



AcelRx Announces Positive Phase 2 Results from a Study of ARX-01 Sufentanil NanoTabs in Treating Post-Operative Pain

Study in major abdominal surgery patients achieved primary and secondary endpoints

REDWOOD CITY, Calif., June 29, 2009 -- AcelRx Pharmaceuticals, Inc. today announced positive results from the second Phase 2 clinical study evaluating the safety and efficacy of its ARX-01 Sufentanil NanoTabs™ for the management of acute post-operative pain in patients requiring opioid analgesia during hospitalization. Compared to placebo, patients receiving ARX-01 Sufentanil NanoTabs for management of post-operative pain following major abdominal surgery reported statistically significant reductions in pain intensity over the 12-hour study period.

This multicenter, double-blind, placebo-controlled study included 88 patients undergoing major abdominal surgery randomized to receive either 10 mcg or 15 mcg doses of ARX-01, or placebo for post-operative pain. Study drug was administered sublingually, as needed to treat pain with a minimum re-dosing interval of 20 minutes. Patients were allowed to drop out of the study at any time. The primary efficacy endpoint was SPID-12 (a cumulative measure of the difference in pain intensity over the 12-hour study compared to baseline). Both ARX-01 10 mcg and 15 mcg treatment groups showed statistically significant reductions in pain intensity over the study period ($p < 0.001$ for each) based on the last observation carried forward imputation method, with similar results for alternate imputation methods (worst and baseline observations carried forward). Additionally, the proportion of patients who dropped out due to inadequate analgesia, a clinically meaningful secondary endpoint, was also significantly different from placebo ($p < 0.001$) for both treatment groups. ARX-01 was well tolerated; the most common adverse event reported was mild to moderate nausea with similar incidence between all treatment groups (including placebo). There were no serious adverse events related to study drug.

Study investigator, anesthesiologist Dr. Neil Singla, CEO of Lotus Clinical Research Inc., Pasadena, CA, stated, "The ARX-01 product has the potential to offer a major advance in the management of inpatient acute pain, liberating patients from the IV connection to a PCA pump, while still providing effective pain control appropriate even for patients who are restricted from oral medication. Patients appear to tolerate the Sufentanil NanoTabs well, and following the end of the 12-hour study period when they were switched to IV PCA morphine, many requested that they be returned to study drug. To me, these patients' requests are as demonstrative as any more quantitative endpoint of the product's advantages from the patient perspective."

The current data support the previously reported positive results for ARX-01 from the first Phase 2 study which evaluated the safety and efficacy of ARX-01 Sufentanil NanoTabs in patients undergoing elective unilateral knee replacement surgery. Additionally, an open-label Phase 2 study is currently ongoing with the primary objective of assessing the functionality of the handheld device component of the ARX-01 Sufentanil NanoTab PCA System in patients undergoing unilateral knee replacement surgery.

AcelRx Chief Medical Officer, Pamela Palmer, M.D., Ph.D., commented, “The Phase 2 results from both knee replacement and major abdominal surgery studies demonstrate that a wide variety of patients experiencing moderate-to-severe post-operative pain are able to achieve significant pain relief with our non-invasive approach to patient-controlled analgesia utilizing sublingual Sufentanil NanoTabs. We are pleased with the efficacy results, as well as with the overall side-effect profile of ARX-01 which was indistinguishable from placebo in both studies.”

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 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-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 NanoTab 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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