



AcelRx Publishes a Review of Hospital-Based Opioid Patient-Controlled Analgesia, Risks and Pharmacoeconomics

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- Zalviso Clinical Program Highlighted in Publication in Hospital Pharmacy -

REDWOOD CITY, Calif., March 25, 2016 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of moderate-to-severe acute pain, reported that a review article entitled "[Evolution of Patient-Controlled Analgesia: From Intravenous to Sublingual Treatment](#)" has been published in the peer-reviewed journal, *Hospital Pharmacy*. This article provides insights into patient-controlled analgesia (PCA) systems, the choice of opioid, risks, and costs associated with PCA usage in U.S. hospitals. Beyond intravenous (IV) PCA, the article also discusses noninvasive options in development, such as the transdermal, inhaled, oral and sublingual delivery of opioids. **Zalviso™** (sufentanil sublingual tablet system) is profiled as a novel sublingual PCA system in development, and the entirety of the clinical program is reviewed.

Joseph F. Dasta, M.Sc., MCCM, FCCP, professor emeritus in the College of Pharmacy at Ohio State University and adjunct professor at the University of Texas College of Pharmacy, and co-author of this article, commented, "Multimodal approaches to pain management that rely on non-opioid analgesics are employed in many hospitals in this country, yet opioids are still often required to quell the acute pain immediately following surgery. Data that we have reviewed from clinical studies of this sublingual sufentanil tablet system indicate that sublingual sufentanil could provide the necessary management of moderate-to-severe acute pain while avoiding some of the pitfalls inherent with current IV PCA systems."

About Zalviso

Zalviso is designed to deliver 15 mcg sufentanil, a high therapeutic index opioid, formulated in a proprietary non-invasive sublingual dosage form via a novel hand-held, factory-programmed, PCA system. AcelRx has completed three Phase 3 clinical trials of Zalviso in patients with moderate-to-severe acute pain: two placebo-controlled efficacy and safety trials and one open-label active comparator trial, in which Zalviso was compared to IV PCA morphine. Each of the three Phase 3 trials achieved its primary endpoint. Based on FDA feedback, AcelRx will also conduct an open-label clinical study, known as IAP312, of Zalviso in post-operative patients. This study will primarily measure the rate of device errors, including the failure to dispense medication as well as the incidence of misplaced or dropped tablets, which will further evaluate the overall performance of the Zalviso System.

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) 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 and completion along with anticipated results of IAP312 for Zalviso; anticipated results and timing of the completion of the SAP302 and SAP303 studies for ARX-04; AcelRx's planned pathway forward towards gaining approval of Zalviso in the United States; 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 design, timely enroll 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 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 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 Annual Report on Form 10-K filed with the SEC on March 7, 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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