FDA Advisory Committee Votes in Support of ALKS 3831 for the Treatment of Schizophrenia and Bipolar I Disorder

October 9, 2020

DUBLIN, Oct. 9, 2020 /PRNewswire/ -- Alkermes plc (Nasdaq: ALKS) today announced positive voting outcomes from the joint meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee, appointed by the U.S. Food and Drug Administration (FDA). The committees met to discuss ALKS 3831 (olanzapine/samidorphan), 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 committees jointly voted that samidorphan meaningfully mitigates olanzapine-associated weight gain (16 yes, 1 no) and that the safety profile of ALKS 3831 has been adequately characterized (13 yes, 3 no, 1 abstention).

"The favorable outcome of today's joint advisory committee meeting represents an important milestone for the patients, clinicians and families who may benefit from new medicines for the treatment of schizophrenia and bipolar I disorder. The personal testimonies shared during today's open public hearing reinforced the need for treatment approaches that consider patients' overall mental and physical health," said Craig Hopkinson, M.D., Chief Medical Officer and Executive Vice President of Research & Development at Alkermes. "The ALKS 3831 development program is part of our ongoing commitment to develop new therapeutic options for adults living with serious mental illness. Today's outcome marks an important step for this program and we look forward to working with the FDA as it completes its review of the ALKS 3831 New Drug Application."

In addition, the committees jointly voted that labeling is sufficient to mitigate the risks related to the opioid antagonist action of samidorphan (11 yes, 6 no). Alkermes' proposed labeling contraindicates the use of ALKS 3831 in patients who are opioid-dependent or chronically using opioids, and the company has proposed a comprehensive education plan, which includes dissemination of information to potential prescribers and pharmacists.

The joint advisory committee's recommendations, while not binding, will be considered by the FDA in its review of the ALKS 3831 New Drug Application (NDA). The Prescription Drug User Fee Act (PDUFA) target action date for the ALKS 3831 NDA is Nov. 15, 2020.

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.

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 review of the ALKS 3831 NDA, including the company's interactions with the FDA, 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: data from the ALKS 3831 clinical development program may be interpreted by the FDA in different ways than the company or the advisory committee interprets it; the FDA may not agree with the company's regulatory approval strategy or components of the ALKS 3831 NDA , 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; the FDA's view of the adequacy and sufficiency 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; 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; 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 Oct. 7, 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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