AcelRx Pharmaceuticals to Present at the 17th Annual ASRA Pain Medicine Meeting

November 14, 2018

REDWOOD CITY, Calif., Nov. 14, 2018 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (NASDAQ: ACRX), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the use in medically supervised settings, today announced an upcoming presentation at the 17th Annual Pain Medicine Meeting of the American Society of Regional Anesthesia and Pain Medicine (ASRA). The presentation is part of the Emerging Technology Moderated Poster session. ASRA's Annual Pain Medicine Meeting will take place November 15-17, 2018 in San Antonio, TX.

This presentation analyzes postoperative analgesic drug dosing in a multi-center, randomized open-label, parallel-group study comparing IV morphine sulfate to sufentanil sublingual tablets (SST). Over the first five hours, patient dosing in each treatment arm suggests that a single 15 mcg or 30 mcg tablet has the equivalent analgesic effect to approximately 2.5 mg or 5 mg of IV morphine, respectively.

Details on the presentation are as follows:

Title: IV Morphine Equivalence of the Sufentanil Sublingual Tablet Based on Dosing Analyses from a Phase 3 Active Comparator Trial (Moderated Poster #6012)

Authors: Timothy Melson, MD of Helen Keller Hospital; Harold Minkowitz, MD of the Memorial Hermann Memorial City Medical Center in Houston, TX; Jacob Hutchins, MD of University of Minnesota; and Pamela P. Palmer, MD, PhD and Karen DiDonato, MSN, RN of AcelRx Pharmaceuticals.

Date/Time: Friday, November 16, 2018; 10:30am-12:15pm CT

Location: Session MP-06a, Cibolo 4, JW Marriott San Antonio Hill Country

The American Society of Regional Anesthesia and Pain Medicine (ASRA) is one of the largest subspecialty medical societies in anesthesiology with nearly 5,000 members in 66 countries on 6 continents. For more information, please visit www.asra.com.

About DSUVIA™(sufentanil sublingual tablet, 30 mcg)

DSUVIA™, known as DZUVEO™ outside the United States, approved by the FDA in November 2018, is indicated for use in adults in a certified medically supervised healthcare setting, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. DSUVIA was designed to provide rapid analgesia via a non-invasive route and to eliminate dosing errors associated with IV administration. DSUVIA is a single-strength solid dosage form administered sublingually via a single-dose applicator (SDA) by healthcare professionals. Sufentanil is an opioid analgesic currently marketed for intravenous (IV) and epidural anesthesia and analgesia. The sufentanil pharmacokinetic profile when delivered sublingually avoids the high peak plasma levels and short duration of action observed with IV administration. The European Medicines Agency (EMA) approved DZUVEO for marketing in Europe in June 2018. For more information, please visit www.DSUVIA.com.

LIMITATIONS OF USE

Not for home use or for use in children. Discontinue treatment with DSUVIA before patients leave the certified medically supervised healthcare setting. Not for use for more than 72 hours. The use of DSUVIA beyond 72 hours has not been studied. Only to be administered by a healthcare provider.

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, reserve DSUVIA for use in patients for whom alternative treatment options [e.g., non-opioid analgesics or opioid combination products]: have not been tolerated, or are not expected to be tolerated, have not provided adequate analgesia, or are not expected to provide adequate analgesia.

The Full Prescribing Information for DSUVIA contains the following Boxed Warning:

WARNING: ACCIDENTAL EXPOSURE AND DSUVIA REMS PROGRAM: LIFE-THREATENING RESPIRATORY DEPRESSION; ADDICTION, ABUSE AND MISUSE; CYTOCHROME P450 3A4 INTERACTION; AND RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Accidental Exposure and DSUVIA REMS Program:
Accidental exposure to or ingestion of DSUVIA, especially in children, can result in respiratory depression and death. Because of the potential for life-threatening respiratory depression due to accidental exposure, DSUVIA is available only through a restricted program called the DSUVIA REMS Program. DSUVIA must only be dispensed to patients in a certified medically supervised healthcare setting. Discontinue use of DSUVIA prior to discharge or transfer from the certified medically supervised setting.

Life-Threatening Respiratory Depression:
Serious, life-threatening, or fatal respiratory depression may occur with the use of DSUVIA. Monitor for respiratory depression, especially during initiation of DSUVIA.

Addiction, Abuse, and Misuse:
DSUVIA exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess patient's risk before prescribing DSUVIA, and monitor all patients regularly for the development of these behaviors or conditions.

Cytochrome P450 3A4 Interaction:
The concomitant use of DSUVIA with cytochrome P450 3A4 inhibitors may result in an increase in sufentanil plasma concentrations, which could increase or prolong adverse drug reactions and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in sufentanil plasma concentration. Monitor patients receiving DSUVIA and any CYP3A4 inhibitor or inducer.

Risks From Concomitant Use With Benzodiazepines or Other CNS Depressants:
Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation.

IMPORTANT SAFETY INFORMATION
DSUVIA is contraindicated in patients with significant respiratory depression; acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; known or suspected gastrointestinal obstruction, including paralytic ileus; and known hypersensitivity to sufentanil or components of DSUVIA.

DSUVIA contains sufentanil, a Schedule II controlled substance. As an opioid, DSUVIA exposes users to the risks of addiction, abuse, and misuse. Potential serious adverse events caused by opioids include addiction, abuse, and misuse, life-threatening respiratory depression, neonatal withdrawal syndrome, risks of concomitant use or discontinuation of cytochrome P450 3A4 inhibitors and inducers, risks from concomitant use with benzodiazepines or other CNS depressants, risk of life threatening respiratory depression in patients with chronic pulmonary disease or in elderly, cachectic, or debilitated patients, adrenal insufficiency, severe hypotension, risks of use in patients with increased intracranial pressure or impaired consciousness, gastrointestinal disorders and seizure disorders. DSUVIA should be used with caution in patients with severe liver or kidney impairment.

For Important Safety Information including full prescribing information, visit: www.DSUVIA.com**.**

Clinical and Rehabilitative Medicine Research Program (CRMRP)
DSUVIA was 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 use in medically supervised settings. AcelRx's proprietary, non-invasive sublingual formulation technology delivers sufentanil with consistent pharmacokinetic profiles. The Company has one approved product in the U.S., DSUVIA (sufentanil sublingual tablet, 30 mcg), known as DZUVEO in Europe, indicated for the management of acute pain severe enough to require an opioid analgesic for adult patients in certified medically supervised healthcare settings, and one product candidate, Zalviso® (sufentanil sublingual tablet system, SST system, 15 mcg) being developed as an innovatively designed patient-controlled analgesia (PCA) system for reduction of moderate-to-severe acute pain in medically supervised settings. DZUVEO and Zalviso are both approved products in Europe.

For additional information about AcelRx, please visit www.acelrx.com.

View original content to download multimedia:http://www.prnewswire.com/news-releases/acelrx-pharmaceuticals-to-present-at-the-17th-annual-asra-pain-medicine-meeting-300750664.html

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