The European Commission Grants Marketing Authorization for VUMERITY® (diroximel fumarate) as Oral Treatment for Relapsing-Remitting Multiple Sclerosis

November 16, 2021

- VUMERITY is a next-generation oral fumarate treatment for people with relapsing-remitting MS with established efficacy and well-characterized safety, building on Biogen's leadership in MS oral therapies
- Phase 3 data have demonstrated that treatment with VUMERITY results in low discontinuation rates due to its gastrointestinal (GI) tolerability profile
- European Union authorization follows approvals in United States, Great Britain and Switzerland, providing patients another important option as they consider treatment initiation in the context of COVID-19

CAMBRIDGE, Mass., Nov. 16, 2021 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced that the European Commission (EC) has granted marketing authorization for VUMERITY® (diroximel fumarate) to treat adults with relapsing-remitting multiple sclerosis (MS). VUMERITY is a next-generation fumarate that offers the convenience of an oral medication with the established efficacy and well-characterized safety of TECFIDERA® (dimethyl fumarate). Globally, an estimated 2.8 million people live with MS, with more than 1 million people in Europe living with the disease.[1,2]

"The approval of VUMERITY provides a new oral treatment option with low gastrointestinal discontinuation rates that may help patients to start and adhere to treatment," said Simon Faissner, M.D., PhD, Assistant Professor at the Department of Neurology, Ruhr-University Bochum. "This medication allows for MS patients in the EU to be treated without having to think about dietary restrictions or when to take a dose in relation to mealtimes which, when treating a chronic disease, may provide patients with additional flexibility in their daily lives."

The EC's approval of VUMERITY is based on data from pharmacokinetic bridging studies comparing VUMERITY and TECFIDERA to establish bioequivalent exposure of monomethyl fumarate, the active metabolite, and relied in part on the well-established long-term efficacy and safety profile of TECFIDERA. The approval was also based on findings from EVOLVE-MS-2, a large, randomized, double-blind, five-week, multi-center Phase 3 study to evaluate the gastrointestinal (GI) tolerability of VUMERITY compared to TECFIDERA in patients with relapsing-remitting MS. In EVOLVE-MS-2, the rate of overall treatment discontinuation was lower in participants treated with VUMERITY compared to those treated with TECFIDERA (1.6% compared to 6%, respectively). The difference in the discontinuation rates due to GI tolerability was 0.8% for VUMERITY compared to 4.8% for TECFIDERA. Additionally, flushing was reported in 32.8% of VUMERITY-treated patients and in 40.6% of TECFIDERA treated patients. There were no serious events of flushing or discontinuations due to flushing in the study.

"This approval is a significant step forward in improving treatment adherence for people living with relapsing MS, which can make a meaningful difference on treatment outcomes impacting their daily lives," said Maha Radhakrishnan, M.D., Chief Medical Officer at Biogen. "The authorization of VUMERITY in the EU brings people with MS a new oral treatment option to meet their individual preferences and needs, with well-established efficacy and a positive GI tolerability profile that continues to be evaluated in the real-world setting."

VUMERITY was first approved by the U.S. Food and Drug Administration in October 2019 and is also approved in Great Britain and Switzerland. Since its launch in the U.S., real-world data have reinforced the positive GI tolerability profile of VUMERITY and confirmed that the experience demonstrated in clinical trials is consistent with clinical practice.[3] Biogen continues to file regulatory submissions in other countries.

About VUMERITY® (diroximel fumarate)
VUMERITY is an oral fumarate with a distinct chemical structure from TECFIDERA (dimethyl fumarate), approved in the U.S. for the treatment of relapsing forms of multiple sclerosis in adults, to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease. Once in the body, VUMERITY rapidly converts to monomethyl fumarate, the same active metabolite of dimethyl fumarate providing similar efficacy and safety profiles.

VUMERITY is contraindicated in patients with known hypersensitivity to diroximel fumarate, dimethyl fumarate or to any of the excipients of VUMERITY; and in patients taking dimethyl fumarate. Serious side effects for VUMERITY are based on data from dimethyl fumarate (which has the same active metabolite as VUMERITY) and include anaphylaxis and angioedema, progressive multifocal leukoencephalopathy, which is a rare opportunistic viral infection of the brain that has been associated with death or severe disability, a decrease in mean lymphocyte counts during the first year of treatment, herpes zoster and other serious infections, liver injury and flushing. The most common adverse events, obtained using data from dimethyl fumarate (which has the same active metabolite as VUMERITY), were flushing, abdominal pain, diarrhea and nausea.

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

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 69 countries, and more than 530,000 patients have been treated with it, representing more than 1,000,000 patient-years of exposure across clinical trial use and patients prescribed TECFIDERA.[4]

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.

For information on TECFIDERA prescribing information in the EU, please visit: https://www.ema.europa.eu/en/medicines/human/EPAR/tecfidera. 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
As pioneers in neuroscience, Biogen discovers, develops, and delivers worldwide innovative therapies for people living with serious neurological diseases as well as related therapeutic adjacencies. One of the world's first global biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Sir Kenneth Murray, and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today, Biogen has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, and is providing the first and only approved treatment to address a defining pathology of Alzheimer's disease. Biogen is also commercializing biosimilars and focusing on advancing the industry's most diversified pipeline in neuroscience that will transform the standard of care for patients in several areas of high unmet need.

In 2020, Biogen launched a bold 20-year, $250 million initiative to address the deeply interrelated issues of climate, health, and equity. Healthy Climate, Healthy Lives™ aims to eliminate fossil fuels across the company's operations, build collaborations with renowned institutions to advance the science to improve human health outcomes, and support underserved communities.

The company routinely posts information that may be important to investors on its website at www.biogen.com. To learn more, please visit www.biogen.com and follow Biogen on social media – Twitter, LinkedIn, Facebook, 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, about potential regulatory discussions, submissions and approvals and the timing thereof; the potential benefits, safety and efficacy of VUMERITY; the results of certain real-world data; and the potential of Biogen's commercial business, including VUMERITY. 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. 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 or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including without limitation actual timing and content of submissions to and decisions made by the regulatory authorities; 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 our drug candidates or expansion of product labeling; failure to obtain regulatory approvals in other jurisdictions; the occurrence of adverse safety events; risks of unexpected costs or delays; failure to protect and enforce our data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; product liability claims; and the direct and indirect impacts of the ongoing COVID-19 pandemic on our 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 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, whether as a result of new information, future developments or otherwise.

References:

1. Walton, Clare. "Rising Prevalence of Multiple SCLEROSIS Worldwide: Insights from the Atlas of Ms, Third Edition." *Multiple Sclerosis (Houndmills, Basingstoke, England)*, U.S. National Library of Medicine, 11 Nov. 2020, pubmed.ncbi.nlm.nih.gov/33174475/.
2. "EMSP - Barometer." *MS Barometer*, European Multiple Sclerosis Platform, 20 Dec. 2020, https://msbarometer.eu/2020.
3. Liseno J, et al. Multiple Sclerosis Patients Treated with Diroximel Fumarate in the Real-World Setting have High Rates of Persistence and Adherence. Neurology. April 13, 2021; 96 (15 Supplement).
4. Combined post-marketing data based on prescriptions and clinical trials exposure to TECFIDERA as of June 30, 2021.

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