



ACELRX ANNOUNCES PERFECT PERFORMANCE OF HANDHELD COMPONENT OF ARX-01 SUFENTANIL NANOTAB PCA SYSTEM IN A PHASE 2 STUDY

Efficacy consistent with positive results from earlier placebo-controlled studies

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AcelRx Pharmaceuticals, Inc. today announced positive results from its first Phase 2 clinical study evaluating the functionality of the handheld device component of its ARX-01 Sufentanil NanoTab™ PCA System for management of acute post-operative pain in patients requiring opioid analgesia during hospitalization. Patients reliably self-administered sufentanil NanoTabs repeatedly over the 12-hour study without any ARX-01 System failures or dosing errors of any kind.

This multicenter, open-label study included 30 patients (median age 68; range 51-74) undergoing elective unilateral knee replacement surgery. Patients self-administered 15 mcg doses of ARX-01 Sufentanil NanoTabs sublingually as needed using the ARX-01 handheld, with a minimal re-dosing interval of 20 minutes. The primary endpoint was device functionality assessed as the proportion of patients who successfully completed the study without any type of System failure. There were no System failures or dosing errors of any kind throughout the study, which included over 375 dispensed NanoTabs. Additionally, preliminary analysis of efficacy results indicated a dropout rate due to inadequate analgesia of less than 10%, consistent with the superior efficacy reported for the 15 mcg dose in two earlier Phase 2 placebo-controlled studies. ARX-01 was well-tolerated, and there were no serious adverse events related to study drug.

AcelRx Chief Engineering Officer, Anil Dasu, commented, "These results confirm the simple usability and consistent functionality of the handheld component of the ARX-01 Sufentanil NanoTab PCA System in the hands of post-surgical patients. Not only have the patients been pleased with the ease of use of the ARX-01 System, but the medical staff has also been highly satisfied with System's ease and speed of set-up and reliability."

In addition to this device functionality study, AcelRx has conducted two placebo-controlled Phase 2 studies of ARX-01 Sufentanil NanoTabs in patients undergoing elective unilateral knee replacement surgery and in patients undergoing major abdominal surgery. Both of those studies demonstrated highly significant efficacy results for the 15 mcg dose relative to placebo in reducing pain intensity over the 12-hour study periods.

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.



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