Alkermes Presents Data Demonstrating Safety and Gastrointestinal Tolerability Profile of ALKS 8700 for the Treatment of Multiple Sclerosis

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— Data From More Than 570 Patients in Ongoing Long-Term Safety Study of ALKS 8700 Demonstrate Low Rates of Discontinuation During Initial Three Months of Treatment —

DUBLIN--(BUSINESS WIRE)--Oct. 27, 2017-- Alkermes plc (NASDAQ: ALKS) today presented safety and gastrointestinal (GI) tolerability data from EVOLVE-MS-1, an ongoing open-label, two-year phase 3 safety study for ALKS 8700, a novel, oral monomethyl fumarate (MMF) prodrug candidate in development for the treatment of relapsing forms of multiple sclerosis (MS). Interim data from more than 570 patients at one and three months of treatment with ALKS 8700 were presented at MSParis2017, the 7th Joint Meeting of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) and the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) in Paris, France.

Safety data from the first month of the EVOLVE-MS-1 study (N=580) showed that treatment with ALKS 8700 was associated with low rates of GI adverse events (AEs) leading to discontinuation (0.5%) and no occurrence of serious GI AEs. The most common AEs during the first month of treatment with ALKS 8700 were flushing (31.7%), pruritus (7.4%) and diarrhea (6.6%). Data from the initial three months of treatment in the study (N=574) support and extend the safety profile for ALKS 8700, with 2.3% of patients reporting serious AEs, and 3.7% experiencing AEs that led to study discontinuation.

“When choosing a treatment regimen for a chronic disease like MS, patients and their healthcare providers must weigh multiple factors, including efficacy, safety, tolerability and convenience. Fumarate therapy is recognized in the clinical community as an efficacious option for patients with MS, but it is also known to be associated with GI side effects that may lead to treatment interruption or discontinuation, particularly in the first few weeks following treatment initiation,” said Robert Naismith, M.D., Associate Professor of Neurology, Washington University School of Medicine in St. Louis. “A new treatment option that provides therapeutic levels of fumarate therapy with a differentiated safety profile would be a valuable and welcomed option for members of the MS community.”

“We are encouraged by the safety data presented today for ALKS 8700, a MMF prodrug with distinct physical-chemical properties, as these interim results reinforce the safety and GI tolerability profile we set out to develop in a potential new oral therapy for the treatment of MS,” said Elliot Ehrich, M.D., Executive Vice President of Research and Development at Alkermes. “We are committed to bringing this potential valuable new treatment to patients and providers and remain on track to announce initial data from the GI tolerability study comparing ALKS 8700 to TECFIDERA, and to submit the planned New Drug Application for ALKS 8700 in 2018.”

A poster on the data, titled “EVOLVE-MS-1: A Phase 3, Open-Label, Long-Term Safety Study of ALKS 8700 in Relapsing-Remitting Multiple Sclerosis,” was presented on Friday, Oct. 27 at 3:30 p.m. CEST (9:30 a.m. ET). For more information, including a complete list of abstract titles, please visit the MSParis2017 website at https://www.ectrims-congress.eu/2017.html

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 Multipl**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 adequacy of the EVOLVE-MS development program for ALKS 8700 to serve as the basis for a new drug application (NDA), the commercial potential of ALKS 8700, and the timing of the submission of the NDA to the U.S. Food and Drug Administration (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 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 the 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 Quarterly Reports on Form 10-Q for the quarters ended March 31, 2017, June 30, 2017 and Sept. 30, 2017 and in 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. 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.

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. 26, 2017.

[2] Multiple Sclerosis Association of America. *MS Overview*. Accessed from http://mymsaa.org/ms-information/overview/who-gets-ms/ on Oct. 26, 2017.

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