Statement: Biogen Receives Favorable Decision from European Patent Office on Patent Related to TECFIDERA® (dimethyl fumarate)

October 25, 2024

On October 25, 2024, the European Patent Office (EPO) Opposition Division upheld the validity of Biogen patent EP 2 653 873, which expires in February 2028 and claims treating relapsing remitting multiple sclerosis using dimethyl fumarate dosed at 480 mg per day, which is the European Medicines Agency (EMA) recommended maintenance dose for TECFIDERA® (dimethyl fumarate). This decision may be appealed to the EPO's Technical Boards of Appeal and the validity of this patent is also subject to challenge in individual European Union (EU) countries.

TECFIDERA is expected to have regulatory marketing protection in the EU until February 3, 2025.

About TECFIDERA® (dimethyl fumarate)
TECFIDERA, a treatment for relapsing forms of multiple sclerosis (MS) in adults, is the most prescribed oral medication for relapsing MS in the world and has been shown to reduce the rate of MS relapses, slow the progression of disability and impact the number of MS brain lesions, while demonstrating a well-characterized safety profile in people with relapsing forms of MS. TECFIDERA is approved in 76 countries, and more than 600,000 patients have been treated with it, representing more than 1,400,000 patient-years of exposure across clinical trial use and patients prescribed TECFIDERA.1

TECFIDERA is contraindicated in patients with a known hypersensitivity to dimethyl fumarate or any of the excipients of TECFIDERA. Serious side effects include anaphylaxis and angioedema, and cases of progressive multifocal leukoencephalopathy, a rare opportunistic viral infection of the brain which has been associated with death or severe disability, have been seen with TECFIDERA patients in the setting of prolonged lymphopenia although the role of lymphopenia in these cases is uncertain. Other serious side effects include a decrease in mean lymphocyte counts during the first year of treatment, herpes zoster and other serious infections, liver injury and flushing. In clinical trials, the most common adverse events associated with TECFIDERA were flushing, abdominal pain, diarrhea and nausea.

Please click here for Important Safety Information and full Prescribing Information, including Patient Information for TECFIDERA in the U.S., or visit your respective country's product website.

About Biogen
Founded in 1978, Biogen is a leading biotechnology company that pioneers innovative science to deliver new medicines to transform patients' lives and to create value for shareholders and our communities. We apply deep understanding of human biology and leverage different modalities to advance first-in-class treatments or therapies that deliver superior outcomes. Our approach is to take bold risks, balanced with return on investment to deliver long-term growth.

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, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including about certain patent grants and the timing thereof; These forward-looking statements may be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potential," "will," "would" and other words and terms of similar meaning.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including without limitation results of litigation, patent office and judicial proceedings, administrative and regulatory proceedings, the extent to which others will respect our intellectual property, our ability to enforce and protect our data, intellectual property and other proprietary rights, uncertainties and challenges relating to intellectual property, and our 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 our expectations in any forward-looking statement. Investors should consider this cautionary statement as well as the risk factors identified in our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission. These statements are based on our current beliefs and expectations and speak only as of the date of this news release. We do not undertake any obligation to publicly update any forward-looking statements.

References:

1. Combined post-marketing data based on prescriptions and clinical trials exposure to TECFIDERA as of December 31, 2023.

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