Alkermes Announces Positive Clinical Trial Results and Streamlined Registration Pathway for ALKS 8700 for Treatment of Multiple Sclerosis

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— Company on Track to Initiate Registration Program for Novel Twice-Daily Oral Candidate by End of 2015 and File New Drug Application in 2018 —

DUBLIN--(BUSINESS WIRE)--Oct. 29, 2015-- Alkermes plc (NASDAQ: ALKS) today provided an update on its regulatory strategy and positive clinical trial results for ALKS 8700, a novel, oral monomethyl fumarate (MMF) molecule in development for the treatment of multiple sclerosis (MS). ALKS 8700 is designed to rapidly and efficiently convert to MMF in the body and offer differentiated features as compared to the currently marketed dimethyl fumarate, TECFIDERA®.

Regulatory update: Based on a meeting with the U.S. Food and Drug Administration (FDA), Alkermes plans to file a 505(b)(2) New Drug Application (NDA) using pharmacokinetic bridging data from studies comparing ALKS 8700 and TECFIDERA, as well as a two-year phase 3 safety study of ALKS 8700 in approximately 600 patients with MS. Importantly, this means that Alkermes will not be required to conduct a separate phase 3 efficacy study in patients with MS. In addition, Alkermes intends to initiate a randomized, head-to-head study comparing the gastrointestinal (GI) tolerability of ALKS 8700 and TECFIDERA in approximately 420 patients with MS in mid-2016. Alkermes expects to complete these studies and file the NDA in 2018.

Clinical update: Alkermes recently completed a randomized, double-blind phase 1 comparative pharmacokinetic study evaluating plasma MMF levels achieved by administration of single doses of ALKS 8700 and TECFIDERA. Initial data from this study showed that ALKS 8700 met the pharmacokinetic criteria for bioequivalence to TECFIDERA. The most common adverse events (AEs) in the study were flushing, dizziness and constipation for ALKS 8700, and flushing, nausea and diarrhea for TECFIDERA. Based on these results, Alkermes has selected the ALKS 8700 dose to be used in the registration program. Alkermes will need to conduct additional preclinical studies and pharmacokinetic studies to further support pharmacokinetic comparability to TECFIDERA.

“With these positive pharmacokinetic bridging results and agreement with the FDA on our regulatory strategy in hand, our path to approval for ALKS 8700 has been clarified. A key component of the program is the comparison of GI tolerability, as we see this as an opportunity to potentially provide new benefits to MS patients,” said Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. “We remain on track to advance ALKS 8700 twice-daily into phase 3 development with the initiation of the two-year safety study later this year, and we plan to file the NDA in 2018.”

Recent Phase 1 Study Design and Results

This phase 1, randomized, double-blind clinical study evaluated the safety, tolerability and single-dose pharmacokinetics (PK) of ALKS 8700 compared to active control in 35 healthy volunteers. In this two-treatment, two-period crossover design, subjects received a single dose of either ALKS 8700 or TECFIDERA, followed by the other agent in the subsequent treatment period, thereby enabling a crossover comparison of PK and tolerability within the same subjects. Initial data from this study showed that ALKS 8700 met the pharmacokinetic criteria for bioequivalence to TECFIDERA.

The most common AEs in the study were flushing, dizziness and constipation for ALKS 8700, and flushing, nausea and diarrhea for TECFIDERA. No serious AEs or discontinuations due to AEs were observed in the study. Alkermes will present safety and PK data from the phase 1 study at an upcoming medical meeting and submit the results for publication in a peer-reviewed journal.

About ALKS 8700

ALKS 8700 is an oral, novel and proprietary monomethyl fumarate (MMF) molecule in development for the treatment of multiple sclerosis (MS). ALKS 8700 is designed to rapidly and efficiently convert to MMF in the body and to offer differentiated features as compared to the currently marketed dimethyl fumarate, TECFIDERA®.

About Multiple Sclerosis

Multiple sclerosis (MS) is an unpredictable, often disabling disease of the central nervous system (CNS), which interrupts the flow of information within the brain, and between the brain and body.[1] MS symptoms can vary over time and from person to person. Symptoms may include extreme fatigue, impaired vision, problems with balance and walking, numbness or pain and other sensory changes, bladder and bowel symptoms, tremors, problems with memory and concentration and mood changes, among others.[1] Approximately 400,000 individuals in the U.S. and 2.5 million people worldwide have MS, and most are diagnosed between the ages of 15 and 50.[2]

About Alkermes

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 and multiple sclerosis. 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.

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 continued clinical development of ALKS 8700 for the treatment of MS, the timing of the commencement of the phase 3 studies of ALKS 8700, the number of patients enrolled in the phase 3 studies, if a separate phase

3 efficacy study of ALKS 8700 in patients with MS will be required, and the timing of the submission of the NDA to the FDA for ALKS 8700. You are cautioned that forward-looking statements are inherently uncertain. Although the company 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 preclinical and early clinical results for ALKS 8700 will be predictive of future clinical study results; whether future clinical trials for ALKS 8700 will be initiated or completed on time or at all; changes in the cost, scope and duration of the ALKS 8700 clinical trials; whether ALKS 8700 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 ALKS 8700; whether regulatory submissions for ALKS 8700 will be submitted on time or at all; whether adverse decisions by regulatory authorities occur; whether the pharmacokinetic, phase 3 and other studies conducted for ALKS 8700 will meet FDA's requirements; and those risks described in the Alkermes plc Quarterly Report on Form 10-Q for the period ended Sept. 30, 2015 and Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2014, and in any other subsequent filings made by the company with the U.S. Securities and Exchange Commission (SEC), which are available on the SEC's website at www.sec.gov. The information contained in this press release is provided by the company as of the date hereof, and, except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking information contained in this press release.

TECFIDERA® is a registered trademark of Biogen MA Inc.

[1] National Multiple Sclerosis Society. *Multiple Sclerosis: Just the Facts*. Accessed from http://www.nationalmssociety.org/NationalMSSociety/media/MSNationalFiles/Brochures/Brochure-Just-the-Facts.pdf on Oct. 28, 2015.

[2] Multiple Sclerosis Association of America. MS Overview. Accessed from http://mymsaa.org/about-ms/overview/ on Oct. 28, 2015.

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