Biogen Idec Receives Notification of PDUFA Date Extension

October 18, 2012

WESTON, Mass.--(BUSINESS WIRE)--Today Biogen Idec (NASDAQ: BIIB) announced that the U.S. Food and Drug Administration (FDA) has extended the initial PDUFA date for its review of the New Drug Application (NDA) for the marketing approval of BG-12 (dimethyl fumarate), the company's oral therapeutic candidate for the treatment of multiple sclerosis (MS). The 3 month extension is a standard extension period.

The FDA has indicated that the extension of the PDUFA date is needed to allow additional time for review of the application. The agency has not asked for additional studies.

About Dimethyl Fumarate

Dimethyl fumarate, also known as BG-12, is an investigational oral therapy in late-stage clinical development for the treatment of RRMS, the most common form of MS. Dimethyl fumarate is the only currently known investigational compound for the treatment of RRMS that has experimentally demonstrated activation of the Nrf-2 pathway.

Dimethyl fumarate 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 www.biogenidec.com.

Contact:

MEDIA CONTACT:
Biogen Idec
Jeff Boyle, +1 781-464-3260
or
INVESTOR CONTACT:
Biogen Idec
Kia Khaleghpour, +1 781-464-2442