Alkermes Completes Patient Enrollment in Pivotal Weight Study of ALKS 3831 for Schizophrenia

April 26, 2018

-- Topline Results From ENLIGHTEN-2 Study Expected in Q4 2018 --

DUBLIN, April 26, 2018 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced completion of patient enrollment in ENLIGHTEN-2, the second 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 multicenter, randomized, double-blind phase 3 study will evaluate the weight gain profile of ALKS 3831 compared to olanzapine, an established atypical antipsychotic agent with proven efficacy but also metabolic liabilities, in patients with stable schizophrenia over a six-month treatment period. Topline results are expected in the fourth quarter of 2018.

"Designed to harness the well-established antipsychotic efficacy of olanzapine while mitigating its significant weight and metabolic liabilities, ALKS 3831 represents a promising potential new treatment option for patients suffering from schizophrenia," said Craig Hopkinson, M.D., Chief Medical Officer and Senior Vice President of Medicines Development and Medical Affairs at Alkermes. "ENLIGHTEN-2 is designed to confirm and build upon the favorable weight profile observed in the previously reported randomized, olanzapine-controlled 300-patient phase 2 study. Completion of patient enrollment in the ENLIGHTEN-2 weight study marks a significant milestone in the development of this important potential new medicine, and we look forward to reporting results later this year."

Clinical data from ENLIGHTEN-2, if successful, and positive data from the previously reported ENLIGHTEN-1 study will form the basis of a New Drug Application (NDA) that we plan to submit to the U.S. Food and Drug Administration (FDA) for ALKS 3831 for the treatment of schizophrenia.

Positive topline data from ENLIGHTEN-1, the first key phase 3 study from the ENLIGHTEN development program, were reported in June 2017. This study evaluated the antipsychotic efficacy, safety and tolerability of ALKS 3831 compared to placebo over four weeks in 403 patients experiencing an acute exacerbation of schizophrenia. ENLIGHTEN-1 met its prespecified primary endpoint, with ALKS 3831 demonstrating statistically significant reductions from baseline in Positive and Negative Syndrome Scale (PANSS) scores compared to placebo ($p<0.001$). Data from the study also showed that the olanzapine comparator arm achieved similar improvements from baseline PANSS scores compared to placebo ($p=0.004$). The most common adverse events for both the ALKS 3831 and olanzapine treatment groups were weight gain, somnolence and dry mouth.

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, and long-term safety.

About ALKS 3831

ALKS 3831 is an investigational, novel, once-daily, oral atypical antipsychotic drug candidate 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-2 study results; the therapeutic value, development and regulatory 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. 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 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 ENLIGHTEN 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, 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 hereof. Except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking statements 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 Apr. 25, 2018 from http://report.nih.gov/NIHfactsheets/ViewFactSheet.aspx?csid=67&key=S#S.

Alkermes Contacts:

For Investors:
Eva Stroynowski +1 781 609 6823
Sandy Coombs +1 781 609 6377

For Media:
Sherry Feldberg +1 781 609 6276

View original content with multimedia:http://www.prnewswire.com/news-releases/alkermes-completes-patient-enrollment-in-pivotal-weight-study-of-alks-3831-for-schizophrenia-300636663.html

SOURCE Alkermes, Inc.