Alkermes Announces Completion of Patient Enrollment in Pivotal Antipsychotic Efficacy Study of ALKS 3831 for Schizophrenia

May 1, 2017

— Topline Results From ENLIGHTEN-1 Study Expected Mid-2017 —

DUBLIN--(BUSINESS WIRE)--May 1, 2017-- Alkermes plc (NASDAQ: ALKS) today announced completion of patient enrollment in ENLIGHTEN-1, the first of two key phase 3 studies in the ENLIGHTEN clinical development program for ALKS 3831, an investigational, novel, once-daily, oral atypical antipsychotic drug candidate for the treatment of schizophrenia. The multinational, randomized, double-blind phase 3 study is designed to evaluate the antipsychotic efficacy of ALKS 3831 compared to placebo over four weeks in patients experiencing an acute exacerbation of schizophrenia. The study also includes a comparator arm of olanzapine, an established atypical antipsychotic agent with proven efficacy but also metabolic liabilities, including significant weight gain. Topline results from the study are expected in mid-2017. ALKS 3831 is designed to provide the strong antipsychotic efficacy of olanzapine with favorable weight and metabolic properties.

“There is a clear and compelling clinical rationale for developing an antipsychotic with the powerful efficacy of olanzapine while addressing the significant weight gain associated with its use,” said Elliot Ehrich, M.D., Chief Medical Officer of Alkermes. “The completion of enrollment of this carefully conducted, multinational study represents an important milestone in the development program for ALKS 3831, as it moves us one step closer to providing this potential, important new treatment option to patients suffering from schizophrenia. We look forward to progressing ALKS 3831 through development and reporting the results of the ENLIGHTEN-1 study in mid-2017.”

ENLIGHTEN-2, the second key study from the ENLIGHTEN development program for ALKS 3831, is ongoing and enrolling patients with data expected mid-2018. The study is designed to evaluate the weight gain profile of ALKS 3831 in patients with schizophrenia over a six-month treatment period compared to olanzapine. The clinical data from the ENLIGHTEN-1 and ENLIGHTEN-2 studies, if successful, will form the basis of a New Drug Application (NDA) to be submitted to the U.S. Food and Drug Administration (FDA) for ALKS 3831 for the treatment of schizophrenia.

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, as well as long-term safety.

Further information about the ENLIGHTEN studies can be found at www.clinicaltrials.gov.

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.[1] 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,[2] 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 timing of receipt and reporting of the ENLIGHTEN-1 and ENLIGHTEN-2 study results; the therapeutic value, development plans and commercial potential of ALKS 3831; and the adequacy of the ENLIGHTEN clinical development 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 ENLIGHTEN key studies for ALKS 3831 will be completed on time or at all; 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]Komossa, K. et al. Olanzapine versus other atypical antipsychotics for schizophrenia. *Cochrane Database of Systematic Reviews*. 2010, Issue 3. Art. No.: CD006654.

[2]National Institutes of Health. *Schizophrenia*. Accessed on April 28, 2017 from http://report.nih.gov/NIHfactsheets/ViewFactSheet.aspx?csid=67&key=S#S.

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