



Alkermes Announces Notice of Allowance of U.S. Patent for a Novel Fumarate Prodrug for Multiple Sclerosis

January 6, 2014

—Company Plans to File IND and Advance MMF Prodrug Formulations Into the Clinic in Mid 2014 —

DUBLIN--(BUSINESS WIRE)--Jan. 6, 2014-- [Alkermes plc](#) (NASDAQ:ALKS) today announced that the United States Patent and Trademark Office (USPTO) has issued a Notice of Allowance for U.S. Patent Application 14/032,736, entitled "Prodrugs of fumarates and their use in treating various diseases." The allowed composition of matter claims will cover Alkermes' MMF prodrug, ALKS 8700, a proprietary, small-molecule prodrug of monomethyl fumarate (MMF) for the treatment of multiple sclerosis. The Notice of Allowance resulted from a prioritized examination granted by the USPTO, and the allowed claims are directed toward a novel MMF prodrug that is designed to rapidly and efficiently convert to MMF in the body. Alkermes expects to file an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) and initiate a phase 1 study of ALKS 8700 in mid 2014.

"This patent allowance is a critical step in solidifying our intellectual property protection for our MMF prodrug program and our lead MMF prodrug candidate, ALKS 8700, which we continue to advance toward an IND filing and phase 1 study initiation in mid 2014," stated Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. "Our world-class formulation expertise and prodrug capabilities put Alkermes in a unique position to create and develop prodrug formulations that rapidly and efficiently convert to MMF in the body and that are designed to offer differentiated dosing and tolerability, as compared to the currently marketed dimethyl fumarate prodrug, TECFIDERA®."

Alkermes expects this patent to issue within the next few months and to expire no earlier than 2033. A Notice of Allowance is issued after the USPTO makes a determination that a patent can be granted from an application.

About Multiple Sclerosis

Multiple sclerosis (MS) is a chronic, often disabling, disease that attacks the central nervous system (CNS), which is made up of the brain, spinal cord and optic nerves. Symptoms may be mild or severe, ranging from numbness in the limbs to paralysis or loss of vision. The progression, severity and specific symptoms of MS are unpredictable and vary from one person to another. MS affects more than 2.3 million people worldwide.¹ Best current estimates indicate that there are at least 400,000 people with MS in the United States.²

About Alkermes plc

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, including, but not limited to, whether Patent Application 14/032,736 will issue; whether such issued patent will adequately protect the company's MMF prodrugs, including ALKS 8700, against competition; the expiration date and strength of such patent; and the therapeutic value, development plans and commercial potential of the company's prodrug program, including ALKS 8700 for the treatment of multiple sclerosis. 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 the validity and enforceability of Patent Application 14/032,736, if issued, will be challenged by one or more third parties and upheld; whether preclinical and early clinical results for the company's MMF prodrug program, including ALKS 8700, will be predictive of future clinical study results; whether the company's MMF prodrugs, including ALKS 8700, will be shown to be ineffective or unsafe during clinical studies; decisions by the FDA or foreign regulatory authorities regarding the company's MMF prodrug program, including ALKS 8700, for the treatment of multiple sclerosis; potential changes in cost, scope and duration of clinical trials of the company's MMF prodrug program, including those for ALKS 8700, for the treatment of multiple sclerosis; and those risks described in the Alkermes plc Annual Report for the year ended March 31, 2013, and in other 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 any forward-looking information contained in this press release.

TECFIDERA® is a registered trademark of Biogen Idec.

¹ National Multiple Sclerosis Society (NMSS). FAQs about MS. Date accessed: January 3, 2014. <http://www.nationalmssociety.org/about-multiple-sclerosis/what-we-know-about-ms/faqs-about-ms/index.aspx>

² National Multiple Sclerosis Society (NMSS). MS Prevalence. Date accessed: January 3, 2014. <http://www.nationalmssociety.org/about-the-society/ms-prevalence/index.aspx>



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