



Biogen Receives Favorable Decision from Court of Justice of the European Union Relating to TECFIDERA® (dimethyl fumarate) Regulatory Data and Marketing Protection

March 16, 2023

CAMBRIDGE, Mass., March 16, 2023 (GLOBE NEWSWIRE) -- [Biogen Inc.](#) (Nasdaq: BILB) today announced that the Court of Justice of the European Union decided in favor of Biogen, the European Medicines Agency (EMA), and the European Commission in their appeal of a General Court decision annulling the EMA's refusal to evaluate a generic version of TECFIDERA® (dimethyl fumarate) because of TECFIDERA's regulatory data and marketing protection. With this favorable decision, Biogen believes that TECFIDERA is entitled to regulatory marketing protection in the European Union until at least February 4, 2024. Biogen will seek to enforce this protection and continue to enforce its EP 2 653 873 patent related to TECFIDERA, which expires in 2028.

Biogen's Full Year 2023 Financial Guidance issued on February 15, 2023, assumed a favorable decision such as this in this case.

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, and two co-developed treatments to address a defining pathology of Alzheimer's disease. 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 - [Twitter](#), [LinkedIn](#), [Facebook](#), [YouTube](#).

Biogen Safe Harbor

This press release contains forward-looking statements, relating to: our regulatory data and marketing protection, our patent protection; our 2023 financial guidance; strategy and plans; potential of, and expectations for, and our commercial business and pipeline programs; These forward-looking statements may be accompanied by such words as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "potential," "possible," "prospect," "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 trials may not be indicative of full results or results from later stage or larger scale clinical trials 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: our dependence on sales from our products; uncertainty of long-term success in developing, licensing, or acquiring other product candidates or additional indications for existing products; failure to compete effectively due to significant product competition in the markets for our products; failure to successfully execute or realize the anticipated benefits of our strategic and growth initiatives; difficulties in obtaining and maintaining adequate coverage, pricing, and reimbursement for our products; our dependence on collaborators, joint venture partners, and other third parties for the development, regulatory approval, and commercialization of products and other aspects of our business, which are outside of our full control; the potential impact of the conflict in Ukraine; risks associated with current and potential future healthcare reforms; risks related to commercialization of biosimilars; failure to obtain, protect, and enforce our data, intellectual property, and other proprietary rights and the risks and uncertainties relating to intellectual property claims and challenges; the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in early stage clinical trials may not be predictive of results in later stage or large scale clinical trials or trials in other potential indications; risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates; the occurrence of adverse safety events, restrictions on use with our products, or product liability claims; risks relating to technology failures or breaches; problems with our manufacturing processes; risks relating to management and personnel changes, including attracting and retaining personnel; failure to comply with legal and regulatory requirements; the risks of doing business internationally, including currency exchange rate fluctuations; risks relating to investment in our manufacturing capacity; the direct and indirect impacts of the ongoing COVID-19 pandemic on our business; risks relating to the distribution and sale by third parties of counterfeit or unfit versions of our products; risks relating to the use of social media for our business; results of operations, and financial condition; fluctuations in our operating results; risks related to investment in properties; the market, interest, and credit risks associated with our investment portfolio; risks relating to share repurchase programs; risks relating to access to capital and credit markets; risks related to indebtedness; change in control provisions in certain of our collaboration agreements; fluctuations in our effective tax rate; environmental risks; and any other risks and uncertainties that are described in other reports we have filed with the U.S. Securities and Exchange Commission. These statements speak only as of the date of this press release. We do not undertake any obligation to publicly update any forward-looking statements.

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