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

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Study achieved primary and secondary endpoints and showed rapid onset of pain relief in cancer patients experiencing breakthrough pain

REDWOOD CITY, Calif., May 25, 2010 – 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 Cancer Breakthrough Pain

Many patients with cancer-related pain are treated chronically with pain medication, but still experience episodes of severe pain that "breaks through" this base level of pain control. Typically the pain flare occurs with rapid onset and lasts approximately 15-60 minutes. Patients may experience several of these breakthrough pain episodes per day. Currently, oral transmucosal fentanyl-based products are the only approved treatments for cancer breakthrough pain. These products have prolonged plasma half-lives that extend well beyond four hours for most dosage strengths and due to their varying pharmacokinetics, patients may experience variable onset of analgesia.

About ARX-02

AcelRx is developing ARX-02, a novel sublingual Sufentanil NanoTab product candidate, as a new treatment option for patients with cancer breakthrough pain. Sufentanil is a strong opioid that is approximately 5-10 times more potent than fentanyl, yet has an 80-fold wider safety margin (therapeutic index), as determined in animal studies. The NanoTab is a very small tablet designed to allow rapid uptake of sufentanil following placement under the tongue, maximizing transmucosal drug uptake and limiting the proportion of swallowed drug. ARX-02 enables rapid onset of pain relief with a consistent, relatively short duration of action, more closely matching the timing of a breakthrough pain episode.

About AcelRx Pharmaceuticals, Inc.

AcelRx 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 AcelRx Pharmaceuticals visit http://www.acelrx.com.

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