



Study of DSUVIA® Showing Significant Reduction in Postoperative Opioids and Better OBAS Scores Compared to Control Group to be Presented at the American Society of Regional Anesthesia (ASRA) Annual Meeting

May 13, 2021

HAYWARD, Calif., May 13, 2021 /PRNewswire/ -- AcclRx Pharmaceuticals, Inc. (Nasdaq: ACRX), (AcclRx), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in a medically supervised setting, today announced a poster presentation at the 46th Annual Regional Anesthesiology and Acute Pain Medicine Meeting reviewing the results of a study on the intraoperative administration of DSUVIA (sufentanil sublingual tablet; SST) 30 mcg for the management of acute pain in an ambulatory surgery center. The primary objective of this study was to determine if SST 30 mcg given prior to emergence from anesthesia was efficacious in reducing initial post anesthesia care unit (PACU) pain scores compared to a control group. Secondary outcomes included opioid use and percentage of patients opioid free in PACU, and time until ready to discharge.

The study was a prospective, randomized, controlled trial conducted at an ambulatory surgery center with patients aged 18-80 undergoing orthopedic surgery under general anesthesia. A total of 50 patients were included in the final analysis. There were no significant differences in baseline characteristics or duration of surgery between the two groups. The pain score on arrival to PACU was not significantly different between either group. However, patients in the SST group required 50% less opioids in the PACU ($p=0.018$), with significantly more of them opioid-free (36% vs 8%; $p=0.037$). Furthermore, SST-treated patients had improved overall benefit of analgesia scores (OBAS) compared to the control group ($p=0.006$). OBAS is a validated 7-item tool that assesses pain intensity, adverse effects and patients' satisfaction with analgesia.

The authors concluded that while SST 30 mcg administered intraoperatively did not affect patients' pain scores on arrival to PACU, patients that received SST did show improvement in PACU opioid requirements and OBAS scores, with more of them opioid-free in the PACU. The authors stated that the most compelling result of this study was the significant difference in OBAS and percent of opioid-free patients in the SST group, reflecting greater patient satisfaction with SST, which is more meaningful than a single pain score assessed at any given point in time. Objectively, the higher patient satisfaction was supported by the significantly lower rescue opioid requirement observed in the SST group. Limitations of the study include that the SST was not compared to an active comparator, in that it did not allow for preemptive opioid analgesia in the control group. Also, as the data collection ended at discharge, the authors were unable to assess any additional analgesic benefit of SST beyond the immediate postoperative period.

Details of the presentation and the link to the poster is as follows: <https://epostersonline.com/ASRASPRING21/node/694?view=true>

Title: *Intraoperative sublingual sufentanil for acute pain in the ambulatory surgery center*

Date & Time: Thursday, May 13, 2021; 10:30am-12:00pm ET

Location: Disney's Yacht & Beach Club, Lake Buena Vista, FL

Presenter: Justin A. Mottaghi, MD

One of the investigators of the study is a paid consultant for AcclRx but was not compensated for this study.

About DSUVIA (sufentanil sublingual tablet), 30 mcg

DSUVIA®, known as DZUVEO® in Europe, 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 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 AcclRx Pharmaceuticals, Inc.

AcclRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings. AcclRx'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), 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 AcclRx, please visit www.acclrx.com.



[in-postoperative-opioids-and-better-obas-scores-compared-to-control-group-to-be-presented-at-the-american-society-of-regional-anesthesia-asra-annual-meeting-301290765.html](https://www.asra-anesthesia.org/in-postoperative-opioids-and-better-obas-scores-compared-to-control-group-to-be-presented-at-the-american-society-of-regional-anesthesia-asra-annual-meeting-301290765.html)

SOURCE AcelRx Pharmaceuticals, Inc.

Investor Contacts - Raffi Asadorian, CFO, AcelRx, investors@acelrx.com