New Phase 3 Interim Results Support Safety and Efficacy of Diroximel Fumarate in Multiple Sclerosis

May 30, 2019

- *Diroximel fumarate significantly reduced disease activity in newly diagnosed relapsing multiple sclerosis (MS) patients and those previously treated with interferons or glatiramer acetate*
- *Data show treatment discontinuations due to gastrointestinal (GI) events occurred at a low rate over one year*

CAMBRIDGE, Mass., May 30, 2019 (GLOBE NEWSWIRE) -- Biogen Inc. (Nasdaq: BIIB) announced today new interim data from the ongoing open-label, pivotal EVOLVE-MS-1 study indicate that the investigational treatment diroximel fumarate was generally well tolerated in people with relapsing multiple sclerosis (MS). These results were presented at the annual meeting of the Consortium of Multiple Sclerosis Centers (CMSC) in Seattle (May 28–June 1). Diroximel fumarate, a novel oral fumarate candidate in development with Alkermes plc (Nasdaq: ALKS), is under review with the U.S. Food and Drug Administration with a PDUFA (Prescription Drug User Fee Act) target action date in the fourth quarter of 2019. Biogen intends to market diroximel fumarate under the conditionally approved brand name VUMERITY™.

“The results we are presenting at CMSC add to the body of evidence supporting the tolerability of diroximel fumarate and its potential effectiveness in relapsing MS patient populations, including newly diagnosed and early switch patients,” said Michael Ehlers, executive vice president, research & development at Biogen. “We are excited about these data for diroximel fumarate and believe this distinct oral fumarate has the potential to be a meaningful treatment option for people living with MS.”

EVOLVE-MS-1 is an ongoing, single-arm, open-label, two-year, Phase 3 study evaluating the safety and exploring the efficacy of diroximel fumarate in patients with relapsing-remitting MS. The study plans to enroll approximately 1,000 patients. Interim results from 696 patients treated with diroximel fumarate for a median of approximately one year were presented in safety and efficacy analyses at the CMSC meeting.

Researchers explored the efficacy of diroximel fumarate in a sub-group analysis of EVOLVE-MS-1 that included patients naive to prior disease-modifying therapy treatment or those previously treated with an interferon (IFN) or glatiramer acetate (GA). New results in patients treated with prior IFN/GA showed that diroximel fumarate was associated with significant improvements in radiological and clinical endpoints over one year compared to baseline. Adjusted annualized relapse rate was reduced by 72 percent with diroximel fumarate between baseline and Week 48. Additionally, the mean number of gadolinium-enhancing (Gd+) lesions was reduced by 64 percent with diroximel fumarate compared to baseline, and the percentage of patients with no Gd+ lesions at Week 48 was 89 percent compared to 74 percent at baseline.

Additional new data illustrate the tolerability profile of diroximel fumarate in relapsing-remitting MS patients over one year. In the study, diroximel fumarate demonstrated low rates of gastrointestinal (GI) adverse events leading to discontinuation (0.7 percent). The incidence of GI adverse events in patients treated with diroximel fumarate over the one-year treatment period was 30.9 percent. The GI events were generally mild or moderate in severity, typically appeared within the first month of treatment and tended to resolve quickly in the vast majority (89 percent) of patients.

The data presented at CMSC add to the current knowledge base of diroximel fumarate and the interim results Biogen shared at the American Academy of Neurology annual meeting earlier this month (May 4–10) on the potential safety and effectiveness of diroximel fumarate in relapsing MS, particularly in newly diagnosed patients. In addition, the GI tolerability of diroximel fumarate as compared to dimethyl fumarate is being evaluated in the ongoing EVOLVE-MS-2 study, with results expected later this year.

Featured Data Presentation Details:

- Tolerability of Diroximel Fumarate in Patients with Relapsing-Remitting MS: Analysis of Gastrointestinal and Flushing Events in the Phase 3 EVOLVE-MS-1 Study – *Poster DXT41 -- Thursday, May 30, 6:30 – 7:30 p.m. PT*
- Efficacy of Diroximel Fumarate in Relapsing-Remitting MS Patients Who Are Newly Diagnosed or Previously Treated with Interferons or Glatiramer Acetate – *Poster DXT42 – Thursday, May 30, 6:30 – 7:30 p.m. PT*

About Diroximel Fumarate
Diroximel fumarate is a novel oral fumarate candidate in development for the treatment of relapsing forms of MS with a distinct chemical structure. Diroximel fumarate is designed to rapidly convert to monomethyl fumarate in the body and it is hypothesized that it may have the potential to offer differentiated gastrointestinal (GI) tolerability as compared to dimethyl fumarate. Alkermes is conducting the EVOLVE-MS-2 study in patients with relapsing-remitting MS, a five-week, head-to-head study versus dimethyl fumarate to evaluate GI tolerability in addition to the EVOLVE-MS-1 study. 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. Diroximel fumarate will be marketed under the brand name VUMERITY™, which has been conditionally accepted by the FDA and will be confirmed upon approval.

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 and only approved treatment for spinal muscular atrophy and is focused on advancing neuroscience research programs in MS and neuroimmunology, Alzheimer’s disease and dementia, movement disorders, neuromuscular disorders, acute neurology, neurocognitive disorders, pain and ophthalmology. Biogen also commercializes biosimilars of advanced biologics.

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 diroximel fumarate; results from the EVOLVE-MS-1 study; the clinical development program for diroximel fumarate, including the enrollment of the EVOLVE-MS-1 study; potential regulatory approval and the timing thereof; clinical trial results and plans; our research and development program for the treatment of MS; the identification and treatment of MS; 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; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of our drug candidates, including diroximel fumarate; 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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