USPTO Dismisses Inter Partes Review Petition of Biogen's Patent 514 for TECFIDERA® (Dimethyl Fumarate)

September 2, 2015

Today Biogen (NASDAQ: BIIB) announced that the Patent Trial and Appeal Board (PTAB) of the United States Patent and Trademark Office (USPTO) declined to institute an inter partes review of U.S. Patent 8,399,514 ("514 patent"), which covers the dosing regimen of daily administration of 480 mg of TECFIDERA (dimethyl fumarate). TECFIDERA is the most prescribed oral treatment for multiple sclerosis (MS) globally.

"TECFIDERA is a significant advance for the treatment of MS and this result speaks to the pioneering efforts by Biogen to bring this therapy to patients," said George A. Scangos, Ph.D., chief executive officer of Biogen. "Patent protection is critical to enabling biopharmaceutical companies to develop new therapies and advance science and medicine."

About TECFIDERA®

TECFIDERA is an oral therapy for relapsing forms of MS,[1] including relapsing-remitting MS, the most common form of MS. TECFIDERA is currently approved in the United States, the European Union, Canada, Australia and Switzerland. Through a robust clinical trial program and commercial launches starting with the United States in March 2013, more than 155,000 patients have been treated with TECFIDERA worldwide.[2]

TECFIDERA has been proven to reduce the rate of MS relapses, slow the progression of disability and the number of MS brain lesions, while demonstrating a favorable safety and tolerability profile in a broad range of patients with relapsing forms of MS.1 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 of TECFIDERA.

The efficacy and safety of TECFIDERA have 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 additional important safety information, and the United States full prescribing information, please visit www.tecfidera.com.

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.biogen.com.

[1] TECFIDERA is approved in the European Union for relapsing-remitting multiple sclerosis

[2] Biogen data on file

Contact:

Biogen (Media):
Kate Niazi-Sai, +1 781-464-3260
public.affairs@biogen.com
or
Biogen (Investors):
Carlo Tanzi, Ph.D., +1 781-464-2442
IR@biogen.com