



ACELRx ANNOUNCES POSITIVE PHASE 2 RESULTS FROM A STUDY OF ARX-02 SUFENTANIL NANOTAB™ BREAKTHROUGH PAIN MANAGEMENT SYSTEM IN TREATING CANCER BREAKTHROUGH PAIN

Study Achieved Primary and Secondary Endpoints and Showed Rapid Onset of Pain Relief in Cancer Patients Experiencing Breakthrough Pain

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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 analgesic efficacy in this patient population. For example, the time-weighted Total Pain Relief (TOTPAR) for ARX-02 separated from placebo at 10 minutes ($p = 0.049$), the earliest time point recorded. In addition, there was no statistical difference in the frequency of any class of adverse events between ARX-02 and placebo treatments.

Pamela Palmer, MD, PhD, AcelRx Chief Medical Officer stated, "Sufentanil, the active agent in ARX-02, is a highly lipophilic drug with rapid transit time to the brain effector sites. The early onset of analgesia demonstrated by significant pain relief as early as 10 minutes in this study suggests that ARX-02 is ideal for the indication of breakthrough pain. In addition, the shorter plasma half-life seen with ARX-02 more closely matches effective opioid levels to the duration of a breakthrough pain event compared to commercially available fentanyl-based breakthrough pain products."

About Kaiser Permanente Ventures:

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