Injectable therapy blocks opioid euphoria, withdrawal symptoms in trial

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A study led by investigators in the University of Kentucky Center on Drug and Alcohol Research (CDAR) has demonstrated a weekly injectable formulation of buprenorphine, CAM2038, suppresses symptoms of withdrawal in patients with opioid use disorder (OUD).

CDAR director Sharon Walsh, the primary author on the study, and co-investigator Michelle Lofwall found CAM2038 effective in blocking the euphoria stimulated by opioid use and suppressing opioid withdrawal in patients not seeking treatment for an OUD. The findings are monumental in establishing the efficacy of an injection-based buprenorphine treatment that produces a blockade against the effects of illicit opioids. In addition, the study supports the use of a depot formulation for treating OUD, which eliminates the risks of overdose, misuse and diversion associated with the current pill formulations of buprenorphine therapy. Camurus, a Swedish firm, engineered CAM2038 as a novel therapeutic for treating individuals with OUD and consulted substance use disorder experts at the UK CDAR to coordinate the clinical trial.

Walsh presented the results and implications of the randomized, double-blind trial at the College on Problems of Drug Dependence annual conference on June 22. The clinical trial was conducted at three sites across the country, including the UK CDAR, from October 2015 to April 2016. The investigators tested 24-milligram and 32-milligram dosages of CAM2038 on 47 participants with moderate-to-severe OUD. The investigators found the injections sustained the suppression of opioid withdrawal through the weekly injection interval and participants tolerated both dosage levels.

The investigators reported that CAM2038 blocked the effects of a high potency opioid, indicating the formula works against the effects of a non-therapeutic opioid used in conjunction with the treatment.

"We've learned this therapy effectively blocks the effects of another opioid and produces sustained withdrawal suppression—two mechanisms by which a pharmacotherapy can lead to reduced illicit drug use," Walsh said. "We can help more patients improve their health and psychosocial functioning if we reduce illicit drug use and drug injection behaviors. This study will be part of the submission for CAM2038 to be reviewed for approval by the Food and Drug Administration in the coming months. Sustained release formulations have the prospect of changing the treatment landscape, reaching more patients and reducing the risk of misuse and diversion of daily products."

The study, "Association Between Buprenorphine Weekly Depot (CAM2038) and Hydromorphone Blockade in Individuals with Opioid Use Disorder: A Phase 2 Study," will appear in the September issue of the *JAMA Psychiatry*.

In addition to directing the CDAR, Walsh serves as a professor of behavioral science and psychiatry in the UK College of Medicine. Lofwall is a clinical researcher, addiction psychiatrist and associate

professor of behavioral science and psychiatry.

Approximately 33 million individuals around the world use opioids for non-medical purposes. Drug overdose is the leading cause of accidental death in America, with more than 50,000 lethal drug overdoses reported in 2015.

Provided by University of Kentucky