



AcelRx Pharmaceuticals Reports Positive Results from a Phase 2 Clinical Trial of Sublingual Sufentanil NanoTabs™ in Treating Post-Operative Pain

Proof-of-Concept Study Achieved Primary and Secondary Endpoints

REDWOOD CITY, Calif., December 9, 2008 -- AcelRx Pharmaceuticals, Inc. today announced positive results from a Phase 2 clinical study evaluating the safety and efficacy of its lead product candidate, ARX-01, for the treatment of moderate-to-severe inpatient acute pain following knee replacement surgery. The primary endpoint evaluated pain intensity (Sum of the Pain Intensity Difference – SPID12) over the 12-hour study period compared to baseline. Results demonstrated that compared to placebo, patients receiving 15 mcg of ARX-01 experienced a statistically significant reduction in pain intensity over the study period, based on the worst observation carried forward imputation method (WOCF), $p=0.015$. Additionally, at the 15 mcg dose, the study met an important secondary endpoint compared to placebo, the percentage of patient dropouts due to inadequate analgesia, $p=0.006$. Further, no serious or unexpected adverse events related to ARX-01 were reported in the study.

ARX-01 is a sublingual formulation of the opioid pain medication, sufentanil. ARX-01 is based on the company's proprietary NanoTab™ dosage form, which enables delivery of sufentanil by the non-invasive oral transmucosal (sublingual) route.

"We chose a very painful surgery in an elderly patient population to showcase the efficacy and safety of Sublingual Sufentanil NanoTabs in treating acute post-operative pain," said Pamela Palmer, M.D., Ph.D., chief medical officer of AcelRx Pharmaceuticals. "The superior attributes of both the drug and the dosage form enabled these highly encouraging Phase 2 results."

This multicenter, double-blind, randomized, placebo-controlled, dose-finding Phase 2 study evaluated the safety and efficacy of ARX-01 in patients undergoing elective unilateral knee replacement surgery. In the study, 101 patients were randomized to receive either placebo or one of three different dosage strengths of ARX-01: 5mcg, 10mcg or 15mcg of sufentanil. Doses were delivered sublingually as needed to treat pain with a 20-minute minimum re-dosing interval and patients were allowed to drop out of the study at any time. Positive results were also obtained for the primary endpoint following treatment with the 15mcg dose compared to placebo using two alternate methods for imputing missing data from drop-outs: baseline observation carried forward (BOCF), $p = 0.007$, and last observation carried forward (LOCF), $p = 0.018$. Importantly, there were no events of clinically significant respiratory depression for any dosing group. Based on these positive results, AcelRx intends to further advance clinical development of ARX-01 in 2009.

"We are pleased by the wonderful clinical results of our Phase 2 post-operative acute pain study," said Thomas A. Schreck, chairman and chief executive officer of AcclRx Pharmaceuticals. "This is the culmination of a great deal of hard work by a team of efficient, dedicated people over the last two years, and is therefore very gratifying indeed. This trial has the benefit of validating Sublingual Sufentanil NanoTabs as a robust product candidate for its initial in-hospital acute pain indication, as well as providing the foundation of safety and efficacy for the other programs in our pipeline."

About ARX-01 Sublingual Sufentanil NanoTabs

Sufentanil is currently approved as an intravenous (IV) anesthetic and is also indicated for epidural administration during labor and delivery. Due to their small size, ARX-01 Sublingual Sufentanil NanoTabs are convenient, well-tolerated, have high bioavailability and provide lower peak plasma levels compared to IV administration.

About the ARX-01 Oral Patient-Controlled Analgesia System

The ARX-01 Oral Patient-Controlled Analgesia (PCA) system is based on a proprietary pre-programmed, hand-held dispenser being developed by AcclRx. The AcclRx dispenser is designed to be hospital compliant for administration of Sublingual Sufentanil NanoTabs, while providing features directed to patient safety and convenience.

About Acute In-Hospital Pain

Acute pain management in the hospital, in particular post-operative analgesia, remains a significant challenge for healthcare providers. Current treatment methods include IV PCA, continuous epidural infusion, as well as other regional anesthesia techniques. IV PCA relies on a computerized pump that is attached to a patient's IV catheter. A variety of opioids, most frequently morphine, may be patient-administered via the PCA pump. The invasive nature of IV PCA delivery and the potential for programming errors when setting up the pump are well-known disadvantages of this method of pain control.

About AcclRx Pharmaceuticals, Inc.

AcclRx 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 AcclRx Pharmaceuticals visit <http://www.acclrx.com>.

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