Alkermes and Biogen Announce U.S. Food and Drug Administration Acceptance of Diroximel Fumarate New Drug Application for Multiple Sclerosis

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DUBLIN, Ireland and CAMBRIDGE, Mass., Feb. 25, 2019 (GLOBE NEWSWIRE) -- Alkermes plc (Nasdaq: ALKS) and Biogen Inc. (Nasdaq: BIIB) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for diroximel fumarate (BIIB098), a novel oral fumarate in development for the treatment of relapsing forms of multiple sclerosis (MS). The NDA has been assigned a PDUFA (Prescription Drug User Fee Act) target action date in the fourth quarter of 2019. If approved, Biogen intends to market diroximel fumarate under the brand name VUMERITY ™, which has been conditionally accepted by the FDA and will be confirmed upon approval.

“The NDA filing acceptance for diroximel fumarate further demonstrates the productive collaboration between Alkermes and Biogen and brings us closer to our shared goal of offering a new therapeutic option for people with MS,” said Craig Hopkinson, M.D., chief medical officer and senior vice president, medicines development and medical affairs at Alkermes. “We believe diroximel fumarate has the potential to be a meaningful new offering for patients with MS, and we look forward to continued engagement with the FDA throughout the review process.”

“For more than two decades Biogen has been at the forefront of delivering new medicines to MS patients,” said Michael Ehlers, M.D., Ph.D., executive vice president, research and development at Biogen. “We are encouraged by the FDA’s acceptance of the NDA for diroximel fumarate, which we believe could help elevate the treatment of this complex and often debilitating disease.”

Alkermes is seeking approval of diroximel fumarate under the 505(b)(2) regulatory pathway, referencing Biogen’s dimethyl fumarate data. The NDA submission includes data from EVOLVE-MS-1, a Phase 3, open-label, two-year safety study in relapsing-remitting MS (RRMS) patients. It is hypothesized that the distinct chemical structure of diroximel fumarate may impact its gastrointestinal (GI) tolerability. Alkermes is conducting EVOLVE-MS-2, a head-to-head GI tolerability study versus dimethyl fumarate, with results expected later this year.

About the Diroximel Fumarate Clinical Development Program
The key components of the clinical development program of diroximel fumarate include the EVOLVE-MS-1 study, a Phase 3, open-label, two-year safety study in relapsing-remitting MS (RRMS) patients, along with pharmacokinetic bridging studies comparing diroximel fumarate and dimethyl fumarate. In addition, Alkermes is conducting the EVOLVE-MS-2 study in patients with RRMS, a five-week, head-to-head gastrointestinal (GI) tolerability study versus dimethyl fumarate.

About Diroximel Fumarate
Diroximel fumarate (BIIB098) is a novel oral fumarate candidate in development for the treatment of relapsing forms of MS. Diroximel fumarate is designed to rapidly convert to monomethyl fumarate in the body and may have the potential to offer differentiated GI tolerability due to its chemical structure as compared to dimethyl fumarate.

About Alkermes plc
Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases. The company has a diversified commercial product portfolio and a substantial clinical pipeline of product candidates for chronic diseases that include schizophrenia, depression, addiction, multiple sclerosis and oncology. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio. For more information, please visit Alkermes’ website at www.alkermes.com.

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. 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 Alzheimer’s disease and dementia, MS and neuroimmunology, movement disorders, neuromuscular disorders, acute neurology, neurocognitive disorders, pain and ophthalmology. Biogen also manufactures and 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.

Alkermes Note Regarding Forward-Looking Statements
Certain statements set forth in this press release constitute “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements concerning: the potential therapeutic and commercial value of diroximel fumarate for the treatment of relapsing forms of MS; expectations regarding the tolerability of diroximel fumarate; expectations regarding future interactions with the FDA and expected timelines for potential approval by the FDA of the NDA for diroximel fumarate for the treatment of relapsing forms of MS; the potential confirmation by the FDA of its conditional acceptance of the proposed brand name for diroximel fumarate; and Biogen’s marketing plans for diroximel fumarate. Alkermes cautions that forward-looking statements are inherently uncertain. Although Alkermes believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees and they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those expressed or implied in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: whether the results from the head-to-head study to evaluate the GI tolerability of diroximel fumarate compared to dimethyl fumarate will show that diroximel fumarate has a differentiated GI tolerability profile; whether preclinical and clinical results for diroximel fumarate will be predictive of future clinical study results or real-world results; changes in the cost, scope and duration of the diroximel fumarate development and regulatory program; whether diroximel fumarate could be shown ineffective or unsafe during clinical studies, and whether, in such instances, Alkermes may not be permitted by regulatory authorities to undertake new or additional clinical studies of diroximel fumarate; whether the NDA for diroximel fumarate, including the proposed brand name for diroximel fumarate, will be approved by the FDA; if approved, whether diroximel fumarate will be commercialized successfully; whether the potential commercial and therapeutic benefits of collaboration with Biogen under the license and collaboration agreement between Alkermes and Biogen will be achieved; and those risks described in the Alkermes Annual Report on Form 10-K for

the year ended Dec. 31, 2018 and in subsequent filings made by Alkermes with the U.S. Securities and Exchange Commission (SEC), which are available on the SEC's website at www.sec.gov. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release.

Biogen Safe Harbor

This press release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including statements about potential regulatory approval and the timing thereof; the potential clinical effects of diroximel fumarate; the potential benefits, safety and efficacy of diroximel fumarate; clinical trial results and plans; the treatment of MS; the potential of Biogen's commercial business and pipeline programs, including diroximel fumarate; the anticipated benefits and potential of Biogen's collaboration arrangements with Alkermes; and risks and uncertainties associated with drug development and commercialization. These forward-looking statements may be accompanied by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "possible," "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 regarding 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 Biogen's drug candidates, including diroximel fumarate; the risk that Biogen or Alkermes may not fully enroll their respective clinical trials or enrollment will take longer than expected; the actual timing and final results of the EVOLVE-MS-2 study; unexpected concerns may arise from additional data, analysis or results obtained during Biogen's clinical trials; the occurrence of adverse safety events; the risks of other unexpected hurdles, costs or delays; failure to protect and enforce Biogen's 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 Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the Securities and Exchange Commission. These statements are based on Biogen's current beliefs and expectations and speak only as of the date of this press release. Biogen does 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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