AcelRx Pharmaceuticals Announces Peer-Reviewed Publication On the Use of DSUVIA® For In-Office Rhinology Procedures

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Study is the first to report on the use of DSUVIA® in the rapidly growing field of rhinology where otolaryngologists are performing painful nasal and sinus procedures in the office which were historically conducted only in ambulatory surgery centers or hospitals

HAYWARD, Calif., March 1, 2023 /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 the publication of a report arising from a series of rhinology procedures successfully performed using sufentanil sublingual tablet 30 mcg (SST; DSUVIA) in *Otolaryngology Case Reports*. The study was lead-authored by otolaryngologist Dr. Ashley Sikand and entitled "Evaluation of Sufentanil Sublingual Tablet 30 mcg for Perioperative Pain Management of In-Office Rhinology Procedures."

The single-center, prospective, case series study was conducted at the Ear, Nose and Throat Consultants of Nevada in Las Vegas, NV and evaluated a total of 77 patients with respect to quality of perioperative pain management in patients undergoing a combination of rhinology procedures. Patients ranged in age from 22 – 73 years of age with the majority classified as American Society of Anesthesiologists (ASA) Physical Status 1 or 2 (healthy or mild systemic disease), and only 8% classified as ASA 3 (severe systemic disease). Most patients underwent a combination of procedures including balloon sinuplasty, submucosal resection of inferior turbinates and septoplasty. Patients were premedicated with oral lorazepam 1-2 mg to decrease anxiety followed by oral ondansetron 4 mg as a prophylactic antiemetic. SST 30 mcg was then administered sublingually. Throughout this preoperative period, topical and infiltrated local anesthetic was applied to the nasal cavity. The procedures ranged in duration from 30 to 90 minutes. Patients were comfortable throughout the procedure and no patient required additional dosing of analgesics. The authors reported that the prolonged analgesic tail produced by the 13-hour half-life of SST allowed patients to utilize fewer oral opioids once they were home.

Vital signs and oxygen saturation were monitored during the procedures and there was no incidence of vital sign instability and no supplemental oxygen was required, although oxygen and reversal agents were available if needed. One patient experienced nausea and two patients experienced vomiting after the procedures were completed.

"We are now routinely performing complex rhinology procedures in our office procedural suite and, while local anesthetics are the mainstay of analgesia for these procedures, certain patients need additional opioid-level analgesia for acute pain management," stated Dr. Sikand. "Administering DSUVIA sublingually in combination with anesthetizing the nasal cavity allows a rapid and profound analgesia that extends throughout the duration of the procedure. Patients are alert enough to respond to questions but are very comfortable throughout these procedures as well as during the transition home, improving the overall patient experience. DSUVIA has increased both physician and staff satisfaction as well as patient satisfaction with the level of analgesia during these procedures."

"Office-based rhinology is a rapidly growing field that allows patients and physicians to avoid the more costly and inconvenient ambulatory surgery centers and hospitals. The only limitation to the office-based approach is patient tolerability of these painful procedures," stated Dr. Pamela Palmer, Founder and Chief Medical Officer of AcelRx. "Dr. Sikand is a leader in this field, having developed and taught these surgical protocols for the past decade. We are excited that DSUVIA can help patients manage acute pain during rhinology surgery in an office-based setting with a well-tolerated side-effect profile."

About DSUVIA (sufentanil sublingual tablet), 30 mcg
DSUVIA®, branded 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/DZUVEO was designed to provide rapid analgesia via a non-invasive route and to eliminate dosing errors associated with intravenous (IV) administration. DSUVIA/DZUVEO 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, markets the drug in Europe.

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 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 is an approved product in Europe.

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

Forward-looking statements

This press release contains forward-looking statements based upon AcelRx's current expectations. These and any other forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking terminology such as "potential," "believe," "expect," "expects," "expected," "intended", "anticipate," "may," "will," "enable," "should," "seek," "approximately," "intends," "intended," "plans," "planned," "planning," "estimates," "benefits," or the negative of these words or other comparable terminology. The discussion of financial trends, strategy, plans or intentions may also include forward-looking statements, which are predictions, projections and other statements about future events that are based on current expectations and assumptions. These forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those projected, anticipated or implied by such statements, including: (i) risks relating to AcelRx's product development activities and ongoing commercial business operations; (ii) risks related to the ability of AcelRx and its business partners to implement development plans, launch plans, forecasts and other business expectations; (iii) risks related to unexpected variations in market growth and demand for AcelRx's commercial and developmental products and technologies; (iv) risks related to AcelRx's liquidity and its ability to maintain capital resources; (v) AcelRx's ability to retain its listing on the Nasdaq exchange; and (vi) risks relating to AcelRx's ability to obtain regulatory approvals for its developmental product candidates. Although it is not possible to predict or identify all such risks and uncertainties, they may include, but are not limited to, those described under the caption "Risk Factors" and elsewhere in AcelRx's annual, quarterly and current reports (i.e., Form 10-K, Form 10-Q and Form 8-K) as filed or furnished with the Securities and Exchange Commission (SEC) and any subsequent public filings. You are cautioned not to place undue reliance on any such forward-looking statements, which speak only as of the date such statements were first made. To the degree financial information is included in this press release, it is in summary form only and must be considered in the context of the full details provided in AcelRx's most recent annual, quarterly or current report as filed or furnished with the SEC. AcelRx's SEC reports are available at www.acelrx.com under the "Investors" tab. Except to the extent required by law, AcelRx undertakes no obligation to publicly release the result of any revisions to these forward-looking statements to reflect new information, events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.

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