



## **Alkermes Announces Data on ALKS 5461 and ALKS 3831 to Be Presented at 53rd Annual NCDEU Meeting**

May 22, 2013

DUBLIN--(BUSINESS WIRE)--May. 22, 2013-- [Alkermes plc](#) (NASDAQ: ALKS) today announced that clinical data on ALKS 5461, a novel drug candidate for major depressive disorder (MDD) in patients who have an inadequate response to standard therapies for clinical depression, and ALKS 3831, a novel antipsychotic candidate for the treatment of schizophrenia, are scheduled to be presented at the 53<sup>rd</sup> Annual New Clinical Drug Evaluation Unit (NCDEU) Meeting in Hollywood, Fla., May 28-31, 2013.

Key presentations include:

### Tuesday, May 28, 2013, at 3:45 p.m. EDT

Oral presentation: "Early Development of ALKS 3831: A Novel Drug Candidate for the Treatment of Schizophrenia" will be given by Bernard Silverman, M.D., Vice President, Clinical Development, Alkermes, Inc., during the session titled "Pharma Pipelines."

### Wednesday, May 29, 2013, at 11:15 a.m. EDT

Poster 84: "Early Development of ALKS 3831: A Novel Drug Candidate for the Treatment of Schizophrenia" will be presented by Mark Todtenkopf, Ph.D., Senior Scientist, Alkermes, Inc.

### Thursday, May 30, 2013, at 11:45 a.m. EDT

Poster 79: "A Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Safety and Efficacy of ALKS 3831 in the Prevention of Olanzapine-Induced Weight Gain in Healthy Male Volunteers" will be presented by John M. Kane, M.D., Chairman of Psychiatry, The Zucker Hillside Hospital, and Vice President, Behavioral Health Services, North Shore-LIJ Health System.

### Friday, May 31, 2013, at 8:30 a.m. EDT

Oral presentation: "Opioid Modulation: A Novel Mechanism for the Treatment of Depression: Results of the ALKS 5461 Phase 2 Study" will be given by Maurizio Fava, M.D., Director of the Depression Clinical and Research Program at Massachusetts General Hospital and Slater Family Professor of Psychiatry at Harvard Medical School, during the session titled "New Therapeutic Opportunities for the Treatment of Depression."

A full list of all Alkermes abstracts being presented at the NCDEU meeting is available at <http://www.ncdeumeeting.org/>.

### **About ALKS 5461**

ALKS 5461 is a proprietary investigational medicine with a novel mechanism for the treatment of major depressive disorder (MDD). The mechanism of action for ALKS 5461 in the treatment of depressive symptoms is based on modulation of the opioid system in the brain, employing a balanced combination of agonism and antagonism of opioid receptors. ALKS 5461 consists of buprenorphine, a partial agonist, and ALKS 33, a potent mu-opioid antagonist, and is designed to be a once-daily, non-addictive medicine.

### **About ALKS 3831**

ALKS 3831 is a proprietary investigational medicine designed as a broad spectrum treatment for schizophrenia. ALKS 3831 is comprised of ALKS 33, a novel opioid modulator that acts as a 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 offer the therapeutic benefits of olanzapine to a wider range of patients with schizophrenia. ALKS 3831 will also be studied to evaluate its utility in patients with schizophrenia and comorbid substance abuse.

### **About New Clinical Drug Evaluation Unit (NCDEU) Meeting**

NCDEU is a scientific meeting that focuses on the latest developments in psychopharmacologic clinical research and related methodology. The meeting brings together over 1,200 academic and industry investigators, research pharmacists, nurses, social workers, psychologists and other clinicians. NCDEU focuses on timely issues in psychiatric clinical research and includes presentations and information from the American Society of Clinical Psychopharmacology (ASCP) and its federal partners, National Institute of Mental Health (NIMH), National Institute on Drug Abuse (NIDA), National Institute on Alcohol Abuse and Alcoholism (NIAAA), the Food and Drug Administration (FDA) and the European Medicines Agency (EMA). For more information, visit [www.ncdeumeeting.org](http://www.ncdeumeeting.org).

### **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](http://www.alkermes.com).

### **Note Regarding Forward-Looking Statements**

Certain statements set forth above may 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 of the company's products. These statements are neither promises nor guarantees and are subject to a variety of risks and uncertainties, many of which are beyond the company's control, which could cause actual results to differ materially from those contemplated in these forward-looking statements.

These risks and uncertainties include, among others, whether the results of the company's clinical development activities will be predictive of real-world results or of results in subsequent clinical trials; and those risks described in the company's Annual Report on Form 10-K for the year ended March 31, 2012, and in other filings made by the company with the Securities and Exchange Commission ("SEC") and which are available on the SEC's website at [www.sec.gov](http://www.sec.gov). Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date they are made. 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.



Source: Alkermes plc

Alkermes Contacts:

For Investors:

Rebecca Peterson, +1 781-609-6378

or

For Media:

Jennifer Snyder, +1 781-609-6166