



Journal of Clinical Psychiatry Publishes Data from Alkermes' Phase 3 ENLIGHTEN-1 Efficacy Study of ALKS 3831 in Patients With Schizophrenia

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DUBLIN, March 4, 2020 /PRNewswire/ -- [Alkermes plc](#) (Nasdaq: ALKS) today announced the publication of results from the phase 3 ENLIGHTEN-1 clinical trial of ALKS 3831 (olanzapine/samidorphan) in the peer-reviewed publication, [Journal of Clinical Psychiatry](#). ENLIGHTEN-1 was a four-week study evaluating the efficacy, safety and tolerability of ALKS 3831 compared to placebo in 403 patients experiencing an acute exacerbation of schizophrenia. Positive topline data from the ENLIGHTEN-1 study were first reported in June 2017. A New Drug Application (NDA) for ALKS 3831 is currently under U.S. Food and Drug Administration (FDA) review, with a Prescription Drug User Fee Act (PDUFA) target action date of Nov. 15, 2020.

"Despite the availability of many therapeutic options for schizophrenia and bipolar I disorder, there remains a persistent unmet need for new and effective antipsychotic medicines," said Jelena Kunovac, M.D., M.S., Founder and President of Altea Research, and publication co-author. "If approved, ALKS 3831 has the potential to be a compelling addition to the treatment landscape for these serious and chronic diseases."

"The ALKS 3831 development program is an example of Alkermes' commitment to developing new treatment options that may help people living with serious mental illness," said Craig Hopkinson, M.D., Executive Vice President, Research & Development and Chief Medical Officer at Alkermes. "We look forward to continuing to work with the FDA as it reviews the NDA for ALKS 3831, with the goal of helping to bring this potential new medicine to patients and their families."

ENLIGHTEN-1 is one of two key studies included in the ALKS 3831 ENLIGHTEN clinical development program. ENLIGHTEN-2, the second phase 3 study, assessed weight gain with ALKS 3831 compared to olanzapine over six months. Positive topline data from the ENLIGHTEN-2 study were reported in November 2018.

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 unusual 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; timing and expectations regarding interactions with the FDA for ALKS 3831, 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: whether the preclinical and clinical results of the ALKS 3831 studies and the PK bridging data contained in the NDA 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 and, 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 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 March 3, 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/>

Alkermes Contacts:

For Investors: Sandy Coombs, +1 781 609 6377

For Media: Gretchen Murphy, +1 781 609 6419



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