



Virtual FDA Advisory Committee Meeting to Review New Drug Application for ALKS 3831 for Treatment of Schizophrenia and Bipolar I Disorder Tentatively Scheduled for Oct. 9, 2020

August 21, 2020

DUBLIN, Aug. 21, 2020 /PRNewswire/ -- [Alkermes plc](#) (Nasdaq: ALKS) today announced that a joint meeting of the U.S. Food and Drug Administration's (FDA) Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee to review the New Drug Application (NDA) for ALKS 3831 (olanzapine/samidorphan) has been tentatively scheduled for Oct. 9, 2020. 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 Prescription Drug User Fee Act (PDUFA) action date for the ALKS 3831 NDA is Nov. 15, 2020.

It is expected that the advisory committee panel will review the efficacy, safety, and benefit-risk profile of ALKS 3831 for the proposed indications of schizophrenia and bipolar I disorder. As announced previously, the company expects the advisory panel to focus on the clinical meaningfulness of ALKS 3831's attenuation of olanzapine-associated weight gain, including the magnitude of weight effect and the impact of ALKS 3831 on laboratory-based metabolic parameters. Since that time, the company has learned that the panel will also discuss certain potential clinical risks related to the interaction of ALKS 3831, which includes samidorphan, an opioid receptor antagonist, and opioids in the intended patient populations.

"We look forward to engaging with members of the joint advisory committee panel in a robust discussion of the clinical evidence for ALKS 3831," said Craig Hopkinson, M.D., Chief Medical Officer and Executive Vice President of Research & Development at Alkermes. "For adults living with schizophrenia or bipolar I disorder, populations already prone to shortened life expectancy and cardiovascular comorbidities, the significant weight gain often associated with olanzapine can represent a major clinical liability. Patients and healthcare providers may benefit from additional treatment options that help manage disease symptoms while mitigating weight gain. We are committed to bringing this potential new medicine to adults living with schizophrenia or bipolar I disorder."

The NDA submission and clinical development program for ALKS 3831 are supported by data from 27 clinical studies, including 18 studies evaluating ALKS 3831 and nine studies evaluating samidorphan alone. Throughout the clinical development program, ALKS 3831 showed evidence of antipsychotic efficacy, safety and tolerability, including attenuation of olanzapine-associated weight gain.

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. 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 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 current expectations regarding the timing and substance of the FDA's joint advisory committee meeting to review the ALKS 3831 NDA, including the joint advisory committees' consideration of the clinical meaningfulness of ALKS 3831's attenuation of olanzapine-associated weight gain, including the magnitude of weight effect and the impact of ALKS 3831 on laboratory-based metabolic parameters, and potential clinical risks related to the interaction of ALKS 3831 with opioids in the intended patient populations; and the company's additional expectations regarding the ALKS 3831 NDA, including the FDA's PDUFA target action date for the NDA and the adequacy of the data contained in the NDA to serve as the basis for approval of ALKS 3831 for the treatment of adults with schizophrenia and the treatment of adults with bipolar I disorder. 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 company's operations,

plans and prospects and on the operations of the 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 joint advisory committees' or FDA's views of impact on the risk/benefit profile of ALKS 3831 of the interaction 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; 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, 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 Aug. 20, 2020 from [https://archives.nih.gov/asites/report/09-09-2019/report.nih.gov/nihfactsheets/Pdfs/Schizophrenia\(NIMH\).pdf](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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