AcelRx Pharmaceuticals Announces Publication Analyzing Pooled Dosing and Efficacy Data on Sufentanil Sublingual 30 mcg Tablets

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REDWOOD CITY, Calif., Nov. 13, 2019 /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 a publication analyzing pooled dosing and efficacy data from use of the sufentanil sublingual tablet (SST) 30 mcg among multiple demographic subgroups (age, sex, race, and body mass index). This data, published in the *Journal of PeriAnesthesia Nursing*, was analyzed to aid nurses in understanding the effectiveness and duration of action of SST 30 mcg in the management of moderate-to-severe acute pain across a variety of patient demographics.

In this study, patient characteristics were pooled from three postoperative studies, and one open-label emergency department study, while drug dosing and efficacy data were pooled from postoperative studies. Mean drug doses administered from 0-12 hours was 3.9 for SST 30 mcg, and was less frequent for older (≥65 years) compared to younger patients but was similar among other subgroups. Summed pain intensity difference to baseline over 12 hours (SPID12) was higher (superior) in the SST 30-mcg group compared with placebo across all demographic subgroups.

"We are pleased with the results of this analysis, particularly that a single dosage-strength tablet has efficacy across all the demographic subgroups," commented Dr. Pamela Palmer, AcelRx Chief Medical Officer. "An important reason behind the development of DSUVIA® was to avoid common opioid medication errors occurring with the clear injectable opioids, which come in widely differing concentrations. Also, the timely onset of analgesia and the duration of action allow DSUVIA to fit nicely into the fast-paced environment of the post-surgical recovery room and emergency departments."

About DSUVIA (sufentanil sublingual tablet), 30 mcg
DSUVIA®, known as DZUVEO™ inEurope, approved by the FDA in November 2018, is indicated for use in adults in a certified medically supervised healthcare setting, 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.

For more information, 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 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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