AcelRx Pharmaceuticals Presents Results from Phase 3 Study of ARX-04 following Ambulatory Abdominal Surgeries at Euroanaesthesia

May 26, 2016

REDWOOD CITY, Calif., May 26, 2016 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (NASDAQ: ACRX) today announced that the Company and its investigators will be presenting Phase 3 SAP301 study results at Euroanaesthesia 2016, which is taking place in London, UK on May 28-30, 2016. In the SAP301 study, patients with moderate-to-severe acute pain following abdominoplasty, hernioplasty or laparoscopic abdominal surgeries were randomized to receive either ARX-04 (sufentanil sublingual 30 mcg tablet) or a placebo sublingual tablet. The study met its primary endpoint with statistically significant pain intensity differences to baseline over the 12-hour study period (SPID12) in favor of ARX-04 ($p<0.001$). When analyzed by type of surgery, treatment with ARX-04 resulted in a statistically significant benefit over placebo in each surgery type. ARX-04 was well tolerated in the trial, with nausea, headache and vomiting being the most common treatment-emergent adverse events reported.

Details on the presentation time are as follows:

Date: Monday, May 30, 2016 at 12:15 – 1:45pm (local time)

Title: Safety and efficacy of sufentanil sublingual 30 mcg tablets for the treatment of acute pain following outpatient surgery

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Euroanaesthesia is Europe's largest annual event showcasing the latest and the most relevant information in the fields of anesthesia, perioperative medicine, intensive care, emergency medicine and pain treatment. Upwards of 6,000 delegates from 80 countries are expected to attend. For more information on the conferences, please visit euroanaesthesia2016.esahq.org.

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 advanced ARX-04 into studies in emergency room patients (SAP302) and post-operative patients 40 years and older (SAP303). 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 supplies are available, have been tested with acceptable results, and clinical sites are ready, 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; the planned initiation of the IAP312 clinical trial for Zalviso; anticipated resubmission of the Zalviso NDA to the U.S. Food and Drug Administration, or FDA; the timing of completion of ARX -04 clinical program and submission of ARX-04 NDA to the FDA; and the therapeutic and commercial potential of AcelRx's product candidates, including 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 complete Phase 3 clinical development of ARX-04 and support ARX-04 development under the contract with the Department of Defense; 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 SAP301 study of ARX-04; the market potential for AcelRx's product candidates; 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 May 2, 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-following-ambulatory-abdominal-surgeries-at-euroanaesthesia-300275339.html

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