

# US Patent Office Grants Patent Claiming Dosing Regimen for TECFIDERA™ (Dimethyl Fumarate)

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- Patent Offers Protection Until 2028 and Strengthens Growing Product Patent Portfolio -
- European Patent Office Also Determines Patent Application Covering the Same Dosing Regimen Allowable -

WESTON, Mass.--(BUSINESS WIRE)--Biogen Idec (NASDAQ: BIIB) today announced that the U.S. Patent and Trademark Office (USPTO) has granted U.S. Patent No. 8,399,514, which offers additional protection for TECFIDERA™ (dimethyl fumarate), the company's oral therapeutic candidate for the treatment of multiple sclerosis (MS). The patent, which will expire in 2028, covers the dosing regimen of daily administration of 480 mg of TECFIDERA. This regimen is included in the proposed marketing application for TECFIDERA, which is currently under review by the U.S. Food and Drug Administration (FDA).

"The patent for this dosing regimen is recognition of the remarkable innovation TECFIDERA represents for the MS community," said George A. Scangos, Ph.D., chief executive officer of Biogen Idec. "The tremendous research investment required to study and validate the patented dosing regimen is an example of innovation that leads to meaningful benefits to patients."

The European Patent Office also recently determined that Biogen Idec's application for a patent covering the same dosing regimen of TECFIDERA is allowable. Once granted, this patent would also expire in 2028.

The TECFIDERA dose regimen patents add to the growing portfolio of granted patents covering TECFIDERA.

### **About TECFIDERA**

TECFIDERA is the only currently known investigational compound for the treatment of relapsing-remitting multiple sclerosis (RRMS) 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 currently under review by regulatory authorities in the United States, European Union, Australia, Canada and Switzerland.

### 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 <a href="https://www.biogenidec.com">www.biogenidec.com</a>.

## Safe Harbor

This press release contains forward-looking statements, including statements about the innovation TECFIDERA may represent for the MS community. 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 obtaining regulatory approval for TECFIDERA, uncertainty of success in commercialization of TECFIDERA, our ability to protect our intellectual property rights, 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.

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