



Alkermes Calls for Impartial National Review of Scientific Data Supporting the Use of FDA-Approved Treatment Options for Opioid Dependence

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— *Treatment System is Inadequate and Must Evolve to Meet the Needs of Patients and the Community. Decisions Should be Based on Unbiased Assessment of all Existing Data.* —

WALTHAM, Mass.--(BUSINESS WIRE)--Nov. 9, 2017-- Amid one of the nation's deadliest and most significant public health crises of our time, Alkermes is calling for a formal review by the National Institutes of Health (NIH) of data related to all FDA-approved medication-assisted treatment (MAT) options for opioid dependence. The goal of this review should be to establish a shared national understanding of the characteristics of these medicines and the scientific and medical evidence supporting their use. This review should evaluate the efficacy and safety of these treatment options, the specific patient populations most likely to benefit from them, as well as the data relating to overdose prevention, diversion, illicit use, craving, patient satisfaction and other important aspects of recovery. With a complete understanding of the body of evidence supporting MAT, treatment providers in the community will be better equipped to make data-driven treatment decisions customized to individual patient needs.

"In the face of this epidemic, the country would benefit from a comprehensive review of the three FDA-approved treatment options by an impartial scientific organization, such as NIH and the National Institute on Drug Abuse (NIDA). It is time to advance the discussion, and reject inaccurate and dangerous assertions regarding the quality and extent of data for current FDA-approved medicines," said Elliot Ehrich, M.D., Executive Vice President, Research and Development of Alkermes. "Each of these medicines has an important role to play in our national response to this epidemic."

Alkermes proposes a public meeting, led by NIH/NIDA, which includes presentation and review of medical and scientific data pertaining to FDA-approved medications for opioid dependence, including expert testimony from representatives of NIH, NIDA, the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), the Surgeon General, and the National Institute of Corrections (NIC), and unbiased and unconflicted data-driven patient and professional associations, including the American Academy of Addiction Psychiatry (AAAP). There are abundant data on these medicines, and despite this, myths and misperceptions are perpetuated and, as a result, most patients are not gaining access to MAT.

"As a nation and treatment community, we need to modernize our treatment system to provide patient-centered, data-driven care. Alkermes has been on the front lines of this epidemic for many years working to change the status quo and to address this national emergency," said Richard Pops, Chief Executive Officer of Alkermes. "We will continue our tireless drive to effect positive change for the benefit of patients, their families and the community, and will not allow unsubstantiated comments that impugn the validity of our medicine and integrity of our company to hinder our progress. A comprehensive, NIH-led review of the treatment paradigm would provide an appropriate national platform to elevate this conversation and meaningfully advance our nation's response to this epidemic."

About Opioid Dependence

A chronic brain disease, opioid dependence is characterized by cognitive, behavioral and physiological symptoms in which an individual continues to use opioids despite significant harm to oneself and others.¹ The use of heroin, an illegal opioid drug, and the non-medical use of FDA-approved opioid analgesics, including prescription pain relievers, represents a growing public health problem in the U.S. According to the 2016 U.S. National Survey on Drug Use and Health, nearly 2 million people aged 18 or older had an opioid use disorder.²

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 and multiple sclerosis. 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.

¹ DSM-IV-TR, American Psychiatric Association.

² SAMHSA. *Behavioral Health Trends in the United States: Results from the 2016 National Survey on Drug Use and Health*.



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