



AcelRx Pharmaceuticals Announces Publication of Clinical Data on the Use of Sufentanil Sublingual Tablet during Awake Plastic Surgery Procedures

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Study concluded that awake plastic surgery procedures can be performed using sublingual sufentanil tablet (30 mcg) with minimal side effects and a rapid recovery time

HAYWARD, Calif., Feb. 1, 2022 /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 awake plastic surgery showing a rapid recovery time and minimal side effects with the use of sufentanil sublingual tablet (SST) for pain management.

The article entitled "Awake Plastic Surgery Procedures: The Use of a Sufentanil Sublingual Tablet to Improve Patient Experience" was authored by Dr. Hisham Seify from Newport Plastic Surgery in Newport Beach, California and published in *Aesthetic Surgery Journal Open Forum* with an accompanying video as supplemental material. The study was a prospective single cohort study conducted at his center. Following oral antiemetic prophylaxis with ondansetron, SST was administered approximately 30 minutes prior to the procedure followed by local anesthetic infiltration depending on the procedure. Outcome measures included the number of patients requiring medications during the procedure or in the post-anesthesia care unit (PACU), recovery time and adverse events.

A total of 31 patients were enrolled, including 28 females and 3 males ranging in age from 23-71 years, with an average age of 47 years. The most common procedures were liposuction (71%), facelift (10%), and blepharoplasty (6%) and the mean procedural duration was 81 minutes.

Key findings from the study included:

- All 31 patients completed the plastic surgery procedures successfully without disruption from inadequate analgesia
- No additional analgesics (aside from SST and local anesthetic infiltration) were provided intraoperatively or in the PACU (post anesthesia care unit) for pain
- The average recovery time was 15 ± 4 minutes
- Patient vital signs were stable during the procedures and in recovery, and there was no oxygen desaturation observed and no supplemental oxygen required
- Three patients experienced nausea, only one of which required treatment with oral ondansetron 4 mg in the PACU, and one patient experienced dizziness

Study limitations include that there was a small sample size evaluated, and there was no control group of patients. Data collection is ongoing to examine outcomes in a larger number of patients.

"Awake plastic surgery has advantages including patient preference, affordability, and easier recovery compared to when performed under deeper sedation. Commonly used oral analgesics are often not adequate to provide sufficient analgesia for these procedures. The results from this study illustrate how administering a single dose of SST 30 minutes prior to awake plastic surgery procedures can provide effective pain management with a low rate of adverse events, especially no excessive sedation or impairment of cognitive function in the PACU that would delay discharge," said Dr. Hisham Seify. "The patients' pain was well managed, and they were able to leave the surgery center on average approximately 15 minutes after the procedure. The patients were very pleased with their rapid recovery time. This sublingual analgesic with a rapid onset of action has a side-effect profile consistent with the criteria for minimal sedation and is an important addition to my protocol for awake plastic surgery procedures."

"Published real-world studies continue to demonstrate that DSUVIA® is well tolerated and provides benefits to patients and physicians across various perioperative settings," stated Dr. Pamela Palmer, AcelRx Chief Medical Officer and co-founder. "We look forward to seeing the results of the multiple ongoing studies currently being performed that will provide more real-world evidence of how DSUVIA is being utilized."

Dr. Seify 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; 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 and Zalviso are both approved products in Europe.

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

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