AcelRx Pharmaceuticals Announces Publication of Results from an Investigator-Initiated Trial on Sufentanil Sublingual Tablet (SST) Compared to Standard Intravenous Opioids during Plastic Surgery Procedures Performed under General Anesthesia

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Study found that SST lowered the opioid dose required by patients in the post-anesthesia care unit (PACU) by more than five-fold compared to standard intravenous opioid administration

HAYWARD, Calif., May 10, 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 clinical data from an investigator-initiated trial in patients undergoing lengthy plastic surgery procedures performed under general anesthesia, where use of a single sufentanil sublingual tablet 30 mcg (SST; DSUVIA®) in conjunction with intravenous (IV) opioids was able to dramatically reduce postoperative opioid requirements compared to an equivalent dose of opioids administered only via the IV route.

The article entitled, "Sufentanil sublingual tablet reduces postoperative opioid use following outpatient plastic surgery," was published by the *Aesthetic Surgery Journal Open Forum* as an original article and was authored by Dr. Hisham Seify from Newport Plastic Surgery in Newport Beach, California. The study was a retrospective chart review of patients (n=61) receiving a single 30 mcg SST 30 minutes prior to surgery (for shorter procedures) or 45 minutes prior to surgical extubation (longer procedures). A control group (n=32) underwent similar surgical procedures utilizing standard IV opioid treatment without SST. Outcome measures included PACU opioid use, adverse events, and recovery time compared to traditional IV opioid drug regimens.

The demographics were similar between the two groups with over 90% of patients being female. Average age was 46.1 ± 13.4 in the SST group and 44.1 ± 9.6 in the control group. The most common surgical procedures performed in both groups were bilateral breast augmentations or reductions, often combined with an additional procedure (e.g., liposuction and/or abdominoplasty). There was a trend for procedure duration to be slightly longer for controls (3 hours and 12 minutes) than for the SST group (2 hours and 40 minutes); (P=0.10). As a result, duration of surgery was used as a covariate for subsequent analyses comparing morphine milligram equivalent (MME) opioid administration between the SST and control groups.

Key findings from the study included:

- 92% of SST patients received the dose prior to extubation due to the large proportion of lengthy cases that were performed.
- Almost all control patients (90.6%) required rescue opioids during recovery in the PACU as compared to significantly fewer SST patients (16.4%); (P<0.001).
- While there was no difference in total intraoperative opioid administration between the groups, the average postoperative MME in the PACU was 3.60 ± 2.65 mg for the control group versus over 5-fold lower (0.64 ± 2.31 mg) for the SST group (P<0.001).
- All patients received prophylactic antiemetics, however, 9.4% of patients in the control group required additional antiemetics due to nausea in the PACU, whereas only 1.6% of SST patients required an antiemetic in the PACU.
- Time to discharge was similar, being slightly under an hour in both groups, and not driven by assessment of pain management and/or adverse events. Instead, the actual discharge time was based on standard nursing routines and availability of patient transport.

Study limitations include that it was a chart review and not a prospectively designed, randomized study. In addition, no pain scores or readiness for discharge assessments were performed, which could have been used to assess the potential of SST to facilitate a timelier discharge.

"The vast majority of cosmetic surgical cases are outpatient procedures and patients who are having three- to four-hour surgeries must quickly recover in order to be discharged home," said Dr. Hisham Seify. "Replacing the last intraoperative dose of IV opioids with an equivalent dose of SST dramatically decreased the need for recovery opioids in the PACU, as shown by our study results. Since our PACU protocol was standardized, we didn't observe a more rapid time to discharge in this retrospective study. However, based on these findings, we now know to have our nurses expedite the discharge paperwork for SST-treated patients and tell family members to be ready sooner to drive the patient home," continued Dr. Seify.

"Multiple perioperative studies have now been published demonstrating the ability of DSUVIA® to dramatically reduce opioid requirements in the postoperative period compared to standard IV opioids," stated Dr. Pamela Palmer, AcelRx Chief Medical Officer and co-founder. "Based on standard clinical guidelines, every time an IV opioid is administered in the PACU, the discharge clock is restarted. We also know that increased opioid administration increases the risk of nausea and vomiting, which is one of the top reasons for delayed post-surgical discharge. The adoption of DSUVIA is gaining momentum as physicians are seeing these documented clinical advantages," continued Dr. Palmer.

Note of disclosure: Dr. Seify is a paid consultant for AcelRx and the company provided funding for this study as an investigator-initiated trial.

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, including the following: 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 Aguettant; Niyad™ (nafamostat), 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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