



AcelRx Pharmaceuticals Presents Phase 3 Results from ARX-04 Clinical Program at JAB Burn and Wound Care Symposium

Feb 11, 2016

REDWOOD CITY, Calif., Feb. 11, 2016 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (NASDAQ: ACRX) today announced that a podium presentation will be made at the 38th annual John A. Boswick, M.D. Burn and Wound Care Symposium, which is being held February 14-18, 2016 in Hawaii. This international conference covers the latest advancements in wound healing, burn care, and infection control, and is endorsed by the American Burn Association, Australian-New Zealand Burns Association, Academy of Physicians in Wound Care and the International Society for Burn Injuries.

Details on the presentation time are as follows:

Date: Sunday, February 14th at 10:45am (local time)

Title: Phase 3 Efficacy and Safety Results of Sublingual Sufentanil 30 mcg for the Management of Acute Moderate to Severe Pain

Author(s): Karen P. DiDonato, MSN, RN

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 a study (SAP-302) in emergency room patients. In addition, AcelRx intends to initiate SAP303 in the first quarter of 2016, with a focus on enrolling patients greater than 40 years of age, allowing for administration of ARX-04 for up to 12 hours. 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 in the first quarter of 2016, to support resubmission of the 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 Zalviso and ARX-04; timing for initiation of IAP312 for Zalviso and SAP303 studies for ARX-04; AcelRx's plans to seek a pathway forward towards gaining approval of Zalviso in the United States; and anticipated resubmission of the Zalviso NDA to the FDA. 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 design and 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 ambulatory surgery study of ARX-04 (SAP301); 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 and SAP303 ARX-04 trials and the IAP312 Zalviso 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 November 3, 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.



Logo - <http://photos.prnewswire.com/prnh/20130226/MM67303LOGO>

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/acelrx-pharmaceuticals-presents-phase-3-results-from-arx-04-clinical-program-at-jab-burn-and-wound-care-symposium-300217201.html>

SOURCE AcelRx Pharmaceuticals, Inc.

Timothy E. Morris, Chief Financial Officer, 650.216.3511, tmorris@acelrx.com; Brian Korb, The Trout Group LLC, 646.378.2923, bkorb@troutgroup.com