



AcelRx Pharmaceuticals Presenting ARX-04 Clinical Trial Findings and Cost Analysis at European Congress on Emergency Medicine

Sep 28, 2016

REDWOOD CITY, Calif., Sept. 28, 2016 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (NASDAQ: ACRX), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of moderate-to-severe acute pain, today announced that the Company and investigators will be presenting two e-posters at the European Congress on Emergency Medicine (ECEM), which is being held October 1-5, 2016 in Vienna, Austria. Both e-posters will be displayed on monitors throughout the meeting, and will be available following the conclusion of the conference on the AcelRx [Publications](#) webpage.

The first presentation summarizes the safety and efficacy findings from the [Phase 3 SAP302 study](#) of ARX-04 (sufentanil sublingual tablet, 30 mcg) in patients who were admitted to the emergency department with an injury or trauma associated with moderate-to-severe acute pain. Results from this trial showed substantial reductions in pain intensity (mean 2.9 out of 10 on a validated pain scale) within the first hour among the 76 patients treated with ARX-04. The second e-poster provides insights into the direct and indirect (labor, pharmacy, etc.) costs associated with the administration of intravenous (IV) opioids. Based on an analysis of over 600 hospitals, AcelRx has determined that an initial IV dose of an opioid, such as morphine, hydromorphone and fentanyl, ranges from \$143 to \$145 in U.S. emergency departments.

Details on the presentations are as follows:

1.Title: Efficacy and Safety of Sufentanil Sublingual Tablet 30 mcg for Management of Acute Traumatic Pain in the Emergency Department

Authors: James Miner, MD of the Hennepin County Medical Center in Minneapolis, MN; Harold Minkowitz, MD of the Memorial Hermann Memorial City Medical Center in Houston, TX; Zubaid Rafique, MD of Baylor College of Medicine in Houston, TX; and Karen DiDonato, MSN, RN and Pamela Palmer, MD, PhD of AcelRx Pharmaceuticals

2.Title: Cost of Delivering Intravenous Opioid Analgesia in Emergency Departments in the United States

Authors: Pamela P. Palmer, MD PhD, Brenda Lemus, MD, and Karen DiDonato, MSN, RN of AcelRx Pharmaceuticals; and John House, MS of Premier, Inc.

ECEM is the annual meeting of the European Society for Emergency Medicine, which represents 33 European national emergency medicine societies. The Society strives to advance research, education, practice and standards of the specialty of emergency medicine throughout Europe. More information on the Society may be found at www.eusem.org.

Clinical and Rehabilitative Medicine Research Program (CRM RP)

ARX-04 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 ARX-04

ARX-04 is a non-invasive investigational product candidate consisting of 30 mcg sufentanil tablets delivered sublingually by a healthcare professional using a disposable, pre-filled, single-dose applicator (SDA). Sufentanil is a synthetic opioid analgesic with a high therapeutic index and no known active metabolites.

About AcelRx Pharmaceuticals, Inc.

AcelRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of moderate-to-severe acute pain. The Company's late-stage pipeline includes ARX-04 (sufentanil sublingual tablet, 30 mcg), designed for the treatment of moderate-to-severe acute pain in medically supervised settings; and Zalviso® (sufentanil sublingual tablet system), designed for the management of moderate-to-severe acute pain in adult patients in the hospital setting. Zalviso delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. Zalviso is approved in the EU as well as Norway, Iceland, and Liechtenstein and is investigational and in late-stage development in the U.S. Grunenthal Group holds the rights for Zalviso in Europe and Australia, while AcelRx retains all other world-wide rights.

For additional information about AcelRx's clinical programs, please visit www.acelrx.com.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to the process and timing of anticipated future development of AcelRx's product candidates, ARX-04 (sufentanil sublingual tablet, 30 mcg) and Zalviso® (sufentanil sublingual tablet system), including the ARX-04 clinical trial results; anticipated submission of the New Drug Application, or NDA, for ARX-04 to the U.S. Food and Drug Administration, or FDA; AcelRx's pathway forward towards gaining approval of Zalviso in the U.S.; anticipated resubmission of the Zalviso NDA to the FDA; and the therapeutic and commercial potential of AcelRx's product candidates, including potential market opportunities for ARX-04 and Zalviso. These forward-looking statements are based on AcelRx Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. AcelRx Pharmaceuticals' actual results and timing of events could differ materially from those anticipated in such forward-looking statements, and as a result of these risks and uncertainties, which include, without limitation, risks related to AcelRx Pharmaceuticals' ARX-04 development program, including anticipated submission of the ARX-04 NDA and the fact that the FDA may dispute or interpret differently clinical results obtained from the Phase 3 studies of ARX-04; AcelRx's ability to successfully execute the pathway towards a resubmission of the Zalviso NDA to the FDA; any delays or inability to obtain and maintain regulatory approval of its product candidates including ARX-04 in the United States and Europe, and Zalviso in the United States; the uncertain clinical development process, including adverse events; the risk that planned clinical trials may

not have an effective clinical design, enroll a sufficient number of patients, or be completed on schedule, if at all; the success, cost and timing of all development activities and clinical trials; and other risks detailed in the "Risk Factors" and elsewhere in AcetRx's U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on July 29, 2016. AcetRx 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.



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To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/acetrx-pharmaceuticals-presenting-arx-04-clinical-trial-findings-and-cost-analysis-at-european-congress-on-emergency-medicine-300335441.html>

SOURCE AcetRx Pharmaceuticals, Inc.

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