AcelRx Initiates a Phase 2 Study to Evaluate Functionality of its ARX-01 Sufentanil NanoTab PCA System

May 5, 2009

REDWOOD CITY, Calif., May 5, 2009 -- AcelRx Pharmaceuticals, Inc. today announced that it has initiated a Phase 2 clinical trial of its ARX-01 Sufentanil NanoTab™ PCA System, a proprietary drug/device combination product candidate being developed for management of acute post-operative pain in the hospital setting. The primary objective of this open-label study is to assess the functionality of the ARX-01 System for post-operative pain management in patients undergoing unilateral knee replacement surgery. AcelRx Chief Executive Officer, Thomas Schreck, commented, “We have successfully completed two placebo-controlled Phase 2 studies evaluating the efficacy and safety of Sufentanil NanoTabs in knee replacement and major abdominal surgery patients. Now with this third Phase 2 study we are validating the functionality of the handheld component of the ARX-01 Sufentanil NanoTab PCA System as we advance the ARX-01 clinical program.”

Study investigator David Griffin, MD, of the Orthopaedic Center of Vero Beach, Florida stated, "I am excited about ARX-01; I believe it has the potential to address a large unmet medical need in the management of post-operative pain by allowing patients to manage their pain without the need for an IV line or complicated IV PCA pumps. Seeing the smooth, uneventful initiation of this first study utilizing the ARX-01 Sufentanil PCA System adds to the already compelling Phase 2 data that AcelRx announced in December.”

About Acute Post-Operative Pain

Annually, approximately 8 million patients in the U.S. receive intravenous (IV) patient-controlled analgesia (PCA), typically utilizing morphine, for inpatient post-operative pain, with a similar number in the E.U. 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 infection risk as well as 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.

About ARX-01 Sufentanil NanoTab PCA System

ARX-01 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 ARX-01 Sufentanil NanoTab PCA System avoids many of the limitations of IV PCA approaches by providing a non-invasive, pre-programmed, handheld PCA solution. 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 IV 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-time. In the NanoTab oral transmucosal dosage form, sufentanil demonstrates a therapeutically appropriate pharmacokinetic profile for post-operative PCA usage and has the potential for improved patient tolerability over IV PCA morphine.

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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