction in the risk of confirmed disability progression; p=0.0397.3

"The benefits of taking an efficacious therapy early in the disease course have been shown to improve a patient's long-term prognosis when treatment is initiated before MS has advanced and caused irreparable damage," said Ralf Gold, M.D., professor and chair of the Department of Neurology, St. Josef-Hospital/Ruhr-University Bochum. "The data at ECTRIMS demonstrate that patients initiating treatment with TECFIDERA early in their disease experienced significant reductions in relapse rates and disability progression over time compared to those taking placebo."

Further TECFIDERA Data Presented at ECTRIMS

- Dimethyl fumarate significantly reduced key inflammatory disease outcomes compared to glatiramer acetate (GA)(4)
    - In a post-hoc analysis of the MRI population from the phase 3 CONFIRM study, it was demonstrated that dimethyl fumarate significantly reduced key inflammatory disease outcomes
    - Results showed that a higher proportion of dimethyl fumarate patients were free of inflammatory disease activity at all time intervals over two years versus GA respectively (36% vs. 29% during weeks 0-24, 34% vs. 23% during weeks 24-48, 21% vs. 16% during weeks 48-96).
- Dimethyl fumarate demonstrated a long-term favorable benefit-risk profile throughout six years of follow-up from the ENDORSE study(5)

"Taken together, these data continue to demonstrate the efficacy and safety of TECFIDERA across both newly diagnosed and established patients," said Fiona Thomas, UK Medical Director at Biogen. "Data continue to demonstrate that TECFIDERA reduces disability and relapse activity early in the disease course, meaning that it can help slow the progression of this debilitating disease, which is particularly important in newly-diagnosed or early disease course patients."

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, BD or TDS). 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 (BD or TDS) in ENDORSE. Patients who previously received placebo or GA (CONFIRM only) were randomised 1:1 to TECFIDERA BD or TDS. Following TECFIDERA approval at a dose of 240 mg BD, all subjects continuing in this study received open-label TECFIDERA therapy at 240 mg BD. Patients participating in ENDORSE will be followed for up to eight years.

About DEFINE and CONFIRM

DEFINE (Determination of the Efficacy and safety of oral Fumarate IN relapsing-rEmitting MS) was a global, two-year, randomised, multi-centre, 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, BD or TDS) compared to placebo.

CONFIRM (COmparator and aN oral Fumarate In Relapsing-remitting MS) was a global, two-year, randomised, multi-centre, 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, BD or TDS) compared to placebo and included a reference comparator arm of glatiramer acetate (GA; 20 mg subcutaneous daily injection) versus placebo.

About TECFIDERA® (Dimethyl fumarate)

TECFIDERA is an oral therapy for relapsing forms of MS, including relapsing-remitting MS, the most common form of MS. 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. TECFIDERA is contraindicated in patients with a known hypersensitivity to dimethyl fumarate or any of the excipients. Rare cases of progressive multifocal leukoencephalopathy (PML) have been seen with TECFIDERA patients in the setting of severe and prolonged lymphopenia.

TECFIDERA is currently approved in the United States, the European Union, Canada, Australia and Switzerland. For the full summary of product characteristics, please visit www.medicines.org.uk/emc/medicine/28592.

About Biogen

Through cutting-edge science and medicine, Biogen discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hematologic conditions and autoimmune disorders. Founded in 1978, Biogen is one of the world's oldest independent biotechnology companies 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 www.biogenidec.co.uk.

1. MS Society. Time to Act – a consensus on early treatment, September 2015. Available at: www.mssociety.org.uk/sites/default/files/Time%20to%20Act%20-%20a%20consensus%20on%20early%20treatment.pdf Accessed October 2015.
2. Gold et al. Efficacy of delayed-release dimethyl fumarate in early multiple sclerosis: post-hoc analysis of the phase 3 DEFINE and CONFIRM studies according to baseline disability. The 31st Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), Barcelona, 7-10 October 2015. Accessed October 2015.
3. Marantz et al. Longer-term follow-up of the efficacy of delayed-release dimethyl fumarate in newly diagnosed patients with RRMS: An integrated analysis of DEFINE, CONFIRM, and ENDORSE, P564. The 31st Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), Barcelona, 7-10 October 2015. Accessed October 2015.
4. Kremenchutzky et al. Efficacy of delayed-release dimethyl fumarate vs glatiramer acetate on a novel composite outcome measure of inflammatory disease activity: post-hoc analysis of the CONFIRM study. The 31st Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), Barcelona, 7-10 October 2015. Accessed October 2015.
5. Pozzilli et al. Long-term follow-up of the safety of delayed-release dimethyl fumarate in RRMS: Interim results from the ENDORSE extension study. The 31st Congress of the European Committee for Treatment

and Research in Multiple Sclerosis (ECTRIMS), Barcelona, 7-10 October 2015. Accessed October 2015.

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