AcelRx Pharmaceuticals Reports Publication of Manuscript Analyzing Sufentanil Sublingual Tablets in Patients with Postoperative Pain

November 16, 2017

REDWOOD CITY, Calif., Nov. 16, 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 the publication of a manuscript analyzing sufentanil sublingual tablet 30 mcg for postoperative pain in the peer-reviewed journal, *Pain Medicine.* This manuscript reports on the results of a multicenter, open-label, single-arm study that evaluated moderate-to-severe acute postoperative pain in an older patient population, many with comorbidities, in nine hospitals across the United States. Conclusions of the study highlighted that sufentanil sublingual tablet 30 mcg was effective and well-tolerated for the management of moderate-to-severe acute pain following a variety of surgical procedures, including knee replacement, open-abdominal surgery and bunionectomy.

"Postoperative pain often remains clinically undermanaged and may lead to suboptimal outcomes for the patients," commented Dr. Jacob Hutchins, Assistant Professor in the Department of Anesthesiology at the University of Minnesota. "This study suggests that sublingual sufentanil could provide a non-invasive alternative to intravenous opioids for postoperative acute pain management across multiple surgery types and patient populations."

Details on the publications:
Hutchins J, Leiman D, Minkowitz H, Jove M, DiDonato K, Palmer P. An Open-Label Study of Sufentanil Sublingual Tablet 30 mcg in Patients with Postoperative Pain. *Pain Medicine*. 2017 Nov [Epub ahead of print].

About the Journal:
Pain Medicine is a multi-disciplinary journal dedicated to pain clinicians, educators and researchers with an interest in pain from various medical specialties such as pain medicine, anesthesiology, family practice, internal medicine, neurology, neurological surgery, orthopedic spine surgery, psychiatry, and rehabilitation medicine as well as related health disciplines such as psychology, neuroscience, nursing, nurse practitioner, physical therapy, and integrative health. This scholarly, indexed publication reflects the rapid growth in pain science and practice as well as the field's need for policy, ethical, and forensic commentary on pain and its management. Readers benefit from both cutting-edge original clinical and translational research and scientific reviews.

About DSUVIA™(Sufentanil Sublingual Tablet)
DSUVIA™ (sufentanil sublingual tablet, SST, 30 microgram), known as DZUVEO (formerly ARX-04) outside the United States, is designed to reduce moderate-to-severe acute pain and address dosing errors associated with IV administration via its non-invasive single-dose applicator (SDA) in medically supervised settings. Sufentanil is an opioid analgesic currently marketed for intravenous (IV) and epidural anesthesia and analgesia. The sufentanil pharmacokinetic profile when delivered sublingually potentially avoids the high peak plasma levels and short duration of action observed with IV administration. In the EU, the European Medicines Agency (EMA) has notified the company that the DZUVEO Marketing Authorization Application (MAA) is under scientific review.

Clinical and Rehabilitative Medicine Research Program (CRMRP)
DSUVIA™ is funded in part by the Clinical and Rehabilitative Medicine Research Program (CRMRP) of the U.S. Army Medical Research and Materiel Command (USAMRMC) under contract No. W81XWH-15-C-0046. The CRMRP was established in 2008 to foster research and technology advances for regeneration, restoration, and rehabilitation of traumatic injuries. In accordance with USAMRMC guidelines, in the conduct of clinical research, AcelRx has adhered to the policies regarding the protection of human subjects as prescribed by Code of Federal Regulations (CFR) Title 45, Volume 1, Part 46; Title 32, Chapter 1, Part 219; and Title 21, Chapter 1, Part 50 (Protection of Human Subjects).

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. AcelRx's proprietary, non-invasive sublingual formulation technology delivers sufentanil with consistent pharmacokinetic profiles. The company has two product candidates including DSUVIA™ (sufentanil sublingual tablet, 30 mcg), known as DZUVEO outside the United States, with a proposed indication for the treatment of moderate-to-severe acute pain in medically supervised settings, and ZALVISO® (sufentanil sublingual tablet system, SST system, 15 microgram) being developed as an innovatively designed patient-controlled analgesia (PCA) system for reduction of moderate-to-severe acute pain in medically supervised settings.

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, DSUVIA™ (sufentanil sublingual tablet, 30 mcg), known as DZUVEO outside the United States, and ZALVISO® (sufentanil sublingual tablet system), including evaluation of the CRL and AcelRx's plans for resubmission of the NDA for DSUVIA with the FDA. 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 AcelRx Pharmaceuticals' DSUVIA and DZUVEO development programs, including the EMA review of the DZUVEO MAA, and the possibility that EMA may dispute or interpret differently clinical results obtained from the DZUVEO Phase 2 and 3 studies; the possibility that the FDA may dispute or interpret differently the results of the

ZALVISO development program, the resubmission of the ZALVISO and DSUVIA NDAs to the FDA; any delays or inability to obtain and maintain regulatory approval of its product candidates, including DSUVIA in the United States, DZUVEO in Europe and ZALVISO in the United States; the uncertain clinical development process, including adverse events; the success, cost and timing of all development activities; 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 9, 2017. 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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