



AcelRx Pharmaceuticals Announces Publication of Clinical Data on Decreased Postoperative Opioid Requirements and Enhanced Postanesthesia Recovery Following Perioperative Use of DSUVIA®

Dec 10, 2020

REDWOOD CITY, Calif., Dec. 10, 2020 /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 the publication by the *Journal of Universal Surgery* of clinical data on the use of DSUVIA for acute perioperative pain management.

The article entitled "A Medication Use Evaluation of Sufentanil Sublingual Tablet 30 mcg for the Perioperative Management of Surgical Pain" by lead author Koth Cassavaugh, PharmD, Director of Pharmacy, reports that perioperative dosing of the sublingual sufentanil tablet 30 mcg (SST; DSUVIA) can provide enhanced postanesthesia care unit (PACU) recovery compared to standard intravenous (IV) opioid administration. The evaluation was conducted at Auburn Community Hospital, Auburn, NY, and included 298 patients in a perioperative setting undergoing a wide variety of inpatient and outpatient procedures including abdominal, orthopedic, gynecologic, genitourinary, otolaryngologic and spinal surgeries.

The evaluation focused on 140 patients who were dosed with SST 30 mcg compared to 158 patients who had been dosed with traditional IV opioids during the same time period undergoing the same surgical procedures. Key findings included the following:

- Intraoperative IV opioid use – patients in the control group overall received 66% higher mean dosing of intraoperative IV opioids compared to patients receiving SST ($p<0.001$).
- Postoperative opioid use – the mean opioid requirement of the SST group was less than half of the control group ($p<0.001$), with orthopedic surgery patients having the largest decrease (69%).
- PACU time to discharge – Phase 1 recovery time in the PACU was reduced by an average of 14 minutes across patients in the SST group compared with the control group ($p<0.001$), with the largest decrease in recovery time observed among abdominal surgery patients (23 minutes; 25% reduction).
- Respiratory depression – 3 patients in the control group required naloxone use for respiratory depression whereas no patients in the SST group required naloxone use.

The authors concluded that overall, SST dosed preoperatively or intraoperatively, significantly reduced both PACU opioid dosing requirements and Phase 1 unit discharge time compared to control patients receiving standard IV opioids intraoperatively. SST was well tolerated with no significant adverse events. In addition, the authors noted that decreasing discharge time per patient can have a substantial financial impact when multiplied over thousands of patients each year taking into account surgical throughput inefficiency that congestion in the PACU creates. Study limitations include that it was a single-center, retrospective study of SST dosing in a surgical patient population and both inpatient and outpatient surgery data was combined. The study did not control for whether patients were opiate naïve or opiate tolerant in the treatment groups, however, there is no reason for these patients to be present at a substantially higher frequency in either group. AcelRx did not provide funding for the conduct of the evaluation but did fund medical writing support. AcelRx did not provide any compensation to the authors for the evaluation. Dr. Cassavaugh is a paid consultant of AcelRx.

"We are thrilled this clinical data supports DSUVIA as a well-tolerated and effective pain management solution across a wide variety of both inpatient and outpatient surgical procedures, and also indicates shorter patient recovery time and economic benefits for hospitals," said Dr. Pamela Palmer, AcelRx Chief Medical Officer and co-founder. "Importantly, the findings of reduced overall IV opioid use and PACU discharge time are consistent with other recently published clinical data on the use of DSUVIA in the perioperative environment."

About DSUVIA (sufentanil sublingual tablet), 30 mcg

DSUVIA®, known as DZUVEO™ in Europe, approved by the FDA in November 2018, is indicated for use in adults in certified medically supervised healthcare settings, 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 intravenous (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 previously only marketed for 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 Commission approved DZUVEO for marketing in Europe in June 2018 and the Company is currently in discussions with potential European marketing partners. This release is intended for investors only. For more information, including important safety information and black box warning for DSUVIA, please visit www.DSUVIA.com.

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. AcelRx 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), an investigational product in the U.S., is 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.



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SOURCE AcelRx Pharmaceuticals, Inc.

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