AcelRx Announces Completion of an End of Phase 2 Meeting with FDA for ARX-02, Sufentanil NanoTab™ Breakthrough Pain Management System

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REDWOOD CITY, Calif., October 1, 2010 -- AcelRx Pharmaceuticals, Inc. today announced that it has completed an End-of-Phase 2 meeting with the US Food and Drug Administration (FDA) for ARX-02, a proprietary Sufentanil NanoTabTM Breakthrough Pain Management System for the treatment of cancer breakthrough pain in opioid-tolerant patients. FDA reviewed a package based on the previously announced positive Phase 2 clinical study results to date for ARX-02 and provided AcelRx with guidance on the Phase 3 program design and NDA requirements. Richard King, AcelRx CEO stated, “Given this guidance, we have clarity on the development path for ARX-02 in cancer breakthrough pain. In addition, FDA provided clarity on the development requirements to register ARX-02 for the broader indication of chronic breakthrough pain in opioid-tolerant patients, where we believe that ARX-02 can have an impact on the lives of a broader array of opioid-tolerant patients.”

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, 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 innovative products for the treatment of painful conditions where currently available treatments are not optimal. The company applies its proprietary NanoTab technology for oral transmucosal delivery 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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