



AcelRx Pharmaceuticals Reports Successful Outcome of ZALVISO Phase 3 IAP312 Study on Device Functionality

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**- Study Objective Achieved with 2.2% of Patients Experiencing a Device Error -
- AcelRx Remains on Track to Resubmit NDA by End of 2017 -**

REDWOOD CITY, Calif., Aug. 1, 2017 /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 key results from the Phase 3 IAP312 study of ZALVISO® (sufentanil sublingual tablet system), an investigational product candidate being developed for the management of moderate-to-severe acute pain in adult patients in a hospital setting. Throughout the study in 320 enrolled patients, 2.2% of patients experienced a ZALVISO device error, which was statistically less than the 5% limit specified in the study objectives. Importantly, none of these device errors resulted in an over-dosing event. This 2.2% rate was lower ($p < 0.001$) than the 7.9% rate of device errors during patient use previously reported for the earlier version of the ZALVISO device in the Phase 3 IAP311 study.

In addition, as requested by FDA, the IAP312 study prospectively evaluated the number of inadvertently misplaced tablets which occurred during patient dosing. A small number of inadvertently misplaced tablets (less than 0.1% of total dispensed tablets) was observed in the original Phase 3 studies. However, the presence of inadvertently misplaced tablets had not been routinely assessed as part of the previous protocols. The ZALVISO System allows patients to self-administer a 15 mcg sufentanil sublingual tablet as often as once every 20 minutes as needed for pain control. Throughout the IAP312 study, patients self-administered a total of 7,293 sufentanil tablets. Per the updated ZALVISO training instructions electronically displayed on the hand-held device, 6 patients called the nurse when they failed to properly self-administer a single tablet to allow for proper retrieval and disposal of the tablet. Also, during inspection by the nurse, which occurred every two hours per protocol, a total of 7 misplaced tablets (<0.1% of total dispensed tablets) were discovered with 6 additional patients. No patient had a repeat incidence of an inadvertently misplaced tablet following re-training on the device. This combination of patient training and nurse inspection, along with the tracking features of the ZALVISO device, could potentially address the FDA's concerns regarding drug accountability.

Finally, in this study, 86%, 89% and 100% of patients at the 24, 48 and 72-hour time points, respectively, recorded "good" or "excellent" ratings on the patient global assessment (PGA) of the method of pain control, which measures a patient's satisfaction with their quality of analgesia. Healthcare professional global assessment (HPGA) of the method of pain control was similarly strong, with 91%, 95% and 100% of nurses rating ZALVISO as "good" or "excellent" over each respective 24-hour period. ZALVISO was shown to be well tolerated by study participants, with nausea, hypotension and vomiting representing the most commonly reported adverse events. A total of 5 patients experienced serious adverse events, but all were considered unrelated to study drug by investigators.

Dr. Pamela Palmer, AcelRx co-founder and chief medical officer commented, "It is important that hospitalized patients suffering from moderate-to-severe acute pain have options for self-titrating their analgesic medications to target their individual pain levels. IAP312 demonstrated high levels of patient and nurse satisfaction with the ZALVISO System, which is both non-invasive and pre-programmed. Our expectation is that results from this IAP312 study will provide the FDA with a more complete picture of ZALVISO's functionality and usability. We intend to submit these results, together with our earlier Phase 3 studies - IAP309, IAP310 and IAP311, which met safety and efficacy endpoints as part of our resubmission of a New Drug Application to the FDA by the end of 2017."

In addition, Dr. Harold Minkowitz, a principal investigator in IAP312 as well as the previous ZALVISO Phase 3 trials, and an anesthesiologist at Memorial Hermann Memorial City Medical Center in Houston stated, "The pre-programmed nature of ZALVISO may help mitigate human factor-related errors associated with analgesic dosing that potentially increase morbidity and mortality. The highly favorable patient and HCP satisfaction scores reported for the entire study corroborate my patients' and staff's experience with the ZALVISO System. If approved, ZALVISO could provide physicians and patients a non-invasive, patient-controlled analgesia system for acute pain treatment in the hospital setting."

Conference Call

As previously announced, the company will hold an investment-community conference call on Tuesday, August 1, 2017 at 8:30 am Eastern Time (5:30 am Pacific Time) to discuss top-line results from the Phase 3 IAP312 study. The company also plans to discuss its financial results for the three and six months ended June 30, 2017. A separate press release regarding the company's financial results will also be issued prior to the scheduled call. Please note, this conference call and webcast will replace the previously announced financial results conference call that had been scheduled for August 2, 2017.

Investors who wish to participate in the conference call may do so by dialing (866) 361-2335 for domestic callers, (855) 669-9657 for Canadian callers or (412) 902-4204 for international callers. Those interested in listening to a webcast of the conference call live via the Internet may do so by visiting the Investors page of the company's website at www.acelrx.com and clicking on the webcast link on the Investors home page. The webcast will be archived on the AcelRx website for 90 days following the call.

About ZALVISO® (Sufentanil Sublingual Tablet System)

ZALVISO is a drug/device combination product designed to deliver 15 mcg of sufentanil, a high therapeutic index opioid formulated in a proprietary non-invasive sublingual dosage form, via a novel hand-held, pre-programmed, patient-controlled analgesia (PCA) system. ZALVISO is approved in the European Union where it is marketed by AcelRx's licensee, Grunenthal Group GmbH. ZALVISO remains an investigational product candidate in the United States.

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 moderate-to-severe acute pain. A New Drug Application (NDA) for DSUVIA™ (sufentanil sublingual tablet, 30 mcg), known as ARX-04 outside the United States, with a proposed indication for the treatment of moderate-to-severe acute pain in medically supervised settings, was accepted for filing by the United States Food and Drug Administration (FDA) and has been given a PDUFA date of October 12, 2017. In the EU, the European Medicines Agency (EMA) has notified the company that the ARX-04 (sufentanil sublingual tablet, 30 mcg) Marketing Authorisation Application (MAA) has passed validation and that the scientific review of the MAA is underway.

The company's product candidate, ZALVISO® (sufentanil sublingual tablet system), is designed for the management of moderate-to-severe acute pain in adult patients in the hospital setting. The company recently completed a Phase 3 clinical trial, IAP312, which included input from the FDA on the study protocol. This study was designed to evaluate the effectiveness of changes made to the functionality and usability of the ZALVISO device, to evaluate the incidence of inadvertent dosing, and to take into account comments from the FDA on the study protocol. AcelRx intends to resubmit the NDA for ZALVISO to the FDA by the end of the year. 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 and is investigational and in late-stage development in the United States. Grunenthal Group holds the rights for ZALVISO in Europe, where commercialization across multiple countries is underway.

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 ZALVISO® (sufentanil sublingual tablet system), including AcelRx's pathway forward towards gaining approval of ZALVISO in the United States, including the planned resubmission and timing of the ZALVISO NDA to the FDA; and the therapeutic and commercial potential of AcelRx's product candidates, including potential market opportunities for 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 the possibility that the FDA may dispute or interpret differently the results of the ZALVISO development program, including the results from the IAP312 clinical trial; the successful resubmission of the ZALVISO NDA to the FDA; any delays or inability to obtain and maintain regulatory approval of its product candidates, including ZALVISO in the United States; the uncertain clinical development process, including adverse events; the success, cost and timing of all development activities and clinical trials; the accuracy of AcelRx's estimates regarding expenses, capital requirements and the need for financing; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx's U.S. Securities and Exchange Commission filings and reports, including its latest Quarterly Report on Form 10-Q filed with the SEC on May 8, 2017 and other SEC filings. 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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