New Data Presented at ECTRIMS Reinforce Long-term Benefits of TECFIDERA® (dimethyl fumarate) Over 10 Years

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- *TECFIDERA consistently maintained low levels of disease activity with no increased risk in adverse events over a decade of treatment*
- *Latest interim data from Phase 3 EVOLVE-MS-1 trial show Biogen and Alkermes' investigational treatment, diroximel fumarate, was generally well tolerated with low rates of treatment discontinuation over 18 months*

CAMBRIDGE, Mass., Sept. 11, 2019 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) announced new data to support the consistent, long-term benefits of treatment with TECFIDERA® (dimethyl fumarate) over 10 years, as well as additional diroximel fumarate data that further characterize the tolerability profile of this investigational oral fumarate for relapsing multiple sclerosis (MS). These findings are being presented at the 35th Congress of the European Committee for Treatment and Research in MS (ECTRIMS) and 24th Annual Conference of Rehabilitation in MS in Stockholm (September 11-13).

"Biogen's new data underscore TECFIDERA's role as a meaningful long-term therapy option for relapsing MS, with many patients in the study experiencing no relapses or progression in their disability over a 10-year period," said Alfred Sandrock, Jr., M.D., Ph.D., executive vice president and chief medical officer at Biogen. "We are proud of the strong legacy TECFIDERA has achieved over the years and are excited to continue building our franchise of fumarate products with the potential addition of diroximel fumarate. As a next-generation fumarate, diroximel fumarate offers a differentiated gastrointestinal tolerability profile and, if approved, will be a strong choice for physicians and patients with relapsing MS to consider."

TECFIDERA 10-Year Data Support Long-Term Benefits
New results from the ongoing Phase 3 ENDORSE extension study reinforce the long-term effectiveness and safety of continuous TECFIDERA treatment over a decade. In the analysis, which included participants (n= 192) with at least 10 years of follow up, TECFIDERA was associated with a low incidence of MS relapses and disability progression over time. Results show that approximately half (51 percent) of patients remained relapse-free over the study period. In addition, 64 percent of patients had no confirmed disability progression over the study period, and patients generally maintained the ability to walk without significant disability (79 percent). The well-characterized safety profile of TECFIDERA was consistent over 10 years, with no increased occurrence of serious infections.

Separately, a meta-analysis of real-world evidence to compare the effectiveness of TECFIDERA versus other disease-modifying therapies for relapsing MS is also being presented. The meta-analysis analyzed data from 18 databases of large real-world studies and found that TECFIDERA was significantly more effective than interferon beta, glatiramer acetate and teriflunomide in reducing annualized relapse rate and delaying time to first relapse. TECFIDERA demonstrated comparable effectiveness to fingolimod and was less effective than natalizumab and alemtuzumab. These results are consistent with previously reported comparative effectiveness data and reinforce the strong efficacy of TECFIDERA over platform treatments across multiple data sets.

Data Support Diroximel Fumarate as a Potential New Option for Relapsing MS
Updated interim data from the Phase 3 EVOLVE-MS-1 study support the potential of Biogen and Alkermes' investigational treatment, diroximel fumarate, as a novel oral fumarate. EVOLVE-MS-1 is an ongoing, single-arm, open-label, two-year study evaluating the safety and exploring the efficacy of diroximel fumarate in patients with relapsing-remitting MS and has enrolled approximately 1,000 patients. The interim results, which included data from 888 patients treated with diroximel fumarate for a median of approximately 18 months, corroborate previous data indicating diroximel fumarate is generally well-tolerated in people with relapsing MS.

In the study, most adverse events were mild to moderate in nature. The overall rate of treatment discontinuation due to adverse events was low (7.1 percent), with less than 1 percent of patients discontinuing diroximel fumarate treatment due to gastrointestinal (GI) side effects. These data are further supportive of recently reported topline results from the elective Phase 3 EVOLVE-MS-2 study, in which diroximel fumarate demonstrated statistically superior GI tolerability compared to TECFIDERA on the study's primary endpoint assessing self-reported GI events.

Exploratory efficacy results from EVOLVE-MS-1 suggest diroximel fumarate significantly reduced annualized relapse rate by 79.4 percent and the mean number of gadolinium-enhancing lesions by 64.3 percent from baseline to 24 months, with similar results observed in newly diagnosed patients.

Featured data presentation details:

- Overall Safety and Efficacy Through 10 Years of Treatment with Delayed-release Dimethyl Fumarate in Patients with Relapsing-remitting Multiple Sclerosis (P1397; Poster Session 3, Friday, September 13, 12:15-2:15 pm CET)
- Comparative Effectiveness of Delayed-release Dimethyl Fumarate vs. Other Disease-modifying Therapies in Patients with Multiple Sclerosis: A Network Meta-analysis of Real-world Evidence (P1394; Poster Session 3, Friday, September 13, 12:15-2:15 pm CET)
- Diroximel Fumarate (DRF) in Patients with Relapsing-remitting Multiple Sclerosis: Interim Safety and Efficacy Results from the Phase 3 EVOLVE-MS-1 Study (ePoster; available for duration of congress)

About TECFIDERA®
TECFIDERA is the most prescribed oral medication for relapsing multiple sclerosis (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 415,000 patients have been treated with it, representing more than 780,000 patient-years of exposure across clinical trial use and patients prescribed TECFIDERA. Of these, 6,335 patients (14,065 patient-years) were from clinical trials.[1]

TECFIDERA is contraindicated in patients with a known hypersensitivity to dimethyl fumarate or any of the excipients of TECFIDERA. Rare 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, which then plateaued, and liver function abnormalities, which resolved upon treatment discontinuation. In clinical trials, the most common adverse events associated with TECFIDERA were flushing and gastrointestinal (GI) events.

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 Diroximel Fumarate
Diroximel fumarate is an investigational, novel oral fumarate candidate with a distinct chemical structure in development for the treatment of relapsing forms of MS. Diroximel fumarate is designed to rapidly convert to monomethyl fumarate in the body and, based on bioequivalence data, is referencing TECFIDERA® (dimethyl fumarate) as part of the 505(b)(2) regulatory pathway in the United States. Diroximel fumarate is currently under review with the U.S. Food and Drug Administration (FDA) with a PDUFA (Prescription Drug User Fee Act) target action date in the fourth quarter of 2019. If approved by the FDA, Biogen intends to market diroximel fumarate under the conditionally approved brand name VUMERITY™.

About Biogen
At Biogen, our mission is clear: we are pioneers in neuroscience. Biogen discovers, develops, and delivers worldwide innovative therapies for people living with serious neurological and neurodegenerative 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, Kenneth Murray, and Nobel Prize winners Walter Gilbert and Phillip Sharp, and today has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, commercializes biosimilars of advanced biologics, and is focused on advancing research programs in multiple sclerosis and neuroimmunology, neuromuscular disorders, movement disorders, Alzheimer's disease and dementia, ophthalmology, immunology, neurocognitive disorders, acute neurology, and pain.

We routinely post information that may be important to investors on our website at www.biogen.com. To learn more, please visit www.biogen.com and follow us 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, relating to the potential benefits, safety and efficacy of TECFIDERA and diroximel fumarate; potential clinical effects of TECFIDERA and diroximel fumarate; potential regulatory approval and the timing thereof; the results of certain real-world data; the clinical development program for diroximel fumarate; clinical trial results and plans; the potential of our commercial business and pipeline programs, including diroximel fumarate; the anticipated benefits and potential of our collaboration arrangements with Alkermes; and risks and uncertainties associated with drug development and commercialization. These forward-looking statements may be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "except," "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 the occurrence of adverse safety events and/or unexpected concerns that may arise from additional data or analysis; risks of unexpected costs or delays; regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates, including diroximel fumarate; actual timing and content of submissions to and decisions made by the regulatory authorities regarding our drug candidates, including diroximel fumarate; regulatory submissions may take longer or be more difficult to complete than expected; the risk that we may not fully enroll our clinical trials or enrollment will take longer than expected; unexpected concerns may arise from additional data, analysis or results obtained during our clinical trials; failure to protect and enforce our data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; uncertainty of success in the development and potential commercialization of VUMERITY; risks relating to the potential launch of VUMERITY, including preparedness of healthcare providers to treat patients, the ability to obtain and maintain adequate reimbursement for VUMERITY and other unexpected difficulties or hurdles; product liability claims; and third party collaboration risks. 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.

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[1] Combined post-marketing data based on prescriptions and clinical trials exposure to TECFIDERA as of June 30, 2019.