



AcelRx Pharmaceuticals Provides Update on Reduced FDA REMS Requirements Related to DSUVIA®

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HAYWARD, Calif., May 19, 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 reported that the U.S. Food and Drug Administration (FDA) has recently modified the DSUVIA Risk Evaluation and Mitigation Strategies (REMS) requirements with respect to healthcare setting audits. The goal of the DSUVIA REMS program is to mitigate the risk of respiratory depression resulting from accidental exposure by ensuring that DSUVIA is dispensed only to patients in certified medically supervised healthcare settings.

On April 21, 2022, the FDA revised the DSUVIA REMS program to eliminate the 6-month healthcare setting audit requirement and reduce annual healthcare setting audits to a total of up to 400 sites that have received a shipment of DSUVIA in the past 6 months. Previously, the DSUVIA REMS required AcelRx to audit all healthcare settings within six months of an initial DSUVIA order, and to then continue to audit all such sites annually thereafter (for sites continuing to order DSUVIA within a six-month period), with no limit to the number of sites audited.

"We continue to work closely with the FDA on the DSUVIA REMS program and have established a track record of compliance and safety with DSUVIA, including lack of accidental exposure," said Pamela Palmer, MD, PhD, Co-Founder and Chief Medical Officer of AcelRx. "We believe that it is this history of stewardship and responsibility, which is included in our latest three-year assessment REMS report as submitted to the FDA, that has resulted in the lowering of both the number and frequency of required site audits," continued Dr. Palmer.

About the U.S. Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategies (REMS) Requirements

In general, the FDA's Risk Evaluation and Mitigation Strategies (REMS) programs include a risk mitigation goal and are comprised of information communicated to and/or required activities to be undertaken by one or more participants (e.g., health care providers, pharmaceutical wholesalers and distributors, pharmacists, patients) who prescribe, dispense or take the medication. Together, the goal, communications and/or activities make up the safety and risk mitigation strategy.

Each prong of a REMS program is designed to help one or more of the key participants in that REMS program to address a specific risk or safety concern. The most common role(s) of each of these key participants in a REMS are further [described elsewhere](#). The specific requirements and risk messages of each REMS program is tailored to the specific medication subject to REMS, the nature of its risks, and the likely setting in which the drug will be, or is being, used.

About DSUVIA (sufentanil sublingual tablet), 30 mcg

DSUVIA®, known 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 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. DZUVEO has been approved by the European Medicines Agency and AcelRx's European commercialization partner, Aguetant, will market the drug in Europe.

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 several product candidates. The product candidates include: Zalviso® (sufentanil sublingual tablet system, SST system, 15 mcg), 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 and Zalviso are both approved products in Europe.

This release is intended for investors only. 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 the expected effectiveness and scope of the Company's past and future compliance with its FDA obligations including with respect to the DSUVIA REMS program. 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 "believe," "expect," "expected," "continue," "establish," "may," "will," or the negative of these words or other comparable terminology. The discussion of strategy, compliance programs, and any related 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) the risk that the Company may be found to be not in compliance with its regulatory obligations including those arising under the DSUVIA REMS program; (ii) risks related to the ability of AcelRx to implement its development and commercialization plans in a compliant manner, or meet its forecasts and other business expectations; and (iii) risks that the Company may not be able to effectively commercialize DSUVIA. 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 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) 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 AcelRx's most recent annual, quarterly or current report as filed or furnished with the SEC. 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 new information, events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.



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