



AcelRx Pharmaceuticals Announces European Peer-Reviewed Publication Supporting the Benefits of Sublingual Sufentanil Tablets For Post-Operative Pain Management in the Journal of Clinical Medicine

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Patients reported lower pain scores, required fewer rescue doses and had a shorter hospital stay than patients receiving continuous femoral nerve block

This study of patients following knee replacement surgery adds to a growing database supporting the benefits of using sufentanil sublingual tablets for surgical pain management

HAYWARD, Calif., Dec. 8, 2022 /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 a recent retrospective study published in the *Journal of Clinical Medicine* Special Issue "Advances in Postoperative Pain Management and Postoperative Chronic Pain". The study was lead-authored by orthopedic surgeon Dr. Andrea Angelini and entitled "Sublingual Sufentanil Tablet System for Postoperative Analgesia After Orthopedic Surgery: A Retrospective Study".



The study, which was conducted by investigators at the University of Padova in Italy, retrospectively analyzed a total of 71 patients with respect to quality of postoperative pain management following total knee arthroplasty (TKA). Investigators analyzed data from 50 patients who received sufentanil sublingual tablets (SSTs) postoperatively versus a control group of 21 patients who were treated according to standard pain management protocol with continuous femoral nerve block. All data were obtained from the patients' hospital records and included patient demographic data, data regarding intraoperative management, postoperative analgesia and pain scores. Patients in the control group had similar demographic characteristics (age, comorbidities, type of surgery). Endpoints included pain intensity at rest, number of rescue doses, length of hospital stay and adverse events. Pain was measured using the 11-point Numeric Rating Scale (NRS).

NRS scores were statistically lower in the SSTs group compared to the control group at time T1 ($p=0.008$), which was assessed 24 hours following surgery, and numerically lower at all other time points. Fewer patients in the SSTs group required rescue analgesic doses (5%) compared to the control group (60%) and discharge occurred on average 1.5 days earlier in the SSTs group ($p = 0.039$). Adverse events were noted as being consistently lower in the group administered SSTs, and this was most notably observed to be the case with nausea (10% versus 30%), typically the most frequently reported adverse event with postoperative opioid administration.

"As we have seen in so many other studies evaluating SST, the advantages reported in this study among orthopedic surgical patients include superior analgesia compared to standard of care, a shorter recovery stay, and a very tolerable safety profile," stated Dr. Pamela Palmer, Founder and Chief Medical Officer of AcelRx. "Postoperative pain after major orthopedic procedures, such as a total knee replacement, is a significant postoperative concern and represents a treatment challenge for physicians. Regardless of the mode of SST administration – via either the Zalviso® handheld device such as this study, or nurse-administered DSUVIA® (SST 30 mcg) – the clear benefits of SSTs compared to IV opioids or other modes of analgesia, such as nerve blocks, have been reported in peer-reviewed publications across multiple surgical subspecialties. The publication of this Italian study is timely with respect to the recent launch of DZUVEO in Europe by our partner, Aguetant, as it underscores the inherent benefits of sufentanil sublingual tablets for acute pain management in medically supervised settings."

In October, the Company announced the European launch of SST 30 mcg (DZUVEO®; known as DSUVIA® in the U.S.) by its partner, Aguetant across key European countries, with commercialization in Spain, Portugal and Italy expected to begin in the first half of 2023.

Also in October, at the ANESTHESIOLOGY® Annual Meeting 2022, the Company presented supportive data from an investigator-initiated trial showing the advantages of SSTs over the use of traditional intravenous opioids for the management of analgesia in postoperative spine surgery patients. Additional supportive studies about AcelRx's novel SSTs can be found on the Company's website at <https://www.acelrx.com/media/publications>.

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, Aguetant, 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) which is approved in Europe and is 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 Aguetant; 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 AcclRx, please visit www.acclrx.com.

Forward-looking statements

This press release contains forward-looking statements based upon AcclRx'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," "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 AcclRx's product development activities and ongoing commercial business operations; (ii) risks related to the ability of AcclRx 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 AcclRx's commercial and developmental products and technologies; (iv) risks related to AcclRx's liquidity and its ability to maintain capital resources; (v) AcclRx's ability to retain its listing on the Nasdaq exchange; and (vi) risks relating to AcclRx'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 AcclRx'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 AcclRx's most recent annual, quarterly or current report as filed or furnished with the SEC. AcclRx's SEC reports are available at www.acclrx.com under the "Investors" tab. Except to the extent required by law, AcclRx 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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