Biogen Presents Data Demonstrating Improved Gastrointestinal Tolerability With VUMERITY™ (diroximel fumarate) Compared to TECFIDERA® (dimethyl fumarate)

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CAMBRIDGE, Mass., Nov. 22, 2019 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) today announced detailed results from the Phase 3 EVOLVE-MS-2 study demonstrating the improved patient-assessed gastrointestinal (GI) tolerability of VUMERITY™ (diroximel fumarate), a new FDA-approved treatment for relapsing forms of multiple sclerosis (MS), compared to TECFIDERA® (dimethyl fumarate). These EVOLVE-MS-2 results are being presented at the 27th Annual Meeting of the European Charcot Foundation in Italy (Nov. 21-23).

"We know that each patient's journey can vary greatly in MS, so Biogen aims to meet individual treatment goals through our broad MS portfolio," said Alfred Sandrock, Jr., M.D., Ph.D., Executive Vice President, Research and Development, and Chief Medical Officer at Biogen. "TECFIDERA is a clinically meaningful treatment for patients, and we believe VUMERITY now builds upon our franchise as another compelling option for relapsing MS."

EVOLVE-MS-2 is the first study to directly compare the GI tolerability of two relapsing MS treatments. In this study involving relapsing-remitting MS (RRMS) patients, VUMERITY was associated with significantly shorter duration, severity and daily impact of five key GI symptoms, compared to TECFIDERA. Results for the primary endpoint show patients treated with VUMERITY self-reported 46 percent fewer days with intensity scores of ≥2 on the Individual Gastrointestinal Symptom and Impact Scale (IGISIS), compared to TECFIDERA (adjusted rate ratio [95% confidence interval]: 0.54 [0.39−0.75], p = 0.0003). IGISIS is a novel and exploratory scale used by patients in the study to self-assess the intensity and duration of key GI symptoms, including nausea, vomiting, upper and lower abdominal pain and diarrhea. Results observed with TECFIDERA in EVOLVE-MS-2 are consistent with its well-characterized safety profile.

The EVOLVE-MS-2 results also indicate that compared to TECFIDERA, VUMERITY-treated patients had:

- Lower discontinuations due to GI adverse events (AEs) (0.8 percent vs. 4.8 percent).
- Fewer days with IGISIS intensity scores of ≥1 and ≥3 (29 percent relative reduction and 44 percent relative reduction, respectively).
- Fewer days with a self-reported intensity score of ≥1 (30 percent reduction, on the Global Gastrointestinal Symptom and Impact Scale (GGISIS), which assessed the overall intensity of GI symptoms, their impact on daily activities and how bothersome they were. Fewer days with GGISIS intensity scores of ≥2 and ≥3 were also observed.
- A gradual decline in worst IGISIS intensity scores over the five-week treatment period.

These findings using the patient-assessed symptom intensity scales were supported by lower investigator-reported incidences of GI AEs with VUMERITY (34.8 percent) compared to TECFIDERA (49.0 percent). Overall AEs occurred in 78.3 percent of patients with VUMERITY and 83.7 percent with TECFIDERA. Most AEs were mild or moderate in severity. The overall proportion of patients with AEs leading to study discontinuation were 1.6 percent for VUMERITY and 5.6 percent for TECFIDERA.

EVOLVE-MS-2 was a multi-center, double-blind, active-controlled, five-week Phase 3 study designed to evaluate the GI tolerability, including duration and severity, of VUMERITY compared to TECFIDERA in 506 patients with RRMS. The study's primary endpoint assessed the number of days patients reported GI symptoms with a symptom intensity score ≥2 on the IGISIS rating scale. Secondary endpoints evaluated the number of days (relative to exposure) that patients reported GI symptoms with an IGISIS intensity scores of ≥1 or ≥3 in the overall population; IGISIS intensity score of ≥2 in patients from Part B only; GGISIS intensity scores of ≥1, ≥2, or ≥3 in the overall population; and worst (i.e., highest) IGISIS individual symptom score by study week. Patients who completed the five-week treatment period were eligible to enroll in EVOLVE-MS-1, a 96-week, open-label, safety study for VUMERITY.

VUMERITY is now available in the U.S. for relapsing forms of MS.

About VUMERITY ™ (diroximel fumarate)
VUMERITY is a novel, oral fumarate with a distinct chemical structure approved in the U.S. for the treatment of relapsing forms of multiple sclerosis, 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.

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, 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.

About TECFIDERA® (dimethyl fumarate)
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. 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, 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
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. Today Biogen 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. 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 VUMERITY and TECFIDERA; results from the EVOLVE-MS-2 study; the treatment of MS; the potential of Biogen's commercial business, including VUMERITY and TECFIDERA; 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; failure to obtain regulatory approvals in other jurisdictions; risks of unexpected costs or delays; unexpected concerns may arise from additional data, analysis or results obtained during clinical trials; 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 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.