Alkermes Unveils Three New Drug Candidates Demonstrating Productivity of Its R&D Capabilities

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– New Molecular Entities Advancing for the Treatment of Multiple Sclerosis, Pain and Cancer –

– Company Also Highlights Late-Stage CNS Clinical Candidates, Including Aripiprazole Lauroxil, ALKS 5461 and ALKS 3831 –

DUBLIN--(BUSINESS WIRE)--Jul. 17, 2013-- Alkermes plc (NASDAQ: ALKS) today will present an overview of its proprietary pipeline portfolio at its Research and Development (R&D) Day meeting for analysts and investors. For the first time, the company will discuss three new drug candidates including: a monomethyl fumarate (MMF) prodrug program for the treatment of multiple sclerosis; ALKS 7106 for the treatment of pain; and RDB 1419, a cancer immunotherapy candidate based on interleukin-2 (IL-2) and its receptors, Alkermes' first proprietary biologic. These drug candidates demonstrate Alkermes' focus on unmet medical needs in specific patient populations and show the productivity of the company's expanded R&D capabilities.

In addition to the three newly unveiled drug candidates, the company will provide details on its later-stage pipeline candidates, specifically: commercial plans for aripiprazole lauroxil, a once-monthly, long-acting atypical antipsychotic currently in phase 3 development for the treatment of schizophrenia; review of the phase 2 data for ALKS 5461, a proprietary opioid modulator with a novel mechanism for the treatment of major depressive disorder (MDD); and the clinical rationale and development plan, including initiation of a phase 2 clinical study, for ALKS 3831, a proprietary oral compound designed as a broad spectrum antipsychotic treatment for schizophrenia.

"During this R&D Day, a more complete picture of our growth strategy will emerge," commented Richard Pops, Chief Executive Officer of Alkermes. "Today we will be presenting a deeper look into our unique R&D engine that is powering one of the most diverse and exciting pipelines in the biotechnology industry, and bringing to light three innovative product candidates in important therapeutic fields. These new candidates are expected to follow our later-stage CNS product candidates: aripiprazole lauroxil for schizophrenia, ALKS 5461 for major depressive disorder and ALKS 3831 for schizophrenia, which represent growth opportunities over and above our five key commercial products."

"The three new drug candidates that we are unveiling today exemplify the productivity of R&D at Alkermes – which now spans small molecules and biologics – and represent significant opportunities for us to address unmet needs for patients with major, chronic diseases: multiple sclerosis, pain and cancer," stated Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. "Our distinctive approach is to build on a foundation of known pharmacology and clinical practice, then apply our R&D expertise and novel insights to create proprietary medicines with real value for patients and treatment systems. We will highlight for investors at our R&D Day how Alkermes employs a rigorous clinical development process that incorporates state-of-the-art clinical trial techniques and robust study designs so we can obtain data early in the development process to make rapid decisions about the most promising candidates in our pipeline."

R&D Highlights

Alkermes today will provide details on the following new proprietary candidates:

- **MMF Prodrug Program for the Treatment of Multiple Sclerosis:** The company's MMF prodrug program has resulted in novel, small-molecule prodrugs of monomethyl fumarate for the treatment of multiple sclerosis. Alkermes' MMF prodrugs are designed to rapidly and efficiently convert to MMF in the body and to offer advantages over the currently marketed dimethyl fumarate prodrug, TECFIDERA®. Alkermes expects to file an Investigational New Drug (IND) application and initiate a phase 1 study in mid calendar 2014.
- **ALKS 7106 for the Treatment of Pain:** ALKS 7106 is Alkermes' novel, small-molecule drug candidate derived from the company's opioid modulator platform. ALKS 7106 is a potent, oral opioid analgesic designed for the treatment of pain with intrinsically low potential for abuse and overdose death, two liabilities associated with other opioid medicines. Alkermes will present preclinical data showing that ALKS 7106 had more potent analgesic properties than morphine and was well tolerated at doses far in excess of those required for analgesic action. Additional preclinical data for ALKS 7106 demonstrated a ceiling effect on neurotransmitter release over a broad concentration range, suggesting low potential for abuse and overdose death. Alkermes expects to file an IND and initiate a phase 1 study of ALKS 7106 in mid calendar 2014.
- **RDB 1419, a Cancer Immunotherapy Based on IL-2 and its Receptors:** Alkermes will present preclinical data showing that RDB 1419, a novel biologic based on IL-2 and its receptors, preferentially expanded the number of tumor-killing cells involved in immunotherapeutic effects on cancer. Additional preclinical data demonstrated that RDB 1419 inhibited lung metastases in a model of lung cancer. The company will describe how RDB 1419 was engineered using its proprietary fusion protein technology platform to modulate the natural mechanism of action of a biologic and to provide safety and tolerability advantages over existing therapies. Alkermes expects to conduct IND-enabling activities for RDB 1419 in calendar 2014.

Webcast

A live webcast of the company's R&D Day will begin today at 1:00 p.m. EDT (6:00 p.m. BST). The webcast will be available on the Investors tab of the company's website at www.alkermes.com. To ensure a timely connection to the webcast, it is recommended that users register 15 minutes prior to the scheduled webcast. This webcast will be archived on Alkermes' website for one month.

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, statements concerning: the therapeutic value, development plans, and commercial potential of the company's products, including aripiprazole lauroxil, ALKS 5461, ALKS 3831, ALKS 7106, RDB 1419 and the MMF prodrug program. 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: clinical trials of our products may be unsuccessful or not initiated or conducted in a timely manner; regulatory submissions, including INDs, may not occur or be submitted in a timely manner; our products may not show sufficient therapeutic effects or acceptable safety profiles; adverse decisions by regulatory authorities; existing clinical and preclinical data with respect to our products may not be indicative of future clinical or commercial results; and our inability to manufacture successfully our products; and those risks described in the Alkermes plc Annual Report on Form 10-K and Form 10-K/A 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 at 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.

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Source: Alkermes plc

Alkermes:
For Investors:
Rebecca Peterson, +1 781-609-6378
or
For Media:
Jennifer Snyder, +1 781-609-6166