AcelRx Announces Date of FDA Advisory Committee Meeting for DSUVIA™

Sep 11, 2018

DSUVIA Advisory Committee meeting date set for October 12, 2018

REDWOOD CITY, Calif., Sept. 11, 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 Anesthetic and Analgesic Drug Products Advisory Committee of the U.S. Food and Drug Administration (FDA) has planned an Advisory Committee meeting to review the Company's New Drug Application (NDA) for DSUVIA for the management of moderate-to-severe acute pain in medically supervised settings in adult patients.

"We have been actively preparing for this meeting since the beginning of the year, and we're looking forward to sharing our DSUVIA data with the Advisory Committee," said Dr. Pamela Palmer, Co-Founder and Chief Medical Officer at AcelRx. "If approved, we believe that DSUVIA will provide a novel non-invasive treatment option for moderate-to-severe acute pain in medically supervised settings."

The FDA accepted AcelRx's NDA in May 2018. The target action date under the Prescription Drug User Fee Act (PDUFA) is November 3, 2018.

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 healthcare 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 process and timing of the FDA review of the DSUVIA ™ NDA resubmission, and the potential for DSUVIA to provide a novel non-invasive treatment option for moderate to severe acute pain in medically supervised settings. 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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