AcelRx Pharmaceuticals Presents Data from Phase 3 Clinical Trials Evaluating the Safety and Efficacy of Zalviso in Obese Surgical Patients

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REDWOOD CITY, Calif., Nov. 4, 2015 /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 be presenting at ObesityWeek 2015 an analysis from three Phase 3 studies showing that Zalviso™ (sufentanil sublingual tablet system 15 mcg) provides a faster onset of pain relief in obese (BMI ≥ 30 kg/m^2) post-surgical patients than intravenous (IV) patient-controlled analgesia (PCA) with morphine. Specifically, patients who self-administered Zalviso experienced statistically significantly improved pain relief when compared to self-administered IV morphine as measured by pain intensity difference to baseline (PID). Significant differences in PID were observed as early as 45 minutes after the first dose ($p<0.05$), a trend that continued until six hours after the initial dose ($p<0.001$), after which time PID scores equilibrated between the two groups.

"Both of our lead products, Zalviso and ARX-04 (a double-strength dose of sublingual sufentanil 30 mcg administered by a nurse) benefit from sufentanil's lipophilic nature," said Dr. Pamela Palmer, AcelRx Co-founder and Chief Medical Officer. "Lipophilic, or fat-soluble drugs, typically produce rapid drug uptake from mucosal tissues into the plasma and then into the brain, promoting minimal delay between dosing and pain relief. Nurse-administered ARX-04 dosing is designed to address more short-term moderate-to-severe pain treatment. For 2 or 3-day inpatient stays, Zalviso allows patients to self-titrate regardless of body mass so they are able to achieve their individualized pain relief goals without the need for time-consuming dose-adjustments from hospital staff."

Results of the sub-group analysis presented by AcelRx also show that obese patients who administered Zalviso experienced statistically fewer adverse events than did those receiving IV PCA morphine. While overall adverse event rates were comparable, incidence rates of anemia, leukocytosis (increase in white blood cells), vomiting, hypoalbuminemia (decrease in albumin levels), hyponatremia (decrease in sodium levels), urinary retention and pruritus (itching) were all significantly lower in the Zalviso arm compared to the morphine arm ($p\leq0.05$).

Dr. Palmer continued, "We believe that the non-invasive route of administration of Zalviso and ARX-04 sets these drugs apart from analgesics requiring an IV line which can be associated with increased infection risk and decreased mobility. Obese postoperative patients suffer from an increased physiological risk, as well as difficult IV access, and we want to make every effort to keep these patients ambulatory in order to avoid post-operative complications, such as partial lung collapse, deep vein thrombosis, and pulmonary embolism."

Complete results titled "Efficacy and Safety of the Sufentanil Sublingual Tablet System (SSTS) in Class I and II Obese Patients: The Effect of BMI on Analgesic Response" will be presented during ObesityWeek 2015, being held in Los Angeles, CA, from November 2-6, 2015. ObesityWeek is a unique, international event with more than 5,200 attendees from 73 countries focused on the basic science, clinical application, surgical intervention and prevention of obesity. By combining both the American Society for Metabolic & Bariatric Surgery (ASMBS) and The Obesity Society (TOS) annual meetings, ObesityWeek brings together world-renowned experts in obesity to share innovation and breakthroughs in science unmatched around the globe.

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) 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 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. 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 and the Company is working with the FDA regarding the resubmission of the Zalviso NDA and initiation of a clinical study to support 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, 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 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 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 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 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.

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