AcelRx Announces an Investigator-Initiated Study of DSUVIA® in Cardiac Surgery Enhanced Recovery Regimen

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REDWOOD CITY, Calif., Jan. 19, 2021 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), (AcelRx), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in healthcare institutions, today announced an investigator-initiated study with University Hospitals (UH) Cleveland Medical Center that will evaluate the postoperative use of DSUVIA in a prospective cohort of patients undergoing cardiac surgery with cardiopulmonary bypass following a specialized enhanced recovery protocol. Dr. Daniel Asher, cardiac anesthesiologist and Medical Director of the Mather Postanesthesia Care Unit at UH Cleveland Medical Center, will serve as the principal investigator. Key outcomes to be measured include time on mechanical ventilation following completion of the surgical procedure, both intensive care as well as hospital length of stay and total dose of opioids administered from surgery to discharge. These outcomes will be compared to historical controls utilizing current institutional standard of care techniques.

"We look forward to evaluating DSUVIA as part of our cardiac surgery enhanced recovery program which is aiming to better prepare our enrolled subjects for the stress of heart surgery by using contemporary preoperative adjuncts, educational tools, intraoperative monitoring techniques and, importantly, actively reducing the exposure of these patients to IV opioids and their side effects," states the study's co-investigator Dr. Edwin Avery, Vice Chair of Clinical Operations and Professor of Anesthesiology at UH Cleveland Medical Center, and Professor, Anesthesiology and Perioperative Medicine, Case Western Reserve University School of Medicine. "We believe the higher therapeutic index of sufentanil and the lower peak plasma concentrations delivered via the sublingual route compared to bolus IV administration will allow DSUVIA to help us achieve our goal," continues Dr. Avery.

"This investigator-initiated study at UH Cleveland presents another opportunity to assess the benefits of DSUVIA compared to IV opioids," said Dr. Pamela Palmer, Co-Founder and Chief Medical Officer at AcelRx Pharmaceuticals. "The physicians at UH Cleveland Medical Center have chosen DSUVIA for evaluation in their enhanced recovery cardiac bypass program to determine if it provides effective pain relief while minimizing side effects during their postoperative recovery prior to discharge. This cardiac surgery study together with ongoing investigator-initiated trials of DSUVIA for orthopedic and spine surgeries at other top academic institutions allows DSUVIA to be assessed across a broad range of surgical subspecialties 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. 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.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to expected commencement of an investigator-initiated study and the scope of the study, expected findings from the investigator-initiated study and other studies, and the expected commencement of additional studies. 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 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. In addition, such risks and uncertainties may include, but are not limited to, those described in the Company'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. The Company's SEC reports are available at www.acelrx.com under the "Investors" tab. Except to the extent required by law, the Company 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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