AcelRx Pharmaceuticals Presents Results from Phase 3 Study of ARX-04 in the Emergency Department at the International Society for Burn Injuries

August 29, 2016

REDWOOD CITY, Calif., Aug. 29, 2016 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (NASDAQ: ACRX) today announced that the Company and its investigators will be presenting results from the Phase 3 SAP302 study of ARX-04 (sufentanil sublingual tablet, 30 mcg) in 76 patients who were treated for moderate-to-severe acute pain in the emergency department. An oral presentation reviewing these results, including the types of injuries that were sustained by patients in the study, will be made at the International Society for Burn Injuries (ISBI), which is taking place August 29 – September 1 in Miami, Florida.

As previously reported, adult patients treated with ARX-04 in this study experienced a mean pain intensity difference of 2.9 from a baseline of 8.1 on a validated 0 – 10 numeric rating scale at 60 minutes, meeting the study's primary objective. Injuries sustained by patients in SAP302 included fractures, sprains/strains, lacerations and burns, among others. Study participants tolerated ARX-04 well, with nausea (9%), somnolence (5%) and vomiting (4%) comprising the most commonly reported adverse events.

The study additionally concluded that ARX-04 had no overall impact on cognitive function.

Details on the presentation time are as follows:

Date: Monday, August 29, 2016 at 1:30pm (local time)

Title: Efficacy and Safety of Sublingual Sufentanil 30mcg for the Management of Acute Traumatic Pain in the Emergency Department

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The International Society for Burn Injuries' first international congress took place in 1960. In 1965, delegates of the second congress moved to create a permanent organization with the goal of reducing the incidence of burns, as well as improving patient care, especially in developing countries. For more information on the 2016 Congress, please visit http://isbi2016.com.

About ARX-04
ARX-04 is a non-invasive investigational product candidate consisting of a 30 mcg sufentanil tablet 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 moderate-to-severe acute pain in the hospital, and post-operative patients following short-stay surgery, who do not require more long-term patient-controlled analgesia (PCA).

The ARX-04 Phase 3 clinical program is comprised of three studies in patients with moderate-to-severe acute pain: SAP301, a double-blind, placebo-controlled trial in ambulatory abdominal surgery patients; SAP302, an open-label trial in adult emergency room patients; and SAP303, an open-label trial in postoperative patients. Results of SAP301, which were presented in 2015 at the American Society of Anesthesiologists annual meeting, may be viewed on the AcelRx website.

ARX-04 is funded in part by the Clinical and Rehabilitative Medicine Research Program (CRMRP) of the U.S. Army Medical Research and Materiel Command (USAMRMC) under contract No. W81XWH-15-C-0046.

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) designed for the treatment of moderate-to-severe acute pain in a medically supervised setting; and Zalviso® (sufentanil sublingual tablet system) designed 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 recently completed SAP302 (study in emergency room patients) and SAP303 (study in post-operative patients 40 years and older). 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 (IAP312), which AcelRx is planning to initiate once supply testing is complete in order to support its NDA resubmission.

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, ARX-04 (sufentanil sublingual tablet, 30 mcg) and Zalviso® (sufentanil sublingual tablet system), including the ARX-04 clinical trial results; anticipated submission of the New Drug Application, or NDA, for ARX-04 to the U.S. Food and Drug Administration, or FDA; AcelRx's pathway forward towards gaining approval of Zalviso in the U.S.; the anticipated timing, design and results of the IAP312 clinical trial for Zalviso; anticipated resubmission of the Zalviso NDA to the FDA including the scope of the resubmission and the timing of the resubmission, and FDA review time; and the therapeutic and commercial potential of AcelRx's product candidates, including potential market opportunities for ARX-04 and Zalviso. These forward-looking statements are based on AcelRx Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. AcelRx Pharmaceuticals' actual results and timing of events could differ materially from those anticipated in such forward-looking statements, and as a result of these risks and uncertainties, which include, without limitation, risks related to AcelRx Pharmaceuticals' ability to successfully complete Phase 3 clinical development of ARX-04; AcelRx's ability to successfully execute the pathway towards a resubmission of the Zalviso NDA to the FDA, including the initiation and completion of the IAP312 clinical study for Zalviso; any delays or inability to obtain and maintain regulatory approval of its product candidates, including ARX-04 in the United States and Europe, and Zalviso in the United States; the uncertain clinical development process, including adverse events; the risk that planned clinical trials may not begin on time, have an effective clinical design, enroll a sufficient number of patients, or be initiated or completed on schedule, if at all; the success, cost and timing of all development activities and clinical trials, including the Phase 3 ARX-04 SAP302 and SAP303 trials, and the additional clinical trial for Zalviso, IAP312; the fact that the FDA may dispute or interpret differently clinical results obtained to date from the Phase 3 studies of ARX-04 and other risks detailed in the "Risk Factors" and elsewhere in AcelRx's U.S. Securities and Exchange Commission filings and reports, including its Annual Report on Form 10-Q filed with the SEC on July 29, 2016. 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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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/acelrx-pharmaceuticals-presents-results-from-phase-3-study-of-arx04-in-the-emergency-department-at-the-international-society-for-burn-injuries-300318913.html

SOURCE AcelRx Pharmaceuticals, Inc.

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