



AcelRx Announces Initiation of Phase 2 Cancer Breakthrough Pain Program

April 22, 2009

REDWOOD CITY, Calif., April 22, 2009 -- AcelRx Pharmaceuticals, Inc. today announced that it has initiated a Phase 2 clinical trial of ARX-02, a proprietary sublingual sufentanil NanoTab™ product candidate for cancer breakthrough pain control. The primary objective of this multicenter, randomized, placebo-controlled, crossover study is assessment of safety, tolerability and efficacy of ARX-02 relative to placebo in cancer patients experiencing episodic breakthrough pain.

"We are pleased to have initiated the dosing of our first patient in this proof-of-concept study," states AcelRx Chief Executive Officer Thomas Schreck. "Developing a fastacting opioid with a shorter half-life than fentanyl for cancer patients who experience sudden breakthrough pain represents a significant step towards effectively treating pain while minimizing overall opioid exposure."

Pamela Palmer, MD, PhD, AcelRx Chief Medical Officer adds, "The pharmacokinetic profile of ARX-02 is optimal for this patient population. In contrast to fentanyl-based products, the highly consistent time to peak plasma concentration and plasma half-life of two to four hours produces a closer match of effective drug concentration with the breakthrough pain event and allows a high degree of safety if patients need to redose for a second breakthrough pain event."

About breakthrough cancer pain

Many patients with chronic cancer-related pain also experience episodes of severe pain that "breaks through" the regular pain medication. Typically the pain flare lasts approximately 15 - 60 minutes, and patients may experience several 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 beyond four hours for most dosage strengths.

About ARX-02

AcelRx is developing ARX-02, a novel sublingual sufentanil NanoTab product candidate, as a new treatment option for patients with breakthrough cancer 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 the 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.ancelrx.com>.

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