CHMP Issues Positive Opinion for TECFIDERA™ (Dimethyl Fumarate) as a First-Line Treatment for Multiple Sclerosis in the European Union

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-European Commission Decision Anticipated In Second Quarter of 2013-

WESTON, Mass.--(BUSINESS WIRE)--Today Biogen Idec (NASDAQ: BIIB) announced that it has received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) in the European Union (EU) recommending a marketing authorization be granted for TECFIDERA ™ (dimethyl fumarate) as a first-line oral treatment for adults with relapsing-remitting multiple sclerosis (RRMS). The CHMP, on the basis of quality, safety and efficacy data submitted by Biogen Idec, considers there to be a favorable benefit-to-risk balance for TECFIDERA.

The CHMP's recommendation is now referred to the European Commission (EC), which grants marketing authorization for medicines in the European Union. The U.S. Food and Drug Administration is expected to make a decision on the marketing application for TECFIDERA in the United States in the coming days.

"With the CHMP's positive opinion for TECFIDERA, we are one step closer to offering the European MS community a treatment with compelling efficacy and a favorable safety profile in the convenience of a pill – a combination we believe will have a significant positive impact on the way people live with this chronic disease," said George A. Scangos, Ph.D., chief executive officer of Biogen Idec. "Biogen Idec is committed to delivering innovative treatments and setting new standards for the next generation of medicines. We believe TECFIDERA will raise expectations for what people living with MS can achieve with their therapy."

The CHMP opinion for TECFIDERA is based on data from a large clinical development program that included two global Phase 3 studies, DEFINE and CONFIRM, involving more than 2,600 RRMS patients, as well as an ongoing extension study in which some patients have been followed for more than four years. 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 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, twice-daily TECFIDERA significantly reduced ARR by 44 percent ($p<0.0001$) and the proportion of patients who relapsed by 34 percent ($p<0.0001$) compared to placebo at two years. While not statistically significant, TECFIDERA showed a 21 percent reduction in 12-week confirmed disability progression in CONFIRM. In addition, both studies showed TECFIDERA significantly reduced lesions in the brain compared to placebo, as measured by magnetic resonance imaging (MRI).

"Clinical studies demonstrated TECFIDERA was an effective therapy with a favorable safety profile for people with relapsing-remitting MS," said Professor Gavin Giovannoni, Chair of Neurology, Blizard Institute, Barts and The London School of Medicine and Dentistry. "This, combined with its interesting suggested mechanism of action, should position TECFIDERA as a first-line therapy choice."

The most common side effects associated with TECFIDERA seen in clinical trials are flushing and gastrointestinal (GI) events (i.e., diarrhea, nausea, and abdominal pain). Other side effects include a decrease in mean lymphocyte counts during the first year of treatment, which then plateaued. There was no increased risk of malignancy or serious infections associated with TECFIDERA treatment, and no opportunistic infections were observed.

The European Commission decision on TECFIDERA is expected in approximately two months. TECFIDERA will mark the fourth therapy Biogen Idec offers people living with MS.

About TECFIDERA™

TECFIDERA™ (dimethyl fumarate) is an oral therapeutic candidate for the treatment of multiple sclerosis (MS). TECFIDERA is the only currently known investigational compound for the treatment of relapsing-remitting MS that has experimentally demonstrated activation of the Nrf-2 pathway. This pathway provides a way for cells in the body to defend themselves against inflammation and oxidative stress caused by conditions like MS.

In 2011 and 2012, Biogen Idec announced positive data from DEFINE and CONFIRM, two global, placebo-controlled Phase 3 clinical trials that evaluated 240 mg of TECFIDERA, administered either twice a day (BID) or three times a day (TID), for two years. TECFIDERA is also currently under review by regulatory authorities in the United States, Australia, Canada and Switzerland.

About Multiple Sclerosis

Multiple sclerosis (MS) is a chronic, often disabling disease that attacks the central nervous system (CNS), which is made up of the brain, spinal cord and optic nerves. Symptoms may be mild or severe, ranging from numbness in the limbs to paralysis or loss of vision. The progression, severity, and specific symptoms of MS are unpredictable and vary from one person to another. MS affects an estimated 2.5 million people worldwide,[1] with approximately 400,000 sufferers in the European Union.[2] Relapsing-remitting MS is the most common form of the disease, accounting for 85 percent of cases, and is characterized by clearly defined acute attacks with full recovery or with residual deficit upon recovery.[3]

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.

Safe Harbor

This press release contains forward-looking statements, including statements about anticipated regulatory approvals and the potential therapeutic

impact of TECFIDERA. 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. 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 risks associated with obtaining regulatory approval, uncertainty of success in commercialization of TECFIDERA 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. Any forward-looking statements speak only as of the date of this press release and we assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

[1] Multiple Sclerosis International Federation. *About MS – What is MS.* Date Accessed: 21 March 2013. http://www.msif.org/en/about_ms/what_is_ms.html

[2] European Multiple Sclerosis Platform. *MS Fact Sheet.* Date accessed: 21 March 2013. http://www.emsp.org/multiple-sclerosis/ms-fact-sheet

[3] Multiple Sclerosis International Federation. *About MS – Types and Course.* Date Accessed: 21 March 2013. http://www.msif.org/en/about_ms/types_of_ms.html

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