Alkermes Provides Update on FDA Review of ARISTADA™ for the Treatment of Schizophrenia

August 21, 2015

DUBLIN--(BUSINESS WIRE)--Aug. 21, 2015-- Alkermes plc (NASDAQ: ALKS) today announced that the U.S. Food and Drug Administration (FDA) has advised Alkermes that it will not be able to complete its review of the New Drug Application (NDA) for ARISTADA™ (aripiprazole lauroxil) for the treatment of schizophrenia by the Prescription Drug User Fee Act (PDUFA) action date of Aug. 22, 2015. The FDA indicated that this delay was expected to be brief, measured in terms of weeks, but could not confirm specific timing. The FDA also indicated that no additional data or information is required from Alkermes at this time.

"We are confident in the ARISTADA program and our NDA submission, and we will work closely with the FDA as they complete their review," said Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. "We look forward to bringing ARISTADA to market as a potential new treatment option to help address the significant unmet medical needs of patients living with schizophrenia."

About ARISTADA™

ARISTADA is an injectable atypical antipsychotic with one-month and extended-duration formulations in development for the treatment of schizophrenia. Once in the body, ARISTADA converts to aripiprazole. As a long-acting investigational medication based on Alkermes' proprietary LinkeRx® technology, ARISTADA is designed to have multiple dosing options and to be administered in a ready-to-use, pre-filled product format.

About Alkermes

Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases. The company has a diversified commercial product portfolio and a substantial clinical pipeline of product candidates for chronic diseases that include schizophrenia, depression, addiction and multiple sclerosis. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts; a research and manufacturing facility in Athlone, Ireland; and a manufacturing facility in 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 timing and outcome of FDA regulatory review of the NDA submission for ARISTADA for the treatment of schizophrenia and its potential therapeutic value, and the commercial potential of ARISTADA. 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 expressed or implied in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: whether ARISTADA will be approved by regulatory authorities for the treatment of schizophrenia; if approved, whether ARISTADA will be commercialized successfully; whether ARISTADA could be shown ineffective or unsafe; and those risks described in the Alkermes plc Quarterly Report on Form 10-Q for the period ended June 30, 2015 and Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2014, and in any 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.

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