Centralized Marketing Authorizations of Generic Versions of TECFIDERA® are Revoked by the European Commission

December 19, 2023

CAMBRIDGE, Mass., Dec. 19, 2023 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced that the European Commission has revoked the centralized marketing authorizations for generic versions of Biogen's product TECFIDERA® (dimethyl fumarate) held by Accord, Mylan, Neuraxpharm, Polpharma and Teva.

In reaching this decision, the European Commission affirmed that Biogen is entitled to full data protection and marketing protection for TECFIDERA. Biogen welcomes the actions of the European Commission, which confirm the laws governing data exclusivity and marketing protection. Those laws are essential to protecting innovation.

TECFIDERA is entitled to marketing protection until February 3, 2025, and is the only dimethyl fumarate treatment for multiple sclerosis that may be lawfully placed on the market for sale in the EU until that date. Biogen has initiated legal action to defend its market protection rights. Biogen has sufficient supply of TECFIDERA to supply the entire European market.

About Biogen
Founded in 1978, Biogen is a leading global biotechnology company that has pioneered multiple breakthrough innovations including a broad portfolio of medicines to treat multiple sclerosis, the first approved treatment for spinal muscular atrophy, two co-developed treatments to address a defining pathology of Alzheimer's disease, the first treatment to target a genetic form of ALS, the first oral treatment approved for postpartum depression, and the first approved treatment for Friedreich's ataxia. Biogen is advancing a pipeline of potential novel therapies across neurology, neuropsychiatry, specialized immunology and rare diseases and remains acutely focused on its purpose of serving humanity through science while advancing a healthier, more sustainable and equitable world.

We routinely post information that may be important to investors on our website at www.biogen.com. Follow us on social media - Facebook, LinkedIn, X, YouTube.

Biogen Safe Harbor
This news release contains forward-looking statements about the Biogen's supply of Tecfidera; the anticipated benefits and potential of Biogen's collaboration arrangements with Eisai; the potential of Biogen's commercial business and pipeline programs; and risks and uncertainties associated with drug development and commercialization, including data exclusivity and marketing protection. These statements may be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "possible," "potential," "will," "would" and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical studies may not be indicative of full results or results from later stage or larger scale clinical studies and do not ensure regulatory approval. 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 without limitation unexpected concerns that may arise from additional data, analysis or results obtained during clinical studies; the occurrence of adverse safety events; risks of unexpected costs or delays; the risk of other unexpected hurdles; regulatory submissions may take longer or be more difficult to complete than expected; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of Biogen's drug candidates; actual timing and content of submissions to and decisions made by the regulatory authorities; failure to protect and enforce Biogen's data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; product liability claims; third party collaboration risks; and the direct and indirect impacts of the ongoing COVID-19 pandemic on Biogen's business, results of operations and financial condition. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement as well as the risk factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission. These statements speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements.

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