AcelRx Pharmaceuticals Announces Publication of Results from a Clinical Study Assessing Use of Sufentanil Sublingual Tablet for Painful Radiofrequency Microneedling Procedures

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Study results show higher rates of successful procedure completion and higher patient and clinician satisfaction scores compared to topical local anesthesia alone

HAYWARD, Calif., March 31, 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 a study evaluating the use of a sufentanil sublingual tablet (SST) 30 mcg for management of pain of radiofrequency ("RF") microneedling of the face or abdomen. The article entitled "Novel Sublingual Analgesic Improves Patient Tolerance of Face and Body Radiofrequency Microneedling: A Split Face/Abdomen Study" was lead authored by Dr. Talon Maningas and published in the journal *American Journal of Cosmetic Surgery*. Dr. Maningas is a nationally recognized cosmetic surgeon and is certified by the American Board of Cosmetic Surgery, the American Board of Facial Cosmetic Surgery, and the American Osteopathic Board of Otolaryngology.

The study was a prospective, open-label, controlled study at two clinical sites comparing topical local anesthetic alone (control side) to topical local anesthetic plus SST 30 mcg administered 30 minutes prior to initiation of the RF microneedling to the face or abdomen (SST-treated side). The study was a one-way crossover "split" face or abdomen study, meaning one treatment was performed on one side of the face or abdomen and the other treatment on the opposite side, allowing patients to act as their own control. Outcome measures included percent of patients successfully completing the full treatment with prespecified needle depth and RF energy settings, Richmond Agitation-Sedation Scale (RASS) scores which objectively assesses patients' level of agitation or sedation, patient and clinician satisfaction scores, as well as vital signs and adverse events.

A total of 51 patients were evaluated across both sites with 26 patients undergoing RF microneedling of the face and 25 patients undergoing the procedure on the abdomen. The results from the study are as follows:

- Whereas only 45% of patients successfully completed the procedure on their control side, 96% of patients successfully completed the procedure on their SST-treated side ($p < 0.001$).
- Patients were less restless or agitated during the SST-treated side procedure (6% restless or agitated) compared to during the control-side procedure (51% restless or agitated) as measured using the RASS scoring system; $p < 0.001$).
- Patient-reported satisfaction with pain control improved significantly with the SST-treatment side procedure as compared to the control-treated side procedure ($p < 0.001$).
- Clinician (provider) satisfaction with the comfort level of the patient also improved significantly for the SST-treated side compared to the control side ($p < 0.001$).
- Vital signs remained stable with SST treatment compared to the control side and no patient required supplemental oxygen. Nausea and vomiting (each 5.9%) and dizziness (2%) occurred only after the procedure was completed on both sides and symptoms resolved with treatment in the recovery room.

Study limitations include the open-label design and, due to the half-life of SST, the study was performed as a one-way crossover from topical local anesthetic only to topical local anesthetic plus SST.

"RF microneedling is a minimally invasive cosmetic procedure, but at the most effective clinical settings it can be painful for many patients, making tolerance difficult," said Dr. Maningas. "Prior to adopting DSUVIA® in our practice we would either have to reduce the energy settings, yielding less effective results, or perform more invasive anesthesia measures. I now use DSUVIA as a standard of care for my RF microneedling procedures which allows for more patient comfort, a better cosmetic outcome and saves time in our busy practice. While the study showed a low rate of nausea and vomiting, we now pre-treat with an oral antiemetic and rarely see these side effects."

"We have heard repeated physician feedback over the past few years that DSUVIA is significantly improving patient comfort during painful cosmetic procedures, but this is the first prospective, controlled study demonstrating statistically significant superiority over a traditional analgesic regimen," stated Dr. Pamela Palmer, AcelRx Chief Medical Officer and co-founder. "If patients are suffering from pain so severe that it can limit the effectiveness of a procedure, this has to be acknowledged and remedied. DSUVIA provides an effective alternative approach to managing acute pain in these cosmetic procedural suites that can avoid reliance on more complicated methods, such as the use of nerve blocks or IV sedation."

AcelRx did not provided funding for the conduct of the study and no authors were consultants for AcelRx throughout the study conduct. Since acceptance of manuscript for publication, Dr. Maningas has received funding for consulting work from AcelRx.

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, Aguettant.

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™(nafamostat mesylate), 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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Investor Contacts: Raffi Asadorian, CFO, AcelRx, 650-216-3500, investors@acelrx.com