Alkermes Announces Notices of Allowance for U.S. Patents for Four CNS Pipeline Candidates

July 9, 2014

DUBLIN--(BUSINESS WIRE)--Jul. 9, 2014-- Alkermes plc (NASDAQ: ALKS) today announced that the United States Patent and Trademark Office (USPTO) has issued Notices of Allowance for four of Alkermes' pipeline candidates for the treatment of central nervous system (CNS) disorders: aripiprazole lauroxil, ALKS 5461, ALKS 3831 and ALKS 7106. A Notice of Allowance is issued after the USPTO makes a determination that a patent can be granted from an application.

"These patent allowances are a critical component in building a robust intellectual property portfolio for Alkermes' innovative CNS medicines and reflect the significant innovations our scientific teams are making," stated Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. "Aripiprazole lauroxil, ALKS 5461, ALKS 3831 and ALKS 7106 each represent novel therapeutic approaches with potential to address unmet needs in their respective disease areas."

- Aripiprazole lauroxil: The USPTO issued a Notice of Allowance for U.S. Patent Application 13/607,066, entitled "Heterocyclic Compounds for the Treatment of Neurological and Psychological Disorders." The allowed claims will cover methods of treating schizophrenia, mania, bipolar disorder, anxiety or depression by administering a broad class of compounds, including aripiprazole lauroxil, Alkermes' long-acting injectable antipsychotic agent designed to provide patients with once-monthly dosing of a medication that, once in the body, converts to aripiprazole. Alkermes expects this patent to issue within the next few months and expire no earlier than September 2030.
- ALKS 5461: The USPTO issued a Notice of Allowance for U.S. Patent Application 13/715,198, entitled "Compositions of Buprenorphine and a Mu Antagonist." The allowed composition of matter claims will cover ALKS 5461. ALKS 5461 is Alkermes' once-daily, oral investigational medicine with a novel mechanism of action for the adjunctive treatment of major depressive disorder (MDD). Alkermes expects this patent to issue within the next few months and expire no earlier than December 2032.
- ALKS 3831: The USPTO issued a Notice of Allowance for U.S. Patent Application 13/215,718, entitled "Methods for Treating Antipsychotic-Induced Weight Gain" for ALKS 3831, Alkermes' broad-spectrum antipsychotic for the treatment of schizophrenia. The allowed methods of treatment claims will cover the attenuation of weight gain associated with olanzapine in patients with schizophrenia by administering the combination of samidorphan (formerly known as ALKS 33) and olanzapine. Alkermes expects this patent to issue on July 15, 2014 as U.S. Patent No. 8,778,960 and expire no earlier than August 2031.
- ALKS 7106: The USPTO issued a Notice of Allowance for U.S. Patent Application 14/169,305, entitled "4-Hydroxybenzomorphans" for ALKS 7106, Alkermes' novel, small-molecule drug candidate for pain. The allowed composition of matter claims will cover ALKS 7106 and salts thereof. In addition, the Notice of Allowance covers a method of treating pain by administering ALKS 7106. Alkermes expects this patent to issue within the next few months and expire no earlier than November 2025. This Notice of Allowance augments the existing patent portfolio for ALKS 7106 which includes U.S. Patent No. 8,680,112, which covers broad method of treatment claims through 2029.

About Aripiprazole Lauroxil

Aripiprazole lauroxil is an injectable atypical antipsychotic with one-month and two-month formulations in development for the treatment of schizophrenia. Once in the body, aripiprazole lauroxil converts to aripiprazole, which is commercially available under the name ABILIFY®. As a long-acting investigational medication based on Alkermes' proprietary LinkeRx ® technology, aripiprazole lauroxil is designed to have multiple dosing options and to be administered in a ready-to-use, prefilled product format.

About ALKS 5461

ALKS 5461 is a proprietary investigational oral medicine for the treatment of major depressive disorder (MDD). ALKS 5461 is designed to modulate the opioid system in the brain, employing a balanced combination of agonist and antagonist components that act on opioid receptors, and includes a novel opioid modulator, samidorphan, discovered by Alkermes. Samidorphan was formerly referred to as ALKS 33. In October 2013, the U.S. Food and Drug Administration (FDA) granted Fast Track status for ALKS 5461 for the adjunctive treatment of MDD in patients with an inadequate response to standard antidepressant therapies.

About ALKS 3831

ALKS 3831 is a proprietary investigational medicine designed as a broad-spectrum antipsychotic for the treatment of schizophrenia. ALKS 3831 is composed of samidorphan (formerly referred to as ALKS 33), a novel, potent mu-opioid antagonist, in combination with the established antipsychotic drug, olanzapine. ALKS 3831 is designed to attenuate olanzapine-induced metabolic side effects, including weight gain, and to have utility in patients

with schizophrenia whose disease is exacerbated by alcohol use.

About ALKS 7106

ALKS 7106 is a novel, small-molecule drug candidate derived from the company's opioid modulator platform. ALKS 7106 is designed to treat pain with intrinsically low potential for abuse and overdose death, two liabilities associated with other opioid medicines.

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, as amended, including, but not limited to, statements concerning: whether Patent Applications 13/607,066, 13/715,198, 13/215,718 and 14/169,305 will issue; if such Patent Applications are issued, whether the issued patents will adequately protect aripiprazole lauroxil, ALKS 5461, ALKS 3831 and ALKS 7106; the expiration dates and strength of such patents; and the therapeutic value, development plans and commercial potential of aripiprazole lauroxil, ALKS 5461, ALKS 3831 and ALKS 7106. 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 Applications 13/607,066, 13/715,198, 13/215,718 and 14/169,305, if issued, will be challenged by one or more third parties and upheld; whether preclinical and clinical results for ALKS 5461, ALKS 3831 and ALKS 7106 will be predictive of future clinical study results; whether ALKS 5461, ALKS 3831 and ALKS 7106 will be shown to be ineffective or unsafe during clinical studies; decisions by the U.S. Food and Drug Administration (FDA) or foreign regulatory authorities regarding aripiprazole lauroxil, ALKS 5461, ALKS 3831 and ALKS 7106; potential changes in cost, scope and duration of clinical trials of ALKS 5461, ALKS 3831 and ALKS 7106; 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.

Source: Alkermes plc

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