



AcelRx Pharmaceuticals Announces Presentation of Investigator-Initiated Trial Results Comparing AcelRx's Sufentanil Sublingual Tablet (SST) Versus Intravenous Opioids for Postoperative Pain at the ANESTHESIOLOGY® Annual Meeting 2022

Oct 26, 2022

Brigham and Women's Hospital study found that SST-treated patients had significantly lower pain scores in the post-operative care unit (PACU) compared with patients in the two intravenous opioid control groups following major spine surgery

HAYWARD, Calif., Oct. 26, 2022 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), (AcelRx), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings, today announced that the results of a 190-patient, investigator-initiated trial conducted at Brigham and Women's Hospital in Boston, MA, entitled, "The Impact of Sublingual Sufentanil on Postoperative Pain Control in Patients Undergoing Spine Surgery" (abstract # A4262), was presented at the ANESTHESIOLOGY® 2022 annual meeting, held October 21-25, 2022 in New Orleans, LA. The study found that patients who underwent major spine surgery had significantly lower reported postoperative pain scores when treated with sufentanil sublingual tablet (SST), 30 mcg (DSUVIA®) versus intravenous (IV) opioids.

The senior author of the study was Richard Urman M.D., Associate Professor and Founding Co-Director, Center for Perioperative Research, Department of Anesthesiology at Brigham and Women's Hospital. The study was an Institutional Review Board (IRB)-approved, prospective trial comparing an SST-treated cohort (n=30) with a two-arm (n=80 each) historical matched control. Study inclusion criteria consisted of patients 18 years or older undergoing spine surgery (up to 3 levels) and a planned inpatient stay. Both the prospective arm and two retrospective control arms received standard general anesthetic, except the prospective SST arm received intraoperative sufentanil IV infusion and an initial dose of SST immediately following extubation. SST was re-dosed as needed, no more than hourly, in the postoperative care unit (PACU) for numeric rating scale (NRS) pain scores of greater than 3 out of 10. Hydromorphone IV bolus was used for breakthrough pain not controlled by SST. Control Arm 1 received intraoperative remifentanyl IV infusion and Control Arm 2 received intraoperative sufentanil IV infusion and both received hydromorphone IV bolus as the primary analgesic in the PACU as needed for NRS scores of greater than 3. A multi-variable linear regression adjustment and an inverse probability of treatment weighting was used to measure the effectiveness of SST in decreasing postoperative pain scores in the PACU as the primary outcome.

A total of 190 patients were analyzed and demographics were relatively similar among the groups. As a result of the linear regression model, adjusting for age, sex, BMI, ASA classification, surgical invasiveness, and medication history, the authors found that patients in the study group who received SST experienced statistically significantly lower pain scores in the PACU compared with the two IV opioid control groups ($p < 0.001$). The SST group had a mean $\pm$ standard deviation NRS score of 3.2 ± 2.4 , whereas the remifentanyl/hydromorphone group averaged an NRS score of 5.7 ± 2.2 and the sufentanil/hydromorphone group averaged an NRS score of 5.0 ± 2.4 .

The authors concluded that use of SST appears to be an effective alternative analgesic therapy in spine surgery patients who experience moderate to severe postoperative pain resulting in improved pain scores in the PACU, and, that further analysis of the data will examine the impact on postoperative opioid consumption and hospital length of stay.

"The dramatic difference in PACU pain scores reported after major spine surgery is impressive," said Dr. Pamela Palmer, co-founder and Chief Medical Officer of AcelRx, who provided funding for the study. "Remifentanyl and sufentanil are often used as infusions intraoperatively during spine surgery due to their high therapeutic index and rapid clearance, but they are too short-acting to administer as IV boluses in the PACU. Therefore longer-acting IV opioids such as hydromorphone are often used in recovery, but they suffer from a lower therapeutic index, slower blood/brain equilibration and active metabolites, which are associated with delayed adverse events. This study demonstrates the utility of administering sufentanil sublingually to provide an optimal opioid analgesic via a route that allows a significant duration of action, providing significantly better analgesia during the recovery period."

E-Abstracts were presented virtually and made available to registrants throughout the entire meeting from Saturday, October 22 (7:00 a.m. US Central Time) through Tuesday, October 25, 2022 (3:00 p.m. U.S. Central Time). The abstracts remain available and open to meeting attendees for three months after the meeting.

About the ANESTHESIOLOGY 2022 Annual Meeting

The ANESTHESIOLOGY Annual Meeting is the annual meeting for the American Society of Anesthesiologists®. Founded in 1905, the American Society of Anesthesiologists is an educational, research and scientific association of [physicians](#) organized to raise the standards of the medical practice of [anesthesiology](#) and to improve patient care. As of 2021, the organization included more than 55,000 national and international members.

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. DZUVEO has been approved by the European Medicines Agency and AcelRx's European commercialization partner, Aguettant, will market the drug in Europe.

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. 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 several product candidates. The product candidates include: Zalviso® (sufentanil sublingual tablet system, SST system, 15 mcg), an investigational product in the U.S. being developed as an innovatively designed patient-controlled analgesia (PCA) system for reduction of moderate-to-severe acute pain in medically supervised settings; two pre-filled, ready-to-use syringes of ephedrine and phenylephrine licensed for the U.S. from Aguetant; Niyad™, a regional anticoagulant for the extracorporeal circuit; and LTX-608, for the potential treatment of COVID-19, disseminated intravascular coagulation, acute respiratory distress syndrome and acute pancreatitis. DZUVEO is an approved product in Europe.

This release is intended for investors only. For additional information about AcelRx, please visit www.acelrx.com.



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