AcelRx Pharmaceuticals Announces Initiation of Clinical Study with ARX-04 in Emergency Room Patients with Moderate-to-Severe Acute Pain

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REDWOOD CITY, Calif., Oct. 6, 2015 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of moderate-to-severe acute and breakthrough pain, today announced the initiation of an open-label Phase 3 study (SAP302) of ARX-04 for the treatment of adult patients who present in the emergency room with moderate-to-severe acute pain associated with trauma or injury. The primary efficacy endpoint is the summed pain intensity difference (SPID) over 1-hour (SPID1). Safety endpoints, such as adverse events and vital signs will also be assessed, as will the patients' and healthcare providers' satisfaction with the method of pain control. The study is expected to be completed in early 2016.

"In our recently concluded SAP301 study, ARX-04 was shown to provide a rapid onset of action within 15 minutes of administration, making it well-suited for use in an emergency room setting, where speed is critical and where access to intravenous morphine may not be immediately available," stated Dr. Pamela Palmer, co-founder and chief medical officer of AcelRx Pharmaceuticals. "The SAP302 study is intended to provide us with valuable insights into the optimal use of ARX-04 in the emergency room setting, one of our initial target markets. It is also intended to complete the safety database requirements previously agreed to with the FDA."

Howie Rosen, interim CEO of AcelRx, added, "As part of our development program, we expect to meet with the U.S. Food and Drug Administration to review plans for a New Drug Application for ARX-04 and will provide more guidance on regulatory timing following that meeting."

About ARX-04
ARX-04 is a non-invasive investigational product candidate consisting of 30 mcg sufentanil tablets delivered sublingually via a disposable, pre-filled, single-dose applicator (SDA). AcelRx is developing ARX-04 for the management of moderate-to-severe acute pain in a variety of medically supervised settings, including the emergency room, outpatient or ambulatory surgery, non-surgical patients experiencing pain in the hospital, and post-operative patients following short-stay surgery, who do not require more long-term patient-controlled analgesia (PCA). ARX-04 development is funded in part by the US Army Medical Research and Materiel Command (USAMRMC).

About AcelRx Pharmaceuticals, Inc.
AcelRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute pain. The company's late-stage pipeline includes ARX-04 (sufentanil sublingual tablet, 30 mcg) for the treatment of moderate-to-severe acute pain in a medically supervised setting; and Zalviso™ (sufentanil sublingual tablet system) for the management of moderate-to-severe acute pain in adult patients in the hospital setting.

ARX-04 delivers 30 mcg sufentanil, a high therapeutic index opioid, sublingually through a disposable, pre-filled, single-dose applicator. AcelRx has reported positive results from the pivotal Phase 3 SAP301 ambulatory surgery study, and has advanced ARX-04 into a study in emergency room patients. Zalviso delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. In response to the New Drug Application (NDA) AcelRx submitted to the U.S. Food and Drug Administration (FDA) seeking approval for Zalviso, AcelRx received a Complete Response Letter (CRL) on July 25, 2014. The FDA has requested an additional clinical study and the Company is working with the FDA regarding the resubmission of the Zalviso NDA.

For additional information about AcelRx's clinical programs, please visit www.acelrx.com.

Forward Looking Statements
This press release contains forward-looking statements, including, but not limited to, statements related to the process and timing of anticipated future development of AcelRx's product candidates, including the process and timing of anticipated future development of Zalviso and ARX-04; anticipated results and timing of the completion of SAP302 study for ARX-04; the therapeutic and commercial potential of AcelRx product candidates, including Zalviso and ARX-04; AcelRx's plans to seek a pathway forward towards gaining approval of Zalviso in the US; and anticipated resubmission of the Zalviso NDA to the FDA, including the scope and timing of resubmission. These forward-looking statements are based on AcelRx's current expectations and inherently involve significant risks and uncertainties. AcelRx's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to: any delays or inability to obtain and maintain regulatory approval of its product candidates, including Zalviso and ARX-04; the market potential for its product candidates, including Zalviso and ARX-04, in the United States and Europe; its ability to timely resubmit the Zalviso NDA to the FDA and to receive regulatory approval for Zalviso; the fact that the FDA may dispute or interpret differently positive clinical results obtained to date from the pivotal Phase 3 SAP301 ambulatory surgery study of ARX-04; its ability to complete Phase 3 clinical development of ARX-04; the success, cost and timing of all product development activities and clinical trials, including the SAP302 ARX-04 trial; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx's U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on August 4, 2015. AcelRx undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events or changes in its expectations.

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SOURCE AcelRx Pharmaceuticals, Inc.

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