AcelRx Announces Positive Phase 2 Results From a Study of ARX-02 Sufentanil NanoTab(TM) Breakthrough Pain Management System in Treating Cancer Breakthrough Pain

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REDWOOD CITY, Calif., May 25 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. today announced positive results from a Phase 2 clinical study evaluating the safety and efficacy of the ARX-02 Sufentanil NanoTab™ Breakthrough Pain Management System in the treatment of cancer breakthrough pain in opioid-tolerant patients. The primary endpoint of time-weighted Sum of the Pain Intensity Difference over the first 30 minutes after dosing (SPID-30) was highly statistically significant for ARX-02 compared to placebo ($p < 0.001$). Richard King, AcelRx President and Chief Executive Officer, commented, "AcelRx has now successfully completed Phase 2 studies with all three sufentanil-based development programs in progress at the company. These programs, targeting post-operative patient-controlled analgesia (ARX-01), outpatient procedural sedation (ARX-03) and now cancer breakthrough pain (ARX-02) represent important advances to meet significant unmet medical needs in these patient populations."

The initial open-label titration phase of the study enrolled 42 cancer patients with breakthrough pain. Of those patients, 36 (86%) were successful in titrating to an effective dose of ARX-02 with minimal side effects. In the double-blind, placebo-controlled phase of the study, titrated patients were randomized to receive a blinded sequence of seven doses of ARX-02 and three doses of placebo for use in treating ten distinct breakthrough pain events over the course of a three-week period. Patients recorded their pain intensity and pain relief scores for 60 minutes following administration of study drug or placebo using an electronic diary.

In addition to ARX-02 achieving statistical superiority over placebo on the SPID-30 primary endpoint, key secondary endpoints demonstrate that ARX-02 achieves rapid onset of analg
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[1] http://www.bio-medicine.org/medicine-technology-1/AcelRx-Announces-Positive-Phase-2-Results-From-a-Study-of-ARX-02-Sufentanil-NanoTab-28TM-29-Breakthrough-Pain-Management-System-in-Treating-Cancer-Bre-9047-1/