Alkermes Submits New Drug Application to U.S. Food and Drug Administration for ALKS 3831 for Treatment of Schizophrenia and Bipolar I Disorder

November 19, 2019

DUBLIN, Nov. 19, 2019 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval of ALKS 3831 (olanzapine/samidorphan) for the treatment of schizophrenia and for the treatment of bipolar I disorder. ALKS 3831 is an investigational, novel, once-daily, oral atypical antipsychotic drug candidate designed to provide the efficacy of olanzapine while mitigating olanzapine-associated weight gain. The ALKS 3831 NDA includes data from the ENLIGHTEN clinical development program in patients with schizophrenia, as well as pharmacokinetic (PK) bridging data comparing ALKS 3831 and ZYPREXA® (olanzapine).

"Antipsychotic medications are an important part of the treatment paradigm for both schizophrenia and bipolar I disorder, yet there remains a persistent unmet need for new treatments," said Craig Hopkinson, M.D., Chief Medical Officer and Senior Vice President of Medicines Development and Medical Affairs at Alkermes. "The ALKS 3831 NDA submission exemplifies Alkermes' commitment to developing new therapies to treat serious and prevalent central nervous system disorders and our longstanding dedication to people living with mental health disorders. We are pleased to have submitted an application seeking approval of ALKS 3831 for both of these indications, and we look forward to working with the agency to bring this potential new medication to patients and healthcare professionals."

The ALKS 3831 NDA includes data to support an indication for the treatment of schizophrenia, and an indication for the treatment of manic or mixed episodes associated with bipolar I disorder as a monotherapy or adjunct to lithium or valproate and for maintenance treatment of bipolar I disorder. Alkermes is seeking approval of fixed dosage strengths of ALKS 3831 composed of 10 mg of samidorphan co-formulated with 5 mg, 10 mg, 15 mg or 20 mg of olanzapine.

About the ENLIGHTEN Clinical Development Program
The ENLIGHTEN clinical development program for ALKS 3831 includes two key studies in patients with schizophrenia: the ENLIGHTEN-1 study, which evaluated the antipsychotic efficacy of ALKS 3831 compared to placebo over four weeks, and the ENLIGHTEN-2 study, which assessed weight gain with ALKS 3831 compared to olanzapine over six months. The program also includes supportive studies to evaluate the pharmacokinetic and metabolic profile and long-term safety of ALKS 3831, and pharmacokinetic bridging studies comparing ALKS 3831 and ZYPREXA.

About ALKS 3831
ALKS 3831 is an investigational, novel, once-daily, oral atypical antipsychotic drug candidate for the treatment of schizophrenia and bipolar I disorder. ALKS 3831 is composed of samidorphan, a novel, new molecular entity, co-formulated with the established antipsychotic agent, olanzapine, in a single bilayer tablet.

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,[1] with men and women affected equally.

About Bipolar I Disorder
Bipolar disorder is a brain disorder that causes shifts in a person's mood, energy and ability to function. Patients with this brain disorder may experience debilitating mood shifts from extreme highs (mania) to extreme lows (depression). Bipolar I disorder is characterized by the occurrence of at least one manic episode, with or without the occurrence of a major depressive episode, and affects approximately one percent of the adult population in the United States in any given year.[2]

About Alkermes plc
Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases and oncology. The company has a diversified commercial product portfolio and a substantial clinical pipeline of product candidates for diseases that include schizophrenia, depression, addiction, multiple sclerosis and cancer. 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 potential therapeutic and commercial value of ALKS 3831 for the treatment of schizophrenia and the treatment of bipolar I disorder; and expectations regarding the NDA for ALKS 3831, including the adequacy of the data contained in the NDA to serve as the basis for approval of ALKS 3831 for the treatment of schizophrenia and the treatment of bipolar I disorder and approval of the proposed fixed dosage strengths 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 the NDA for ALKS 3831 will be accepted for review by the FDA; if accepted, whether the preclinical and clinical results of the ALKS 3831 studies and the PK bridging data will meet the regulatory requirements for approval by the FDA for the proposed schizophrenia and bipolar I disorder indications; potential changes in the cost, scope and duration of the ALKS 3831 development and regulatory program; whether ALKS 3831 could be shown ineffective or unsafe during clinical studies; whether the NDA for ALKS 3831 will be approved by the FDA; if approved, whether ALKS 3831 will be commercialized successfully; 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, 2018 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] National Institutes of Health. *Schizophrenia.* Accessed on Nov. 18, 2019 from https://archives.nih.gov/asites/report/09-09-2019/report.nih.gov/nihfactsheets/Pdfs/Schizophrenia(NIMH).pdf.

[2] Merikangas et al. Lifetime and 12-Month Prevalence of Bipolar Spectrum Disorder in the National Comorbidity Survey Replication. *Arch Gen Psychiatry*, 2007 May; 64(5): 543–552. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1931566/

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