



AcelRx Pharmaceuticals Announces Publication of Clinical Data Showing Reduced Hospital Length of Stay and Reduced Opioid Utilization with Use of Sublingual Sufentanil in Total Joint Replacement Surgery

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HAYWARD, Calif., Dec. 15, 2021 /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 of real-world data in patients undergoing total hip or total knee replacement showing decreased hospital length of stay and decreased opioid utilization following administration of sublingual sufentanil to manage acute pain compared to standard IV opioids. The article was published in the *Journal of Orthopaedic Experience and Innovation*.

The article entitled "Reduced opioid use and hospital stay in patients undergoing total knee or total hip arthroplasty when treated with sublingual sufentanil compared with standard analgesic care" was co-authored by Dr. Lawrence Wiesner and Dr. Christian Tvetenstrand from the United Health Services Orthopedic Center in Vestal, New York and Southern Tier Surgical Clinic in Johnson City, New York. The study prospectively evaluated patients who were administered a single sufentanil sublingual tablet 30 mcg (SST; DSUVIA®) in the perioperative period and compared these patients to matched historical control patients receiving standard IV opioids. The outcomes assessed were the overall amount of opioids administered throughout the hospital stay (calculated as morphine milligram equivalents), the patient length of stay, and patient disposition at discharge.

A total of 110 patients were evaluated, with 53 patients prospectively treated with SST and 57 patients in the historical comparator group. Patient demographics, anesthesia techniques and type of surgery were similar between the groups. Patients in both groups averaged over 65 years of age and almost 50% had severe systemic disease, defined as Physical Status III by the American Society of Anesthesiologists.

Key findings included the following:

- The SST group utilized approximately 30% less total morphine milligram equivalents throughout their stay (17.8 ± 2.4 vs 25.0 ± 3.3 for control patients [$P < .05$]).
- Hospital length of stay was approximately 30% shorter for the SST group (0.87 ± 0.12 vs 1.23 ± 0.16 nights [$P < .05$]).
- In the control group, 9 patients (15.8%) were discharged to a skilled nursing facility compared to none in the SST group ($P < .01$). Their average hospital length of stay was 3.3 ± 0.8 nights prior to discharge to the facility and the average morphine milligram equivalent was 49.1 ± 14.6 , almost 3-fold higher than the SST group.

Study limitations include that the control group was a historical cohort, however, both groups received surgery during the COVID pandemic of Summer 2020 and anesthetic techniques, analgesic protocols and discharge criteria were identical between the two groups with the exception of the dosing of SST. Another limitation is that only a single SST dose was evaluated, and it is unclear if additional reductions in opioid utilization might be attained if a second or third dose was utilized over the duration of the patient's postoperative stay.

"The results from this study showing less overall opioid utilization and more rapid discharge following joint replacement are impressive, especially given the fact that only a single dose of DSUVIA was administered. We used to routinely get calls from the floor nurses the day of surgery when the spinal anesthetic had worn off with patients having rebound pain, but those calls immediately diminished following the adoption of DSUVIA into our current practice," states lead author Dr. Wiesner. "The joint replacement patients are older and have many comorbidities, therefore it is advantageous to utilize an opioid that not only provides rapid analgesia with initial dosing, but also has a low peak plasma concentration, a high therapeutic index, and a 13-hour terminal half-life allowing lower postoperative opioid requirements and a faster discharge," continues Dr. Wiesner.

"While Dr. Wiesner and his colleagues practice state-of-the-art multimodal analgesia in their total joint program, by using SST they were able to even further reduce their reliance on IV opioids in the perioperative setting" said Dr. Pamela Palmer, AcelRx Chief Medical Officer and co-founder. "The positive effect this had on patient length of stay and avoiding discharge to a nursing facility is an important clinical outcome for this patient population. Real-world studies continue to show that SST is well tolerated by the older patient population that generally undergoes these total joint procedures," states Dr. Palmer.

Dr. Wiesner is not a paid consultant for AcelRx. Dr. Tvetenstrand is a paid consultant for AcelRx but was not compensated for this study. AcelRx did not provide funding for the conduct of the study but did fund medical writing support.

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 it will be commercialized by AcelRx's European partner, Aguetant.

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, and two pre-filled, ready-to-use syringes of ephedrine and phenylephrine licensed for the U.S. from Aguettant. DZUVEO and Zalviso are both approved products in Europe.

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



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