



AcelRx Pharmaceuticals Announces Clinical Data Reporting High Ratings for Healthcare Professional and Patient Satisfaction Following Use of DSUVIA® for Acute Pain in Hospital Settings

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REDWOOD CITY, Calif., March 25, 2021 /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 pooled analysis of Phase 3 data on the use of DSUVIA for acute pain management in the postoperative and emergency department settings in the *Journal of Pain Research*.

The article entitled "Patient and Healthcare Professional Satisfaction Ratings and Safety Profile of Sufentanil Sublingual Tablets for Treatment of Acute Pain: A Pooled Demographic Analysis" by lead author David Leiman, MD, University of Texas at Houston Department of Surgery and HD Research, Houston TX, reported high ratings for global assessment of the method of pain control and a well-tolerated safety profile for all demographic subgroups following the dosing of sufentanil sublingual tablet 30 mcg (DSUVIA) in postoperative and emergency department patients.

The global satisfaction analysis included a total of 283 patients who had completed the assessments as well as their healthcare professionals who had dosed DSUVIA in the clinical trials. The patient global assessment (PGA) and the healthcare professional global assessment (HPGA) scale is a 4-point scale of "poor", "fair", "good", or "excellent" for the method of pain control and these scores were assessed across the patient demographic subgroups of age, body-mass index (BMI), sex and race. Adverse events across these same demographic subpopulations were also assessed. Key findings included the following:

- The highest percent of excellent scores across all evaluations was for the HPGA in older patients (≥ 65 years), with 61% of healthcare professionals rating pain control in these older patients as "excellent"; there were no statistical differences across older versus younger patients for either PGA or HPGA.
- High ratings by both low (< 30 kg/m²) and high BMI (≥ 30 kg/m²) patients on the PGA were observed with 86% and 85%, respectively, rating "good" or "excellent" on the PGA; similar ratings were seen with the HPGA for these subgroups and no statistical differences were observed between the groups.
- Male and female patients had high ratings on both the PGA and HPGA, with HPGA scores statistically higher for male patients over female patients ($p=0.023$), while PGA scores were similar and not statistically different.
- There were no statistical differences among races for either the PGA or HPGA with each of these subpopulations scoring high percentages of "good" or "excellent" ratings.

DSUVIA was well tolerated throughout the Phase 3 studies with 68% of the 323 total patients evaluated not experiencing any DSUVIA-related adverse events. Adverse events occurring in $\geq 2\%$ of the patients were nausea (22.9%), headache (5.0%), dizziness (4.0%) and vomiting (3.1%). Importantly, the adverse events of decreased oxygen saturation and somnolence were low, occurring in 1.5% and 1.2% of the patients, respectively. Study limitations included a higher enrollment of younger compared to older patients, and opioid-tolerant patients were excluded.

"The results from this pooled analysis of the DSUVIA Phase 3 trials mirror the impressive clinical outcomes that I observed during dosing of DSUVIA in these clinical trial patients as well as patients in my current anesthesia practice," said Dr. Leiman. "The rapid onset and analgesic effectiveness combined with DSUVIA being well tolerated throughout the Phase 3 program, with low respiratory and CNS side-effect rates, makes using DSUVIA an appropriate choice in my patients. The older patients obtaining the highest healthcare professional rating in the "excellent" category does not surprise me as DSUVIA's low peak plasma concentration and high therapeutic index are optimally suited to this patient population," continued Dr. Leiman.

"The consistency of analgesia across the demographic subgroups was notable, especially given the single 30-mcg dose for all patients," said Dr. Pamela Palmer, AcelRx Chief Medical Officer and co-founder. "The patients, whether old or young, obese or non-obese, and regardless of sex or race, reported overall high ratings for the global assessment of pain control and their healthcare professionals also rated these patients with high scores among the different subgroups."

These Phase 3 studies were funded by AcelRx and the Clinical and Rehabilitative Medicine Research Program (CRM RP) of the US Army Medical Research and Materiel Command (USAMRMC). Dr. Leiman is a paid consultant of AcelRx.

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.



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