Alkermes Announces Initiation of Phase 3 Study of ALKS 3831 in Young Adult Patients

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— Designed to Assess Weight Gain Profile of Olanzapine Compared to ALKS 3831 in Patients Diagnosed With Schizophrenia, Schizophreniform or Bipolar I Disorder Who Are Early in Their Illness —

— Supportive Study in the ENLIGHTEN Clinical Development Program for ALKS 3831, an Investigational, Novel, Once-Daily, Oral Atypical Antipsychotic for the Treatment of Schizophrenia —

DUBLIN--(BUSINESS WIRE)--Jun. 8, 2017-- Alkermes plc (NASDAQ: ALKS) today announced the initiation of ENLIGHTEN-Early, a supportive study in the ENLIGHTEN clinical development program for ALKS 3831, an investigational, novel, once-daily, oral atypical antipsychotic drug candidate designed to be a broad-spectrum treatment for schizophrenia. ENLIGHTEN-Early will evaluate the weight gain profile of ALKS 3831 over a 12-week treatment period compared to olanzapine, an established atypical antipsychotic agent with proven efficacy but also metabolic liabilities including significant weight gain, in young adult patients with schizophrenia, schizophreniform or bipolar I disorder who are early in their illness. ALKS 3831 is designed to provide the strong antipsychotic efficacy of olanzapine and a differentiated safety profile with favorable weight and metabolic properties.

“First-episode schizophrenia is a critical phase of the disease where optimal antipsychotic efficacy is crucial to reduce the rate of relapse and potentially improve long-term outcomes. Olanzapine is well-known to be a highly efficacious atypical antipsychotic treatment but is no longer recommended first-line for early-in-illness patients due to its metabolic liabilities,[1]” said Elliot Ehrich, M.D., Executive Vice President, Research and Development of Alkermes. “Designed to provide the powerful antipsychotic efficacy of olanzapine and a safety profile that addresses the substantial negative health impact of weight gain and metabolic consequences associated with olanzapine, ALKS 3831 represents a compelling potential new treatment option for this vulnerable patient population.”

“With a novel pharmacologic approach designed with the real-world needs of patients in mind, we believe that ALKS 3831 has the potential to have a meaningful impact on the treatment of schizophrenia, particularly in this young adult population that has demonstrated susceptibility to antipsychotic weight gain and who could benefit from a highly effective medicine early in the course of their disease,” stated Richard Pops, Chief Executive Officer of Alkermes. “We look forward to continuing to progress ALKS 3831 through clinical development, with expected data readouts from the exploratory metabolic study and the pivotal antipsychotic efficacy study mid-year.”

ENLIGHTEN-Early is a 12-week, multicenter, randomized, double-blind, phase 3 study comparing the weight gain profile of ALKS 3831 to olanzapine in approximately 250 young adults with schizophrenia, schizophreniform disorder or bipolar I disorder who are early in their illness. Safety and tolerability will also be evaluated in the study. All participants in the double-blind portion of the study will be eligible to continue in an open-label safety study of ALKS 3831 for an additional 24 months. The objective of the extension phase of the study is to assess the long-term safety, tolerability and durability of effect of once-daily, oral ALKS 3831.

About the ENLIGHTEN Clinical Development Program

The ENLIGHTEN clinical development program for ALKS 3831 is comprised of two key studies: a study evaluating the antipsychotic efficacy of ALKS 3831 compared to placebo over four weeks and a study assessing weight gain with ALKS 3831 compared to olanzapine in patients with schizophrenia over six months. The program also includes supportive studies to evaluate the pharmacokinetic and metabolic profile of ALKS 3831, the effect on body weight of ALKS 3831 in young adult patients early in their illness, and long-term safety.

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, a novel, new molecular entity co-formulated with the established antipsychotic agent, olanzapine, in a single bilayer tablet.

Weight gain is a common and clinically relevant metabolic side effect of atypical antipsychotic medications, and olanzapine, commercially available as ZYPREXA®, has one of the highest incidences and greatest amounts of weight gain among the widely prescribed products in this class of drugs.[2] ALKS 3831 is designed to provide the strong antipsychotic efficacy of olanzapine and a differentiated safety profile with favorable weight and metabolic properties.

About Schizophrenia

Schizophrenia is a chronic, severe and disabling brain disorder. The disease is marked by positive symptoms (hallucinations and delusions) and negative symptoms (depression, blunted emotions and social withdrawal), as well as by disorganized thinking. An estimated 2.4 million American adults have schizophrenia,[3] with men and women affected equally.

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 therapeutic value, development plans and commercial potential of

ALKS 3831; and the adequacy of the ENLIGHTEN pivotal program to serve as the basis for an NDA for ALKS 3831. 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 expressed or implied in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: whether preclinical and clinical results for ALKS 3831 will be predictive of future clinical study results; whether the ongoing phase 1 metabolic study and the ENLIGHTEN pivotal trials for ALKS 3831 will be completed on time or at all; whether the results of the phase 1 metabolic study will show favorable metabolic effects of ALKS 3831 compared to olanzapine; potential changes in cost, scope and duration of the ALKS 3831 clinical development program; whether ALKS 3831 could be shown ineffective or unsafe during clinical studies; and those risks and uncertainties described under the heading “Risk Factors” in the company’s Annual Report on Form 10-K for the year ended Dec. 31, 2016 and Quarterly Report on Form 10-Q for the quarter ended Mar. 31, 2017 and in 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. 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 or revising any forward-looking information contained in this press release.

ZYPREXA® is a registered trademark of Eli Lilly & Company.

[1]The 2009 Schizophrenia PORT Psychopharmacological Treatment Recommendations and Summary Statements. *Schizophrenia Bulletin*. 2010, Vol. 36 No. 1 pp. 71–93.

[2]Komossa, K. et al. Olanzapine versus other atypical antipsychotics for schizophrenia. *Cochrane Database of Systematic Reviews*. 2010, Issue 3. Art. No.: CD006654.

[3]National Institutes of Health. *Schizophrenia*. Accessed on June 7, 2017 from http://report.nih.gov/NIHfactsheets/ViewFactSheet.aspx?csid=67&key=S#S.

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