



AcelRx Pharmaceuticals Announces Presentation Of Phase 3 Sufentanil Sublingual 30mcg Tablet Data At The European Society Of Emergency Medicine Meeting

October 9, 2015

Clinical Data from Phase 2 and Phase 3 Development Programs Highlight Efficacy and Tolerability of Sublingual Sufentanil in Out-patient Surgical Populations

REDWOOD CITY, Calif., Oct. 9, 2015 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (NASDAQ: ACRX) today announced that a presentation will be made at the annual European Society of Emergency Medicine (EuSEM) meeting to be held October 11th to October 14th, 2015 at the Lingotto Congress Centre in Turin, Italy. The annual EuSEM is the largest meeting of emergency medicine practitioners in the world with over 2000 delegates in attendance and 90 countries represented.

The presentation marks the first time top-line results from the recently completed phase 3 study using sublingual sufentanil 30mcg tablets for the management of moderate to severe acute pain in outpatient abdominal surgery patients, or SAP301, will be revealed to the academic and scientific community. Data from the previously announced phase 2 bunionectomy trial will also be included. Both studies were multi-center, randomized, double-blind and placebo-controlled.

Details on the presentation time are as follows:

Monday, October 12 and Tuesday, October 13, 2015 – Participants will be able to watch the eposters freely on LCD screens throughout the Exhibit Hall and browse them using a tactile computer linked to the screen - Presentation time 9:00am-4:00pm (local time).

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Title: Efficacy and Safety of Sublingual Sufentanil 30mcg for the Management of Acute Pain

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, 30mcg) 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 30mcg 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 (SAP302) in emergency room patients. 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 in late-stage development in the U.S. AcelRx submitted a New Drug Application (NDA) for Zalviso and received a Complete Response Letter (CRL) from the FDA on July 25, 2014. The FDA subsequently requested an additional clinical study to evaluate the effectiveness of product changes made in response to the CRL, and the Company is working with the FDA regarding the resubmission of the Zalviso NDA and initiation of a clinical study to support resubmission.

The Company has two additional pain treatment product candidates, ARX-02 and ARX-03, which have completed Phase 2 clinical development. 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 the SAP302 study for ARX-04; AcelRx's plans to seek a pathway forward towards gaining approval of Zalviso in the U.S.; 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; its ability to successfully complete the additional clinical study requested by the FDA to support resubmission of the Zalviso NDA; 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.

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/acelrx-pharmaceuticals-announces-presentation->

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SOURCE AcelRx Pharmaceuticals, Inc.

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