

Alkermes to Showcase Leadership in Schizophrenia With New Data Presentations at Upcoming Scientific Conferences

May 13, 2019

-- Clinical Data and Health Economics and Outcomes Research to be Presented May 18-22, 2019 at APA and ISPOR Annual Meetings --

DUBLIN, May 13, 2019 /PRNewswire/ -- [Alkermes plc](#) (Nasdaq: ALKS) today announced that it will present data from its mental health portfolio at the American Psychiatric Association (APA) Annual Meeting in San Francisco and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 2019 Conference in New Orleans; both scientific conferences will be held May 18-22, 2019. These presentations underscore Alkermes' growing scientific and clinical presence in the mental health space broadly, and specifically in schizophrenia, and demonstrate the company's commitment to developing new treatment options for patients that aim to provide both strong antipsychotic efficacy and patient-focused safety and tolerability attributes.

"APA and ISPOR are two of the most important meetings of the year for mental health experts and health economics leaders to engage in scientific exchange," said Kanchan Relwani, Vice President of Medical Affairs at Alkermes. "Alkermes has a strong legacy in schizophrenia and addiction, two critical and urgent public health issues in the U.S., and we remain committed to developing new therapies that help address patient needs in these important areas. We look forward to presenting new data to key decision-makers, thought leaders and practitioners."

Highlights of the upcoming presentations at APA include a poster reviewing antipsychotic efficacy results from three double-blind, olanzapine-controlled randomized clinical studies of ALKS 3831 (olanzapine/samidorphan), as well as posters relating to addiction and major depressive disorder. At ISPOR, Alkermes will share insights on the economic burdens of schizophrenia and bipolar I disorder from systematic literature reviews, and will present findings from two qualitative studies exploring patients' treatment experiences with oral antipsychotic medications in individuals with schizophrenia or bipolar I disorder.

"There is increasing recognition in the healthcare community and society at large of the tremendous toll that mental health disorders place on all layers of the healthcare ecosystem, from individual patients, to caregivers, providers and insurers," said Amy O'Sullivan, Vice President of Health Economics and Outcomes Research at Alkermes. "Today, innovators must consider not only the direct clinical impact of new treatment options for patients, but also the potential economic impact of such medications in addressing the costs of previously untreated or undertreated diseases. These economic and patient considerations help inform our development programs, and we look forward to sharing new insights at ISPOR that underscore the ongoing need for new disease management options for patients with schizophrenia and bipolar disorder."

Presentations at the APA Annual Meeting will include:

Schizophrenia

- Poster #P6-090: "Antipsychotic Efficacy of a Combination of Olanzapine and Samidorphan Across Three Olanzapine-Controlled Clinical Studies," will be presented by Adam Simmons, Alkermes, Inc., on Monday, May 20, 2019, 2:00 – 4:00 p.m. PT
- Poster #P7-063: "A Combination of Olanzapine and Samidorphan Mitigates Weight Gain Observed With Olanzapine: Results From the Phase 3 ENLIGHTEN-2 Schizophrenia Study," will be presented by Christoph Correll, M.D., Psychiatry and Molecular Medicine at Hofstra Northwell School of Medicine, on Tuesday, May 21, 10:00 a.m. – 12:00 p.m. PT

Alcohol and Opioid Use Disorder

- Poster #P6-032: "Transition From Buprenorphine Maintenance to Extended-Release Naltrexone: Hybrid Residential-Outpatient Randomized Controlled Trial," will be presented by Paolo Mannelli, M.D., Duke University School of Medicine, on Monday, May 20, 2019, 2:00 – 4:00 p.m. PT
- Poster #P6-034: "Opioid Overdose in Patients Treated With Extended-Release Naltrexone: Postmarketing Data From 2006 to 2018," will be presented by Kimberley Marcopul, Alkermes, Inc., on Monday, May 20, 2019, 2:00 – 4:00 p.m. PT

Major Depressive Disorder

- Poster #P6-092: "Long-Term Treatment With Adjunctive Buprenorphine/Samidorphan Combination in Patients With Major Depressive Disorder: Phase 3 Study Results," will be presented by Michael E. Thase, M.D., Perelman School of Medicine at the University of Pennsylvania, on Monday, May 20, 2019, 2:00 – 4:00 p.m. PT
- Poster #P6-094: "Evaluating the Safety of Buprenorphine/Samidorphan for Adjunctive Treatment of Major Depressive Disorder: A Focus on Buprenorphine-Related Concerns," will be presented by Andrew Cutler, M.D., Meridien Research, on Monday, May 20, 2019, 2:00 – 4:00 p.m. PT
- Poster #P6-095: "The Safety of Buprenorphine/Samidorphan Combination as Adjunctive Therapy for Major Depressive Disorder: A Pooled Analysis of 4 Clinical Trials," will be presented by Andrew Cutler, M.D., Meridien Research, on Monday, May 20, 2019, 2:00 – 4:00 p.m. PT

Presentations at ISPOR 2019 will include:

- Podium Presentation, "Treatment Experiences of Patients With Schizophrenia: Findings From a Qualitative Focus Group Study," will be presented by Leona Bessonova, Ph.D., Alkermes, Inc., on Monday, May 20, 2019, 5:00 – 6:00 p.m. CT
- Poster PMH21, "The Economic Burden of Illness of Schizophrenia in the U.S.," will be presented by Leona Bessonova, Ph.D., Alkermes, Inc., on Monday, May 20, 2019, 3:30 – 7:00 p.m. CT
- Poster PMH64, "Treatment Experiences of Patients With Bipolar I Disorder: A Qualitative Focus Group Study," will be presented by Amy O'Sullivan, Ph.D., Alkermes, Inc., on Monday, May 20, 2019, 3:30 – 7:00 p.m. CT
- Poster PMH20, "The Economic Burden of Bipolar Disorder in the United States: Results From a Systematic Literature Review," will be presented by Leona Bessonova, Ph.D., Alkermes, Inc., on Monday, May 20, 2019, 3:30 – 7:00 p.m. CT

Visit the [APA](#) and [ISPOR](#) annual meeting websites for a list of all presentations taking place at each conference.

About ALKS 3831

ALKS 3831 is an investigational, novel, once-daily, oral atypical antipsychotic drug candidate for the treatment of schizophrenia. 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 ALKS 5461

ALKS 5461 is a fixed-dose combination of buprenorphine, a partial mu-opioid receptor agonist and kappa-opioid receptor antagonist, and samidorphan, a mu-opioid receptor antagonist. ALKS 5461 is a proprietary, investigational, once-daily oral medicine that acts as an opioid system modulator and is being studied for the adjunctive treatment of major depressive disorder (MDD) in patients with an inadequate response to standard antidepressant therapies.

About Alkermes

Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases. The company has a diversified commercial product portfolio and a substantial clinical pipeline of product candidates for chronic diseases that include schizophrenia, depression, addiction, multiple sclerosis and oncology. 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 value of the company's approved products and investigational product candidates and the company's plan for presentations of results from studies of its approved products and investigational product candidates. 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 those risks described in the Alkermes plc Annual Report on Form 10-K for the year ended Dec. 31, 2018, 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. The information contained in this press release is provided by the company as of the date hereof, and, except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking information contained in this press release.

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