FDA Accepts Alkermes' Resubmission of New Drug Application for ALKS 3831

December 29, 2020

- FDA Sets PDUFA Target Action Date of June 1, 2021 -

DUBLIN, Dec. 29, 2020 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced that the U.S. Food and Drug Administration (FDA) has acknowledged receipt of the company's New Drug Application (NDA) resubmission for ALKS 3831 (olanzapine/samidorphan) for the treatment of adults with schizophrenia and adults with bipolar I disorder, and has assigned the application a new Prescription Drug User Fee Act (PDUFA) target action date of June 1, 2021.

The FDA classified the resubmission as a complete, Class 2 response to the Complete Response Letter (CRL) issued in November 2020, following a remote review of records requested under Section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (the "FDCA") relating to the manufacture of ALKS 3831 at the company's Wilmington, OH facility. Subsequent to Alkermes' resubmission of the NDA, the FDA issued a new request for records under Section 704(a)(4) of the FDCA to supplement the information previously provided by the company. Neither the CRL nor this subsequent records request identified or raised any concerns about the clinical or non-clinical data in the NDA and the FDA has not asked Alkermes to complete any new clinical trials to support approval of the application.

Alkermes will continue to work closely with the FDA as it completes its review of the ALKS 3831 NDA and remains committed to making ALKS 3831 available to patients as quickly as possible.

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. Individuals 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 ALKS 3831 (olanzapine/samidorphan)

ALKS 3831 is an investigational, novel, once-daily, oral atypical antipsychotic drug candidate for the treatment of adults with schizophrenia and for the treatment of adults with 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 Alkermes plc

Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines in the fields of neuroscience and oncology. The company has a portfolio of proprietary commercial products focused on addiction and schizophrenia, and a pipeline of product candidates in development for schizophrenia, bipolar I disorder, neurodegenerative disorders 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 adults with schizophrenia and the treatment of adults with bipolar I disorder; the company's expectations regarding next steps for the NDA for ALKS 3831, including the FDA's PDUFA target action date for the NDA and the company's plans to work with the FDA as it completes its review of the NDA; and the company's commitment to making ALKS 3831 available to patients as quickly as possible. 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 data from the company's manufacturing processes may be interpreted by the FDA in different ways than the company interprets it; potential changes in the cost, scope and duration of the ALKS 3831 development and regulatory program following receipt of the FDA's CRL and subsequent records request; whether the FDA will approve the NDA for ALKS 3831 in a timely manner or at all; if approved, whether the FDA will impose conditions on the marketing of ALKS 3831, such as a risk evaluation and mitigation strategy; whether future clinical trials for ALKS 3831, if any, will be completed on time or at all; unanticipated impacts of the COVID-19 pandemic on the operations of the company and on the operations of the regulatory agencies involved in the review and potential approval of ALKS 3831; 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, 2019, the company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 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.

[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 Dec. 28, 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/

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