



AcelRx resubmits New Drug Application for DSUVIA™

May 09, 2018

REDWOOD CITY, Calif., May 9, 2018 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), (AcelRx or the Company), a specialty pharmaceutical company focused on innovative therapies for use in medically supervised settings, today announced the resubmission of the New Drug Application (NDA) for DSUVIA with the U.S. Food and Drug Administration (FDA). AcelRx anticipates that the FDA will acknowledge acceptance of the NDA within 30 calendar days of the resubmission date. AcelRx expects a six-month review by the FDA with a projected PDUFA (Prescription Drug User Fee Act) date in the fourth quarter of 2018.

DSUVIA (sufentanil sublingual tablet, 30 mcg), known as DZUVEO™ in Europe, has a proposed indication for the management of moderate-to-severe acute pain in medically supervised settings, in adult patients. A positive opinion from the Committee for Medicinal Products for Human Use (CHMP) was recently issued recommending approval to the European Medicines Agency (EMA) for DZUVEO. A potential marketing authorization from EMA is expected in the third quarter of 2018.

"The resubmission of the DSUVIA NDA is an important milestone for the Company, and is our third key milestone achieved in the second quarter," stated Vince Angotti, Chief Executive Officer of AcelRx. "This NDA resubmission follows the successful completion of the Human Factors study and the recent receipt of a positive opinion from CHMP for DZUVEO, and it keeps us on the path towards regulatory approvals for DSUVIA in the U.S. and for DZUVEO in Europe this year. Importantly, we believe DSUVIA has the potential, if approved, to provide a non-invasive option for moderate-to-severe acute pain and help U.S. hospitals manage through the intravenous opioid shortage¹ they are experiencing in their facilities today," continued Angotti.

About DSUVIA™ (sufentanil sublingual tablet), 30 mcg

DSUVIA™ (sufentanil sublingual tablet, 30 mcg), known as DZUVEO™ outside the United States, is designed to treat moderate-to-severe acute pain and dosing errors associated with IV administration via its non-invasive single-dose applicator (SDA) in medically supervised settings. 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. In Europe, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion, recommending approval of DZUVEO.

Clinical and Rehabilitative Medicine Research Program (CRM RP)

DSUVIA™ is funded in part by the Clinical and Rehabilitative Medicine Research Program (CRM RP) of the U.S. Army Medical Research and Materiel Command (USAMRMC) under contract No. W81XWH-15-C-0046. The CRM RP 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.

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 process and timing of the FDA review of the NDA resubmission for DSUVIA, the potential for DSUVIA's approval by the FDA, and the timing of the final decision and potential approval by the European Commission regarding DZUVEO. 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 results of the Company's Human Factors study or data supporting AcelRx's 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 of the Company's NDA submission for DSUVIA; any delays or the inability to obtain and maintain regulatory approval of DSUVIA in the United States, DZUVEO in Europe and ZALVISO 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. 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.

¹<https://www.ashp.org/Drug-Shortages/Shortage-Resources/Injectable-Opioid-Shortages-FAQ>



SOURCE AcelRx Pharmaceuticals, Inc.

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