



Alkermes Announces Initiation of Phase 1 Clinical Study of ALKS 8700 for Treatment of Multiple Sclerosis

July 17, 2014

—Large, Randomized Study Will Investigate Multiple Oral Formulations of Novel MMF Molecule —

DUBLIN--(BUSINESS WIRE)--Jul. 17, 2014-- [Alkermes plc](#) (NASDAQ: ALKS) today announced the initiation of a phase 1 clinical study of ALKS 8700, a novel monomethyl fumarate (MMF) molecule in development for the treatment of multiple sclerosis (MS). The randomized, double-blind study will evaluate the safety, tolerability and pharmacokinetics of several oral formulations of ALKS 8700 compared to both placebo and active control groups in approximately 125 healthy volunteers. 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®.

"We expect the results of this study to be highly informative and determine the therapeutic utility and differentiating features of ALKS 8700," said Dr. Elliot Ehrich, Chief Medical Officer of Alkermes. "ALKS 8700 leverages Alkermes' expertise in prodrug chemistry and oral controlled-release formulations to offer potential differentiated tolerability and dosing for patients with MS."

This phase 1 study will investigate the pharmacokinetics and pharmacodynamics of multiple formulations and doses of ALKS 8700, and is designed to determine those suitable to progress into advanced clinical testing. The initiation of the phase 1 study follows Alkermes' filing of an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA), and the issuance of a composition of matter patent for ALKS 8700 from the United States Patent and Trademark Office (USPTO) in March 2014, which is expected to provide patent protection into 2033.

About ALKS 8700

ALKS 8700 is an oral, novel and proprietary monomethyl fumarate (MMF) molecule in development for the treatment of multiple sclerosis (MS). With properties designed to enable improved flexibility in the development of extended-release formulations, 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 and the patent life of the composition of matter patent covering 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 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 completed on time or at all; changes in the cost, scope and duration of the ALKS 8700 clinical trials; whether the validity and enforceability of the composition of matter patent for ALKS 8700 will be challenged by one or more third parties and upheld; whether ALKS 8700 could be 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 for 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 July 16, 2014.

² Multiple Sclerosis Association of America. MS Overview. Accessed from <http://mymsaa.org/about-ms/overview/> on July 16, 2014.



Source: Alkermes plc

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