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

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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