Alkermes Initiates Phase 3 Gastrointestinal Tolerability Study of ALKS 8700 for Treatment of Multiple Sclerosis

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— Head-to-Head Study to Assess Tolerability Profile of ALKS 8700 Compared to TECFIDERA® —

— Novel, Oral, Twice-Daily Drug Candidate Designed to Provide MMF Exposures Equivalent to TECFIDERA With Differentiated Profile —

DUBLIN--(BUSINESS WIRE)--Mar. 16, 2017-- Alkermes plc (NASDAQ: ALKS) today announced the initiation of a new phase 3 study of ALKS 8700, a novel, oral monomethyl fumarate (MMF) prodrug candidate in development for the treatment of relapsing forms 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®. The five-week, head-to-head study will evaluate the gastrointestinal (GI) tolerability of ALKS 8700 compared to TECFIDERA in approximately 420 patients with relapsing-remitting MS (RRMS). This elective study is part of the ongoing clinical development program for ALKS 8700, named EVOLVE-MS (**E**ndea**vo**ring to Advance Treatment for Patients **L**i**v**ing with Multip**l**e Sclerosis). The company plans to submit a New Drug Application (NDA) for ALKS 8700 for the treatment of RRMS to the U.S. Food and Drug Administration (FDA) in 2018.

“ALKS 8700, a MMF prodrug with distinct physical-chemical properties, is designed to provide therapeutic concentrations of MMF in the body and offer differentiated features as compared to the market leader dimethyl fumarate, TECFIDERA, which is associated with gastrointestinal side effects. These adverse events can lead to treatment interruption or discontinuation for patients with MS,” stated Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. “We believe ALKS 8700 may represent a valuable new option for patients suffering from MS who want the efficacy of fumarate therapy with more favorable gastrointestinal tolerability. We look forward to conducting this study and submitting the planned NDA for ALKS 8700 in 2018.”

“This elective study for ALKS 8700 demonstrates Alkermes’ unique approach to fully characterize the potential value of new medicines, reflecting our commitment to integrating inputs from patients, physicians and payers into our development programs in response to an increasingly complex healthcare system,” stated Richard Pops, Chief Executive Officer of Alkermes. “The data from this study will help determine ALKS 8700’s potential advantages for patients and its future positioning in the fumarate market, which represents a $3 billion opportunity in the U.S.”

The phase 3, multicenter, double-blind, active-controlled, five-week study is designed to evaluate the GI tolerability of ALKS 8700 462 mg twice daily compared to TECFIDERA 240 mg twice daily in approximately 420 patients with RRMS. Both treatment groups will include an initial one-week dose titration period. Key GI symptoms, including nausea, vomiting, upper and lower abdominal pain and diarrhea, will be assessed using two patient-reported symptom rating scales: the Individual Gastrointestinal Symptom and Impact Scale (IGISIS) and the Global Gastrointestinal Symptom and Impact Scale (GGISIS). Intensity, frequency and duration of symptoms, as well as effect on daily activities will also be assessed.

About the EVOLVE-MS Clinical Development Program

The key components of the EVOLVE-MS (**E**ndea**vo**ring to Advance Treatment for Patients **L**i**v**ing with Multip**l**e Sclerosis) clinical development program of ALKS 8700 include a two-year safety study and pharmacokinetic bridging studies comparing ALKS 8700 and TECFIDERA. In addition, the program includes an elective head-to-head study comparing the GI tolerability of ALKS 8700 and TECFIDERA.

About ALKS 8700

ALKS 8700 is an oral, novel and proprietary monomethyl fumarate (MMF) prodrug candidate in development for the treatment of relapsing forms 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 and therapeutic value of ALKS 8700

for the treatment of relapsing forms of MS, the number of patients enrolled in the ALKS 8700 phase 3 studies, the adequacy of the EVOLVE-MS development program for ALKS 8700 to serve as the basis for an NDA, the commercial potential of ALKS 8700, and the timing of the submission of the NDA to the FDA for ALKS 8700. The company cautions 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 the results from the head-to-head study to evaluate the GI tolerability of ALKS 8700 compared to TECFIDERA will show that ALKS 8700 has more favorable GI tolerability; whether preclinical and early clinical results for ALKS 8700 will be predictive of future clinical study results; whether clinical trials for ALKS 8700 will be 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 Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2016, and in 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 March 15, 2017.

[2] Multiple Sclerosis Association of America. *MS Overview*. Accessed from http://mymsaa.org/ms-information/overview/who-gets-ms/ on March 15, 2017.

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