



**For Immediate Release**

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## **US WorldMeds Initiates Phase III Trial of Lofexidine for Treatment of Opiate Withdrawal Symptoms**

*Lofexidine would be first non-addictive drug approved in the US to detoxify opiate addicts; has been used in an estimated 200,000 detoxifications in UK*

**Louisville, KY** – US WorldMeds, a Kentucky-based specialty pharmaceutical company, today announced that it is enrolling patients in a Phase III clinical trial, USWM-001, investigating the use of lofexidine hydrochloride (Lofexidine) for the treatment of opiate withdrawal symptoms in opiate dependent individuals. If approved by the Food and Drug Administration (FDA), Lofexidine would be the first non-addictive, non-narcotic treatment for relieving the distressing withdrawal symptoms associated with opiate detoxification approved in the United States.

Investigators are currently recruiting 264 patients to participate in the in-patient, randomized, double-blind trial that will be conducted at 14 sites throughout the United States. The withdrawal treatment period will be eight days per patient. US WorldMeds expects that the Phase III trial, which is a collaborative effort of the company, the National Institute on Drug Abuse (NIDA) and the Department of Veterans Affairs Cooperative Studies Program Coordinating Center in Perry Point, MD, will support a new drug application (NDA) filing with the FDA for Lofexidine for this indication.

“The distressing physical symptoms associated with opiate withdrawal are a major impediment for those who want to end their addictions,” said Paul Breckinridge “Breck” Jones, CEO of US WorldMeds. “The only FDA approved treatment alternatives for opiate detoxification today are drugs that have their own addictive properties. Lofexidine will give a new option to hundreds of thousands of people who are struggling with addictions to heroin and widely prescribed opiate based pain medications such as OxyContin.”

Lofexidine, an alpha-2-adrenergic agonist, is the only non-addictive, non-opiate treatment approved in the United Kingdom (UK) to manage the often debilitating withdrawal symptoms that occur during opiate detoxification. These can include vomiting, sweating, stomach cramps, diarrhea, and muscle pain. Lofexidine has been used in an estimated 200,000 detoxifications over 13 years in the UK, where it is marketed by Britannia Pharmaceuticals as Britlofex®.

Lofexidine has been studied in six prior clinical trials in the United States. In 2003, NIDA took the unusual step of stopping a similar Phase III trial when its Data and Safety Monitoring Board determined it unethical to continue administering placebo to research subjects in withdrawal in the face of lofexidine's overwhelming efficacy. NIDA is also playing a central role in the oversight of US WorldMeds' latest clinical trial of Lofexidine.

"Lofexidine could be the first non-opiate drug for the management of opiate withdrawal. As such, it would occupy a unique niche in managing patients during the opiate withdrawal period" said Dr. Frank Vocci, Director of the Division of Pharmacotherapies and Medical Consequences of Drug Abuse at NIDA.

The National Institutes of Health (NIH) estimates that drug and alcohol addiction affects millions of people in the United States, costing the nation nearly \$500 billion a year – more than diabetes and cancer combined. The number of hardcore heroin abusers in the United States is estimated between 600,000 and 1 million. Addiction to prescription pain medication is on the rise. In June, the U.S. Substance Abuse and Mental Health Services Administration reported that 2.4 million persons initiated non-medical use of prescription pain relievers over a 12 month period – 300,000 more than those who initiated use of marijuana.

Opiate addicts who seek treatment for withdrawal symptoms are most often offered the replacement drug Methadone, an addictive opiate derivative, through community treatment centers.

"Opiate abuse has grown to epidemic proportions," said Jones of US WorldMeds. "Addicts in communities with minimal healthcare resources could have much greater access to addiction treatment if Lofexidine comes to market. I expect that Lofexidine will not need to be closely administered like currently available narcotic treatments. Therefore, once approved, any licensed physician could prescribe it through any pharmacy anywhere in the US. Its availability would not be limited to community clinics that are often located in more urban areas."

US WorldMeds was founded by a diverse group of financial investors who share a strong commitment to impact national and world health. The company's founders acquired a license for Lofexidine from Britannia Pharmaceuticals in 2003 after they became inspired to help solve the chronic addiction problem in their home state of Kentucky, which has experienced significant prescription drug abuse, particularly in rural areas.

Lofexidine trials are currently being conducted at medical facilities throughout the United States, including:

- Alexian Brother Behavioral Health Hospital, Hoffman Estates, IL
- Atlanta Center for Medical Research, Atlanta, GA
- Aurora Psychiatric Hospital, Wauwatosa, WI
- Research Across America, Dallas, TX
- CNS Psychiatric Institute of Washington, Washington, D.C.
- Ocean State Research, Providence, RI
- St. Vincent Catholic Medical Center, Staten Island, NY
- University of Kentucky Center for Human Behavioral Science, Lexington, KY
- University of Texas Health Science Center, San Antonio, TX
- Vanderbilt Psychiatric Hospital, Nashville, TN
- Western Institute of Biomedical Research, Salt Lake City, UT
- Veterans Administration Puget Sound Health Care System, Seattle, WA

- Wayne State Addiction Research Institute, Detroit, MI

**For further information on clinical trial enrollment contact: (502) 753-2095**

**About US WorldMeds**

US WorldMeds is a closely held specialty pharmaceutical company based in Louisville, Kentucky. Founded in 2001, US WorldMeds is focused on identifying, developing and commercializing therapeutic treatments for niche patient populations.

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