# Alkermes Announces U.S. Food and Drug Administration Acceptance of ALKS 3831 New Drug Application for Treatment of Schizophrenia and Bipolar I Disorder

January 28, 2020

DUBLIN, Jan. 28, 2020 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the company's New Drug Application (NDA) 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 NDA has been assigned a Prescription Drug User Fee Act (PDUFA) target action date of Nov. 15, 2020.

"The acceptance of the NDA for ALKS 3831 marks an important milestone toward our goal of offering a new treatment option to people living with schizophrenia or bipolar I disorder. The ALKS 3831 development program builds on Alkermes' commitment to developing new therapeutic options that seek to address unmet needs of patients in large therapeutic areas," said Craig Hopkinson, M.D., Chief Medical Officer at Alkermes. "We believe ALKS 3831 has the potential to be a meaningful new offering for patients with these serious and complex mental health disorders, and we look forward to engaging with the FDA throughout the NDA review process."

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), 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 serious brain disorder marked by positive symptoms (hallucinations and delusions, disorganized speech and thoughts, and agitated or repeated movements) and negative symptoms (depression, blunted emotions and social withdrawal).[1] An estimated 2.4 million American adults have schizophrenia,[2] 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.[3]

**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 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 FDA's PDUFA target action date for the NDA, 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 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]American Psychiatric Association. Schizophrenia Spectrum and Other Psychiatric Disorders. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed. Washington, DC: American Psychiatric Publishing; 2013.

[2] National Institutes of Health. *Schizophrenia.* Accessed on Jan. 27, 2020 from https://archives.nih.gov/asites/report/09-09-2019/report.nih.gov/nihfactsheets/Pdfs/Schizophrenia(NIMH).pdf.

[3] 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/


Alkermes Contacts:

| | | |
|---|---|---|
| For Investors: | Sandy Coombs | +1 781 609 6377 |
| For Media: | Gretchen Murphy | +1 781 609 6419 |


View original content to download multimedia:http://www.prnewswire.com/news-releases/alkermes-announces-us-food-and-drug-administration-acceptance-of-alks-3831-new-drug-application-for-treatment-of-schizophrenia-and-bipolar-i-disorder-300994014.html

SOURCE Alkermes plc