AcelRx Pharmaceutical's sufentanil sublingual tablet (DSUVIA) to be highlighted during a presentation at the Boswick Burn and Wound Symposium

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REDWOOD CITY, Calif., Jan. 31, 2019 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (NASDAQ: ACRX), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings, today announced a presentation about DSUVIA™ and its benefits will be part of the 41st Annual Boswick Burn and Wound Symposium. The symposium will take place February 2-7, 2019.

This presentation details current trends and challenges in emergency departments, including overcrowding and the shortage of intravenous opioids. Sufentanil sublingual tablet 30 mcg (DSUVIA ™) is highlighted as a non-invasive, effective and well-tolerated option for the management of moderate-to-severe acute pain in medically supervised settings.

"We are pleased to welcome this presentation highlighting DSUVIA at this year's Symposium, and are excited to learn more about this novel, non-invasive analgesic," said Paul Glat, MD, FACS, Chairman of the Boswick Burn and Wound Symposium. "DSUVIA has the potential to provide a significant benefit to hospitalized burn patients suffering from moderate-to-severe pain, especially during wound dressing changes."

"DSUVIA provides an innovative option not only to patients with burn injuries, but also patients with a variety of traumatic injuries presenting to the emergency department," said Michael Ritter, MD, FACEP, Chief of Emergency Medicine at Mission Hospital. "This non-invasive sublingual applicator can deliver sufentanil without the time and effort of starting an intravenous line, which may allow more efficient analgesic treatment and patient flow in hospitals, surgical centers and emergency departments."

DSUVIA 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. Please see the full Indication, Limitations of use and Important Safety Information, including the Boxed Warning below.

Details on the presentation are as follows:

Title: *Is That IV Necessary? Recent Advances in Acute Pain Management*
Presenter: Michael Ritter, MD, FACEP, Director of Medical Education, Emergency Department, Mission Hospital & CHOC Children's Hospital at Mission Viejo, CA
Date/Time: Wednesday, February 6, 2019 at 10:30 a.m.
Location: Wailea Beach Marriott – Maui, Hawaii

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. Zalviso is not approved in the U.S. For additional information about AcelRx, please visit www.acelrx.com.

About DSUVIA (sufentanil) sublingual tablet

Indications and Usage

DSUVIA 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.

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.

PLEASE SEE BELOW FOR THE IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

IMPORTANT SAFETY INFORMATION

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 Risk Evaluation and Mitigation Strategy (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 only available 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 healthcare setting.**

Life-Threatening Respiratory Depression
Serious, life-threatening, or fatal respiratory depression may occur with 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 each patient's risk prior to 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 all 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.**
- **Follow patients for signs and symptoms of respiratory depression and sedation.**

Contraindications
Use of 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
- Known hypersensitivity to sufentanil or components of DSUVIA.

Warnings and Precautions

- Accidental ingestion or exposure to even one dose of DSUVIA, especially in children, can result in respiratory depression and death due to an overdose of sufentanil.
- DSUVIA is for use in adult patients only in a certified medically supervised healthcare setting. Use of DSUVIA outside of this setting can increase the risk of accidental exposure in others for whom it is not prescribed, causing fatal respiratory depression. Discontinue use of DSUVIA prior to discharge or transfer from the certified medically supervised healthcare setting. DSUVIA is not for home or pediatric use.
- DSUVIA contains sufentanil, a Schedule II controlled substance. As an opioid, DSUVIA exposes users to the risks of addiction, abuse, and misuse.
- Profound sedation, respiratory depression, coma, and death may result from the concomitant use of DSUVIA with benzodiazepines or other CNS depressants (e.g., non-benzodiazepine sedatives/hypnotics, anxiolytics, tranquilizers, muscle relaxants, general anesthetics, antipsychotics, other opioids, alcohol). Because of these risks, reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate.
- Life-threatening respiratory depression in patients with chronic pulmonary disease or in elderly, cachectic and debilitated patients: monitor patients closely, particularly when initiating DSUVIA therapy and when DSUVIA is used with other drugs that depress respiration. Management of respiratory depression may include close observation, supportive measures, and use of opioid antagonists, depending on the patient's clinical status.

- A potentially life-threatening condition could result from concomitant serotonergic drug administration. Discontinue DSUVIA if serotonin syndrome is suspected. Cases of adrenal insufficiency have been reported with opioid use (usually > 1 month). Presentation and symptoms are non-specific and include nausea, vomiting, anorexia, fatigue, weakness, dizziness and low blood pressure. Confirm diagnosis with testing as soon as possible and, if confirmed, treat with physiologic replacement of corticosteroids and wean patient from opioid.
- As with all opioids, sufentanil may produce bradycardia or hypotension in some patients. Therefore DSUVIA should be used with caution in patients with bradyarrhythmias or hypovolemia.
- DSUVIA should not be used in patients who may be particularly susceptible to the intracranial effects of CO_2retention, such as those with evidence of increased intracranial pressure, impaired consciousness or coma.
- Prolonged use of DSUVIA during pregnancy can result in withdrawal in the neonate, which can be life-threatening. Observe newborns for signs of neonatal opioid withdrawal syndrome and manage accordingly. Advise pregnant women using opioids for a prolonged period of this risk and ensure that appropriate treatment will be available.
- Insufficient data are available on the use of DSUVIA in patients with severe liver or kidney impairment. DSUVIA should be used with caution in such patients due to the importance of these organs in the metabolism and excretion of sufentanil.

Adverse Reactions
Adverse reactions are described, or described in greater detail, in other sections of the Prescribing Information:

- Life-Threatening Respiratory Depression [see *Warnings and Precautions (5.3)*]
- Addiction, Abuse, and Misuse [see *Warnings and Precautions (5.4)*]
- Adrenal Insufficiency [see *Warnings and Precautions (5.9)*]
- Severe hypotension [see *Warnings and Precautions (5.10)*]
- Gastrointestinal Adverse Reactions [see *Warnings and Precautions (5.12)*]
- Seizures [see *Warnings and Precautions (5.13)*]
- Neonatal Opioid Withdrawal Syndrome [see *Warnings and Precautions (5.15)*]

The most commonly reported adverse reactions (≥ 2% and higher than placebo) were nausea, headache, vomiting, dizziness, and hypotension.

Medical Information
For medical inquiries or to report an adverse event, other safety-related information or product complaints for a company product, please contact the AcelRx Medical Information Contact Center at 1-855-925-8476 or AcelRxMedInfo@rmpdc.org.
You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see full Prescribing Information and Directions For Use.

View original content to download multimedia:http://www.prnewswire.com/news-releases/acelrx-pharmaceuticals-sufentanil-sublingual-tablet-dsuvia-to-be-highlighted-during-a-presentation-at-the-boswick-burn-and-wound-symposium-300787332.html

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