



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

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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."

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