AcelRx Pharmaceuticals to Announce Topline Results in Phase 3 Study of ARX-04 in Patients with Post-Operative Moderate-to-Severe Acute Pain

September 14, 2016

Management to host conference call tomorrow at 9:00 a.m. ET (6:00 a.m. PT) Thursday, September 15th

REDWOOD CITY, Calif., Sept. 14, 2016 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (NASDAQ: ACRX) a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute pain, will announce the results of its multicenter, open-label Phase 3 clinical study of ARX-04, known as SAP303. The study was conducted in patients 40 years and older who have moderate-to-severe acute pain following a surgical procedure. Patients were administered one dose of ARX-04 (sufentanil sublingual tablet, 30 mcg) every 60 minutes, as needed for pain management, for up to 12 hours.

Conference Call

AcelRx will conduct a conference call and webcast tomorrow morning, September 15, at 9:00 a.m. Eastern time (6:00 a.m. Pacific time) to discuss this update and the trial results. To listen to the conference call, dial in approximately ten minutes before the scheduled call to 877-407-9129 for domestic and Canadian callers, or 201-493-6753 for international callers. Those interested in listening to the conference call live via the Internet may do so by visiting the Investors section of the company's website at www.acelrx.com and selecting the Webcast link for the ARX-04 Phase 3 Trial Results Call. A webcast replay will be available on the AcelRx website for 90 days following the call by visiting the Investors section of the company's website at www.acelrx.com.

http://acelrx.equisolvewebcast.com/9-15-16

About ARX-04

ARX-04 is a non-invasive investigational product candidate consisting of a 30 mcg sufentanil tablet delivered sublingually in a controlled setting by healthcare professionals using a disposable, pre-filled, single-dose applicator (SDA). Sufentanil is a synthetic opioid analgesic with a high therapeutic index and no known active metabolites.

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 post-operative patients. Results of SAP301, which were presented in 2015 at the American Society of Anesthesiologists annual meeting, and results of SAP302, which were presented at the 2016 Military Health System Research Symposium, 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.

Zalviso delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. Zalviso is approved in the EU as well as Norway, Iceland and Liechtenstein and is investigational and in late-stage development in the US. Grunenthal Group holds the rights for Zalviso in Europe and Australia while AcelRx retains all other world-wide rights.

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.; 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' ARX-04 development program, including anticipated submission of the ARX-04 NDA and the fact that the FDA may dispute or interpret differently clinical results obtained to date from the Phase 3 studies of ARX-04; 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; 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 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-to-announce-topline-results-in-phase-3-study-of-arx-04-in-patients-with-post-operative-moderate-to-severe-acute-pain-300327875.html

SOURCE AcelRx Pharmaceuticals, Inc.

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