FDA Advisory Committee Votes in Favor of Lucemyra (lofexidine) for the Mitigation of Opioid Withdrawal Symptoms

Treatment for Opiate Withdrawal

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LOUISVILLE, Ky., March 27, 2018 /PRNewswire/ — US WorldMeds today announced that the US Food and Drug Administration (FDA) Psychopharmacologic Drugs Advisory Committee voted 11 to 1 to recommend approval of lofexidine for mitigating opioid withdrawal symptoms. If approved, lofexidine will be marketed under the brand name Lucemyra.

The Advisory Committee's discussions were based on US WorldMeds' New Drug Application (NDA) for Lucemyra, which is currently under priority review by the FDA. The NDA includes data from two randomized, double-blind, placebo-controlled clinical trials and several supporting studies that examined the safety and efficacy of Lucemyra.

Lucemyra suppresses the neurochemical surge that produces the acute and painful symptoms of opioid withdrawal. In clinical trials compared to placebo, participants treated with Lucemyra experienced less severe withdrawal symptoms and were more likely to complete a seven-day opioid discontinuation treatment. If approved, Lucemyra will be the first and only non-opioid medication indicated for the mitigation of opioid withdrawal symptoms. Opioid withdrawal symptoms may include feeling sick, stomach cramps, muscle spasms/twitching, feeling of coldness, heart pounding, muscular tension, aches/pains, yawning, runny eyes, insomnia/problems sleeping.

"Today's favorable recommendation brings us one step closer to providing evidence-based medication, and hope for recovery, to people who want to discontinue opioid use and are struggling with the agonizing symptoms of opioid withdrawal, one of the most powerful factors driving opioid dependence and addictive behaviors," said Mark Pirner, M.D., Ph.D., senior medical director. "We look forward to working closely with the FDA to bring this much-needed medication to people in the United States."

The FDA will consider the Advisory Committee's non-binding recommendation in its review of the NDA for Lucemyra. The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date in the second quarter of 2018.

About Opioid Withdrawal

Opioids lower norepinephrine, a brain chemical that supports vital functions like respiration and consciousness. With continued opioid use the brain establishes a new equilibrium by increasing compensatory norepinephrine production in order to maintain normal functioning. When opioids are removed, or the dose significantly reduced, the brain’s increased norepinephrine levels are no longer offset by the presence of the opioids. This results in a norepinephrine surge that produces the acute and painful symptoms of withdrawal.

About Lucemyra (lofexidine)

Lucemyra (lofexidine), an oral tablet, is a selective alpha 2-adrenergic receptor agonist that reduces the release of norepinephrine. In clinical trials, Lucemyra significantly reduced the severity of withdrawal symptoms compared to placebo as reported by patients experiencing opioid withdrawal. This potential new medication is in development for the mitigation of symptoms associated with opioid withdrawal. Lucemyra is not currently approved in the United States.

About US WorldMeds

US WorldMeds is a specialty pharmaceutical company whose treatment options are making a difference in the lives of the patients and communities it serves. US WorldMeds takes an agile and personal approach to pharmaceuticals – pioneering research and product development in therapeutic areas that desperately need new solutions. Headquartered in Louisville, Kentucky, US WorldMeds has global presence and more than 15 years of experience in the development, licensure and commercialization of unique products. For more information about US WorldMeds, visit http://www.usworldmeds.com/. Follow us on Twitter and on LinkedIn.

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