



Alkermes Announces Posting of Briefing Documents for FDA Advisory Committee Meeting on ALKS 3831

October 7, 2020

DUBLIN, Oct. 7, 2020 /PRNewswire/ -- [Alkermes plc](#) (Nasdaq: ALKS) today announced that the U.S. Food and Drug Administration (FDA) has posted on its website briefing documents for the Oct. 9, 2020 joint meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee to review the company's New Drug Application (NDA) for 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.

The joint advisory committee meeting, which is being held virtually, is scheduled to begin at 10:00 a.m. ET on Friday, Oct. 9, 2020. Both Alkermes and the FDA have prepared pre-recorded presentations, which will be viewed by the joint advisory committee prior to the meeting and will not be replayed during the meeting. The briefing materials, including the pre-recorded presentation slides and transcripts, are now posted to the FDA website and can be accessed here: <https://www.fda.gov/advisory-committees/advisory-committee-calendar/updated-time-agenda-and-meeting-materials-october-9-2020-joint-meeting-psychopharmacologic-drugs>.

The FDA has also established a docket for public comment on this meeting. The docket number is FDA-2020-N-1767 and can be accessed here: <https://beta.regulations.gov/document/FDA-2020-N-1767-0001/comment>.

The Prescription Drug User Fee Act (PDUFA) target action date for the ALKS 3831 NDA is Nov. 15, 2020.

About ALKS 3831

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 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 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; and the company's expectations regarding the FDA's PDUFA target action date for the ALKS 3831 NDA. 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: unanticipated impacts of the COVID-19 pandemic on the operations of the company, the FDA or other regulatory agencies involved in the review and potential approval of ALKS 3831; 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; data from the ALKS 3831 clinical development program may be interpreted by the FDA in different ways than the company interprets it; the FDA may not agree with the company's regulatory approval strategies or components of its NDA filing for ALKS 3831, including the company's clinical trial designs, conduct and methodologies, manufacturing processes and facilities; the FDA's determination as to the clinical meaningfulness of the ALKS 3831 weight data, including the effects of ALKS 3831 on metabolic parameters; the FDA's views of the impact on the risk/benefit profile of ALKS 3831 of potential interactions of ALKS 3831 with opioids in the intended patient populations; and the adequacy of the preclinical and clinical results of the ALKS 3831 studies and the PK bridging data and other information included in the ALKS 3831 NDA to meet the FDA's requirements for approval for the proposed schizophrenia and bipolar I disorder indications; 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.

¹American 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 Oct. 6, 2020 from [https://archives.nih.gov/sites/report/09-09-2019/report.nih.gov/nihfactsheets/Pdfs/Schizophrenia\(NIMH\).pdf](https://archives.nih.gov/sites/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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