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## US WorldMeds Receives \$15 Million Grant to Launch New Study

### ***Funding from National Institute on Drug Abuse to support final Phase III clinical trial for Lofexidine for treatment of opiate withdrawal symptoms***

LOUISVILLE, Ky.--(BUSINESS WIRE)--US WorldMeds has begun enrolling patients in a Phase III clinical trial that will complete the development program for lofexidine hydrochloride (Lofexidine) as a new therapeutic for the treatment of withdrawal symptoms associated with opiate detoxification. The trial was made possible by a three-year \$15 million grant from the National Institute on Drug Abuse (NIDA) designed to facilitate progress in Lofexidine's development toward the next stage in the Food and Drug Administration (FDA) approval process.

Lofexidine is approved in the United Kingdom as BritLofex<sup>®</sup> and has been used in successful detoxification of more than 200,000 opiate addicts. US WorldMeds acquired a license for Lofexidine from Britannia Pharmaceuticals in 2003. Lofexidine has been studied in six prior clinical trials in the United States, including an earlier Phase III study of 264 opiate-dependent patients.

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“Through diligence and commitment, our dedicated team has brought Lofexidine to this final stage in the development process, despite numerous challenges,” said P. Breckinridge “Breck” Jones, founder and CEO of US WorldMeds. “We are grateful for the support of our NIDA partners for their collaboration. Both organizations are excited and proud to have launched this Phase III study. We are confident that this funding will allow us to generate the necessary data to secure regulatory approval which will provide access to an important, new treatment option for millions of Americans afflicted with opiate addiction.”

It is anticipated that this new study will provide sufficient evidence to allow US WorldMeds to file a New Drug Application for Lofexidine with the FDA to support US approval. Upon obtaining such approval, Lofexidine would be the first non-narcotic and non-addictive medication approved in the United States for the mitigation or relief of symptoms associated with acute withdrawal from short-acting opioids, such as heroin and commonly used prescription pain medications including Vicodin<sup>®</sup>, Lortab<sup>®</sup>, and Oxycontin<sup>®</sup>.

For the new Phase III study, investigators are recruiting 600 opiate-dependent individuals seeking detoxification at 13 sites throughout the United States. The trial is a randomized, double-blind, placebo controlled investigation evaluating the safety and efficacy of Lofexidine in the treatment of opioid withdrawal symptoms.

In collaboration with NIDA, US WorldMeds will continue to address an unmet medical need in the opioid-dependent population. The number of heroin abusers in the United States is estimated between 600,000 and 1 million. In addition, the United States Substance Abuse and Mental Health Services Administration recently reported that an estimated 22.5 million Americans, aged 12 or older, had used an illicit drug in the last month.<sup>1</sup> According to the National Institutes of Health (NIH), this growing population of illicit drug users “accounts for \$181 billion in health care, productivity loss, crime, incarceration and drug enforcement.”<sup>2</sup>

Only two FDA-approved drugs, methadone and buprenorphine, are currently available to treat opioid withdrawal. Both are opiate products that effectively operate as replacement or substitution therapies, but both have abuse potential and are controlled substances. Lofexidine would be the first non-addictive, non-narcotic treatment to help patients manage debilitating withdrawal symptoms associated with opiate detoxification such as vomiting, sweating, stomach cramps, diarrhea, and muscle pain.

Lofexidine trial sites are located in Atlanta, GA; Austin, TX; Baltimore, MD; Clovis, CA; Dallas, TX; Desoto, TX; Escondido, CA; Lake Charles, LA; Los Angeles, CA; Miami, FL; Oak Park, IL; Orem, UT; and Orlando, FL. For more information on the Phase III Lofexidine trial or to link to contact information for participating centers, visit <http://www.usworldmeds.com/Lofexidine.asp>.

### **About US WorldMeds**

US WorldMeds is a closely-held, Kentucky-based specialty pharmaceutical company. Its mission is to develop, license and commercialize unique and significant specialty pharmaceuticals that address unmet medical needs or overcome limitations of existing products.

US WorldMeds’ overriding mission and focus is to identify specialty products for niche patient groups and to increase access to those treatments across the globe. For more information on US WorldMeds or its product portfolio, visit [www.usworldmeds.com](http://www.usworldmeds.com).

The project described is supported by Award Number U01DA033276 from the National Institute on Drug Abuse. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute on Drug Abuse or the National Institutes of Health.

### **References:**

1. Substance Abuse and Mental Health Services Administration, Results from the 2011 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-44, HHS Publication No. (SMA) 12-4713. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2012, p. 1.

See more at: [http://www.drugwarfacts.org/cms/Drug\\_Usage#sthash.28EUgHte.dpuf](http://www.drugwarfacts.org/cms/Drug_Usage#sthash.28EUgHte.dpuf)

2. *Addiction Science: From Molecules to Managed Care*. National Institute on Drug Abuse, retrieved 5.23.2013. <http://www.drugabuse.gov/publications/addiction-science-molecules-to-managed-care/introduction/drug-abuse-costs-united-states-economy-hundreds-billions-dollars-in-increased-health>

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