Alkermes Announces Positive Topline Results From Phase 1 Study of ALKS 8700 for Treatment of Multiple Sclerosis

February 9, 2015

— Novel, Oral Product Candidate Provided Monomethyl Fumarate Exposures Comparable to TECFIDERA®, With Favorable Gastrointestinal Tolerability —

— Company Plans to Initiate Pivotal Development Program for Twice-Daily Candidate in 2015 —

DUBLIN--(BUSINESS WIRE)--Feb. 9, 2015-- Alkermes plc (NASDAQ: ALKS) today announced positive topline results from a phase 1, randomized, double-blind clinical study of ALKS 8700, a novel 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®. The study evaluated the safety, tolerability and single-dose pharmacokinetics (PK) of several oral formulations of ALKS 8700 compared to both placebo and active control groups in 104 healthy volunteers. Data from the phase 1 study showed that ALKS 8700 was generally well tolerated and provided MMF exposures comparable to TECFIDERA, with less variability and improved gastrointestinal (GI) tolerability. The most common adverse events (AEs) were flushing and GI-related. Based on the positive results from the study, Alkermes will request a meeting with the U.S. Food and Drug Administration (FDA), and plans to advance ALKS 8700 with twice-daily dosing into pivotal development in 2015.

“The results from this study demonstrated ALKS 8700 converts efficiently into MMF after oral administration with the potential to offer improved GI tolerability for patients with MS,” said Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. “This highly informative clinical study provided clear data regarding dose selection and supports our decision to advance ALKS 8700 twice-daily into pivotal development later this year. In addition, it provided new insights into approaches for once-daily dosing options, which we will continue to pursue.”

Phase 1 Study Design and Results

The three-part, randomized, double-blind phase 1 study was conducted in 104 healthy subjects. Part 1 was a single-ascending-dose, placebo-controlled design in 56 subjects to evaluate the safety, tolerability and PK of a range of single doses of ALKS 8700, and determine a dose that would provide MMF exposure comparable to 240 mg TECFIDERA, to be used in Part 2. Part 2 was a two-treatment, two-period crossover design in 16 subjects that compared the PK and tolerability of a single dose of ALKS 8700, 240 mg TECFIDERA or placebo. Part 3 included 32 subjects and evaluated PK of extended-release formulations of ALKS 8700.

In Part 1, doses of ALKS 8700 ranging from 49 mg to 980 mg were evaluated. ALKS 8700 was rapidly converted to MMF, a dose-exposure relationship was observed, with higher MMF exposure associated with increasing ALKS 8700 dose levels, and a dose of ALKS 8700 providing MMF plasma exposure comparable to 240 mg TECFIDERA was identified for Part 2. In Part 2, subjects on active drug received either the selected dose of ALKS 8700 from Part 1 or 240 mg TECFIDERA, followed by the other agent on a subsequent day, thereby enabling a crossover comparison of PK and tolerability within the same subjects. In this part of the study, subjects who received ALKS 8700 demonstrated less variability in MMF exposure than subjects who received TECFIDERA, with a significantly lower maximum plasma concentration (Cmax). The percentage of subjects with GI-related AEs was lower with ALKS 8700 (8.3%) compared to TECFIDERA (41.7%). In Part 3, the PK data of the extended-release formulations of ALKS 8700 provided new insights into approaches for once-daily dosing options, which Alkermes will continue to pursue.

Throughout the study, all dose levels of ALKS 8700 were generally well tolerated. The most common AEs were flushing and GI-related; all AEs were mild or moderate in severity. No serious AEs or discontinuations due to AEs were observed for ALKS 8700 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 that applies its scientific expertise and proprietary technologies to develop innovative medicines that improve patient outcomes. The company has a diversified portfolio of more than 20 commercial drug products and a substantial clinical pipeline of product candidates that address central nervous system (CNS) disorders such as addiction, schizophrenia and depression. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and manufacturing facilities in Gainesville, Georgia and 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 therapeutic value, development plans and commercial potential of 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 projected or suggested 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; and those risks described in the Alkermes plc Transition Report on Form 10-K for the fiscal period ended December 31, 2013, 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 Idec 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 Feb. 6, 2015.

[2] Multiple Sclerosis Association of America. MS Overview. Accessed from http://mymsaa.org/about-ms/overview/ on Feb. 6, 2015.

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