AcelRx Announces Successful Completion of End-of-Phase 2 Meeting on ARX-01, Sufentanil NanoTab PCA System for Post-Operative Pain Management

REDWOOD CITY, Calif., October 30, 2009 -- AcelRx Pharmaceuticals, Inc. today announced that it has successfully completed an End-of-Phase 2 meeting with the FDA for ARX-01, a drug/device combination product based on the company's proprietary NanoTab™ dosage form, which enables delivery of sufentanil by the non-invasive oral transmucosal (sublingual) route. ARX-01 offers a non-invasive alternative to intravenous patient-controlled analgesia (IV PCA) for the management of acute post-operative pain in the hospital setting. The FDA reviewed a package based on positive Phase 2 clinical study results from three Phase 2 trials which demonstrated the functionality of the ARX-01 device and the safety and efficacy of Sufentanil NanoTabs™ for the treatment of moderate-to-severe acute pain following knee replacement surgery and abdominal surgery. The FDA provided AcelRx with guidance on Phase 3 study design, regulatory strategy, and NDA requirements. Commenting on the meeting, Pamela Palmer, MD, PhD, AcelRx Chief Medical Officer stated, "we are glad to have FDA input on the NDA requirements for this novel approach to post-operative pain management. Given this guidance, our path to market is now clear. We believe that ARX-01 will make a meaningful impact on patient lives by addressing the current shortcomings of IV PCA by reducing invasiveness, reducing unintended dosing errors, increasing patient mobility and simplifying the demands on health care providers."

About ARX-01 Sufentanil NanoTab PCA System

Acute pain management in the hospital, in particular post-operative analgesia, remains a significant challenge for healthcare providers. Annually, approximately 8 million patients in the U.S. and a similar number in the European Union, receive IV PCA, typically utilizing morphine, for inpatient post-operative pain. Despite its widespread use, the IV PCA architecture has several limitations. The IV line tethering the patient to the PCA pump discourages mobility, which is a critical factor in preventing post-operative complications and advancing recovery. Furthermore, the invasive nature of the IV delivery mode poses an infection risk, as well as a predisposition to analgesic gaps due to infiltrated and dislodged IV catheters. Additionally, the complexity and programmability of IV PCA pumps introduce opportunities for medication errors,

which in some instances may be fatal. The ARX-01 Sufentanil NanoTab PCA System avoids many of the limitations of IV PCA by providing a non-invasive, pre-programmed, handheld PCA solution.

The ARX-01 Sufentanil NanoTab PCA System is a novel drug/device combination product candidate designed for use in hospital settings to provide non-invasive patient-controlled analgesia and maximize patient satisfaction with post-operative pain management. The handheld component of ARX-01 allows for convenient patient self-administration of Sufentanil NanoTabs sublingually for oral transmucosal absorption. Sufentanil is a high therapeutic index opioid approved for intravenous and epidural administration. Although the analgesic efficacy of sufentanil has been well established, its use has been limited due to its short IV plasma half-life. In the NanoTab oral transmucosal dosage form, sufentanil demonstrates a therapeutically appropriate pharmacokinetic profile for post-operative PCA usage.

AcelRx has reported positive results from three Phase 2 studies with ARX-01: two of these studies were multicenter, double-blind, randomized, placebo-controlled, dose-finding trials that evaluated the safety and efficacy of Sufentanil NanoTabs in patients undergoing elective unilateral knee replacement surgery and major abdominal surgery; a third Phase 2 trial assessed the functionality of the handheld component of the ARX-01 Sufentanil NanoTab PCA System in an open-label, multicenter study in unilateral knee replacement surgery.

About AcelRx Pharmaceuticals, Inc.

AcelRx Pharmaceuticals is a privately held pharmaceutical company dedicated to the development and commercialization of new therapies for the treatment of pain and other conditions where there is an unmet need for improved safety and efficacy. The company applies its proprietary dosage form and delivery technologies to enhance the safety, therapeutic benefit and commercial attractiveness of currently approved compounds. For additional information about AcelRx Pharmaceuticals visit http://www.acelrx.com.

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