



AcelRx Pharmaceuticals Announces Publication of Clinical Data on Reduced Opioid Use and Reduced Time in the Postanesthesia Care Unit (PACU) Following Preoperative Administration of DSUVIA®

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REDWOOD CITY, Calif., Aug. 19, 2020 /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 entitled "Reduced Opioid Use and Reduced Time in the Postanesthesia Care Unit Following Preoperative Administration of Sublingual Sufentanil in an Ambulatory Surgery Setting" by Christian Tvetenstrand, MD and Michael Wolff, MD, in the Journal of Clinical Anesthesia and Pain Management.

"The observations in this study strongly support utilizing DSUVIA over intravenous bolus opioids, consistent with opioid stewardship programs and enhanced recovery after surgery protocols, which focus on minimizing opioid dosing in multimodal analgesic protocols," said Dr. Christian Tvetenstrand, Chairman of Surgery and Director of Trauma, United Health Services Wilson Medical Center, New York. "I strongly believe this data on preoperative DSUVIA administration will result in a paradigm shift in pain management protocols across all ambulatory surgeries, as we have already seen significant cost savings due to less medical intervention and improved patient recovery."

The study compared a prospective group of patients with preoperative dosing of a single sublingual DSUVIA tablet to a historical control group receiving standard intravenous (IV) opioid administration for same-day general surgery procedures. A total of 127 patients were evaluated in the study, with the following key findings:

- Discharge from the PACU occurred 34% faster than controls (36.3 min vs. 54.9 min; $p < 0.001$).
- Significantly fewer DSUVIA treated patients required intraoperative IV opioid following preoperative dosing with DSUVIA compared with the control group (61.7% vs. 97.5%, respectively; $p < 0.001$).
- DSUVIA patients received a total preoperative and intraoperative mean opioid dose of 10.9 milligram morphine equivalents (MME), while the mean dose for controls was 20.0 mg MME ($p < 0.001$).
- Fewer DSUVIA-treated patients required any postoperative opioid (10.5% vs. 63.0%; $p < 0.001$) with overall opioid utilization being reduced by over 50% with DSUVIA use throughout the perioperative setting (11.8 MME vs. 24.6 MME; $p < 0.001$).
- Significantly fewer patients in the DSUVIA group received adrenergic agonists and IV acetaminophen.

The study concluded that the preoperative administration of DSUVIA results in significant reductions in opioid use during outpatient surgery and facilitates shorter PACU stays. Study limitations include that it was an open-label study, the retrospective nature of the control group, and the focus on only general surgery patients.

"The results of this study build on an ever-increasing clinical dataset demonstrating the benefits of sublingual sufentanil. The standard of care for perioperative opioid administration has not been disrupted for over 100 years. We should no longer accept the rapid plasma fluctuations of IV bolus opioid administration as the status quo, as it impacts the patient's hemodynamic status and requires repeated redosing which ultimately results in higher overall opioid exposure," commented Dr. Pamela Palmer, AcelRx Chief Medical Officer and co-founder. "DSUVIA for the first time offers a unique pharmacokinetic profile for an opioid in the perioperative setting and other medically supervised settings. We expect this study to be one of several upcoming datasets to support the broad acceptance of DSUVIA as an alternative to IV opioids."

About DSUVIA (sufentanil sublingual tablet), 30 mcg

DSUVIA®, known as DZUVEO™ in Europe, approved by the FDA in November 2018, 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 in June 2018 and the Company is currently in discussions with potential European marketing partners. 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. AcelRx 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 one product candidate, Zalviso® (sufentanil sublingual tablet system, SST system, 15 mcg), an investigational product in the U.S., is being developed as an innovatively designed patient-controlled analgesia (PCA) system for reduction of moderate-to-severe acute pain in medically supervised settings. DZUVEO and Zalviso are both approved products in Europe. For additional information about AcelRx, please visit www.acelrx.com.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to our expectations for upcoming datasets to

support the broad acceptance of DSUVIA as an alternative to IV opioids. 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 "believes," "expects," "anticipates," "may," "will," "should," "seeks," "approximately," "intends," "plans," "estimates," 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. 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 the risk that upcoming datasets are not published. Although it is not possible to predict or identify all such risks and uncertainties, they may include, but are not limited to, those described 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). 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. 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 events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.



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