FDA Advisory Committee Recommends Approval Of DSUVIA For The Treatment Of Moderate-To-Severe Acute Pain

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REDWOOD CITY, Calif., Oct. 12, 2018 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (AcelRx) (Nasdaq: ACRX), a specialty pharmaceutical company focused on innovative therapies for use in medically supervised settings, announced today that the Anesthetic and Analgesic Drug Products Advisory Committee of the U.S. Food and Drug Administration (FDA) voted 10-3 in favor of recommending the approval of DSUVIA™ for the management of moderate-to-severe acute pain in medically supervised settings for adult patients. Developed to address challenges with existing treatment options and to provide an easy-to-administer dosage form for rapid relief as early as 15 minutes, DSUVIA is a 30 mcg sufentanil tablet in a pre-filled applicator for sublingual administration by a healthcare professional.

"We are pleased with the Advisory Committee's recommendation to approve DSUVIA as a treatment in medically supervised settings for adults experiencing moderate-to-severe acute pain," said Dr. Pamela Palmer, Co-Founder and Chief Medical Officer of AcelRx. "We look forward to continued collaboration with the FDA on the application as we believe DSUVIA represents an important non-invasive acute pain management option with potential to significantly improve the current standard of care."

The company presented DSUVIA efficacy and safety data from two randomized, placebo-controlled studies with a total of 261 patients and two open-label, single-arm studies with a total of 216 patients. In these clinical trials, DSUVIA was shown to be well-tolerated and demonstrated efficacy across a range of patient ages and BMIs as a non-invasive analgesic for the management of moderate-to-severe acute pain.

The Anesthetic and Analgesic Drug Products Advisory Committee is convened upon the request of the FDA to review and evaluate safety and efficacy data of marketed and investigational human drug products for use in anesthesiology and surgery, and makes appropriate recommendations to the Commissioner of Food and Drugs. While the FDA is not bound by the committee's recommendation, it does take its advice into consideration. The Prescription Drug User Fee Act (PDUFA) date for DSUVIA is November 3, 2018.

"The availability of a single-dose, non-invasive opioid, like DSUVIA, could significantly improve my ability to effectively, efficiently and safely alleviate acute pain experienced by my patients," said David Leiman, M.D., Clinical Assistant Professor of Surgery, University of Texas at Houston, and Director, HD Research Corp. "It is my hope that the FDA consider the recommendation of the Advisory Committee and the current need for additional non-invasive opioid analgesic options on behalf of patients and healthcare providers in medically supervised settings."

About DSUVIA (sufentanil sublingual tablet), 30 mcg

DSUVIA (sufentanil sublingual tablet, 30 microgram), known as DZUVEO ™ outside the United States, has a proposed indication for the management of moderate-to-severe acute pain in medically supervised settings, in adult patients and was designed to eliminate dosing errors associated with IV administration via its non-invasive single-dose applicator (SDA) administered by health care professionals. Sufentanil is an opioid analgesic currently marketed for intravenous (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 Medicines Agency (EMA) approved DZUVEO for marketing in Europe in June 2018.

Clinical and Rehabilitative Medicine Research Program (CRMRP)

DSUVIA is funded in part by the Clinical and Rehabilitative Medicine Research Program (CRMRP) of the U.S. Army Medical Research and Materiel Command (USAMRMC) under contract No. W81XWH-15-C-0046. The CRMRP was established in 2008 to foster research and technology advances for regeneration, restoration, and rehabilitation of traumatic injuries. In accordance with USAMRMC guidelines, in the conduct of clinical research, AcelRx has adhered to the policies regarding the protection of human subjects as prescribed by Code of Federal Regulations (CFR) Title 45, Volume 1, Part 46; Title 32, Chapter 1, Part 219; and Title 21, Chapter 1, Part 50 (Protection of Human Subjects).

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 two product candidates including DSUVIA (sufentanil sublingual tablet, 30 mcg), known as DZUVEO in Europe, with a proposed indication for the treatment of moderate-to-severe acute pain in medically supervised settings, and Zalviso® (sufentanil sublingual tablet system, SST system, 15 mcg) 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's clinical programs, please visit www.acelrx.com.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to the safety, efficacy and tolerance of DSUVIA and the potential and timing for it to be approved by the FDA, as well as the potential for DSUVIA to potentially significantly improve the current standard of care. These forward-looking statements are based on AcelRx's current expectations and involve significant risks and uncertainties. AcelRx's actual results and timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, including, without limitation: risks related to the possibility that the data supporting AcelRx's DSUVIA NDA resubmission may be disputed or interpreted differently by the FDA such that it results in further required action by the Company or ultimately does not support approval; any

delays or the inability to obtain and maintain regulatory approval of DSUVIA in the United States, and other risks detailed in the "Risk Factors" and elsewhere in AcelRx's U.S. Securities and Exchange Commission filings and reports, including its Annual Report on Form 10-K filed with the SEC on March 9, 2018 and Quarterly Report on Form 10-Q filed with the SEC on August 2, 2018. AcelRx undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events or changes in its expectations, except as required by law.

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