



AcelRx Pharmaceuticals Presenting Comprehensive DSUVIA Clinical Trial Results at ASRA's Annual Regional Anesthesiology and Acute Pain Medicine Meeting

Apr 06, 2017

REDWOOD CITY, Calif., April 6, 2017 /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, announced that efficacy and integrated safety results from the DSUVIA™ (formerly ARX-04) clinical program would be presented as an e-poster during the Annual Regional Anesthesiology and Acute Pain Medicine Meeting. The e-poster will be presented during a moderated session by Harold Minkowitz, MD, an anesthesiologist at Memorial Hermann Memorial City Medical Center in Houston. This marks the first comprehensive presentation of the integrated efficacy and safety results from the DSUVIA clinical program as submitted to the US Food and Drug Administration in the company's New Drug Application.

In total, 480 patients were enrolled across all four DSUVIA late-phase studies. Two randomized, placebo-controlled studies, SAP202 and SAP301, enrolled patients who had undergone bunionectomy and abdominal surgeries; and two open-label, single-arm trials assessed DSUVIA in the emergency department (SAP302) and in older, post-operative patients, many with comorbidities (SAP303). The presentation concludes that DSUVIA, while still under FDA review, may have benefit as a non-invasive analgesic modality in medically supervised settings requiring short-term treatment of acute moderate-to-severe pain. In the emergency department study, DSUVIA resulted in a 3-point reduction in pain intensity within 60 minutes of administration, with clinically meaningful relief within 15-30 minutes. In general, adverse events were mild-to-moderate in severity with the most commonly reported (≥3%) nausea, headache and vomiting, which occurred in 28.9%, 8.0% and 6.3% of DSUVIA patients, and 21.6%, 13.5% and 1.4% of placebo patients, respectively. No statistical separation was observed between the active and placebo-controlled groups.

The Annual Regional Anesthesiology and Acute Pain Medicine Meeting is hosted by the American Society of Regional Anesthesia and Pain Medicine (ASRA) and is taking place April 6-8, 2017 in San Francisco, CA. For more information on the society, please visit www.asra.com.

Details on the presentations are as follows:

Title: Comprehensive Efficacy and Integrated Safety Results from the Late-Phase Clinical Program of the Sublingual Sufentanil Tablet 30 mcg (Poster ID 3876)
Authors: Harold Minkowitz, MD of the Memorial Hermann Memorial City Medical Center in Houston, TX; Timothy Melson, MD of the Helen Keller Hospital in Sheffield, AL; David Leiman, MD of the Hermann Drive Surgical Hospital in Houston, TX; Karen DiDonato, MSN, RN and Pamela Palmer, MD, PhD of AcelRx Pharmaceuticals
Time/Place: Thursday, April 6, 2017 from 3:45-5:15 pm PT in Salon 5

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 DSUVIA (Formerly ARX-04)

DSUVIA 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. A New Drug Application (NDA) for DSUVIA™ (sufentanil sublingual tablet, 30 mcg), known as ARX-04 outside the United States, with a proposed indication for the treatment of moderate-to-severe acute pain in medically supervised settings, has been accepted for filing by the FDA in the United States. In the EU, the European Medicines Agency (EMA) has notified the Company that the ARX-04 (sufentanil sublingual tablet, 30 mcg) Marketing Authorisation Application (MAA) has passed validation, and that the scientific review of the MAA is underway.

The Company's follow on product candidate, ZALVISO® (sufentanil sublingual tablet system), designed for the management of moderate-to-severe acute pain in adult patients in the hospital setting, is currently enrolling patients in a Phase 3 clinical trial, IAP312. 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 and is investigational and in late-stage development in the U.S. Grunenthal Group holds the rights for ZALVISO in Europe, where a commercial launch has begun.

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, DSUVIA™ (sufentanil sublingual tablet, 30 mcg), known as ARX-04 outside the United States, and ZALVISO® (sufentanil sublingual tablet system), including U.S. Food and Drug Administration, or FDA, review of the New Drug Application, or NDA, for DSUVIA; the potential approval of the DSUVIA NDA by the FDA; the the European Medicines Agency (EMA) scientific review of the ARX-04 Marketing Authorisation Application (MAA); the DSUVIA and ARX-04 clinical trial results; AcelRx's pathway forward towards gaining approval of ZALVISO in the U.S., including successful completion of the IAP312 clinical study for ZALVISO; and the therapeutic and commercial potential of AcelRx's product candidates. These forward-looking statements are based on AcelRx Pharmaceuticals' current expectations and inherently involve

significant risks and uncertainties. AcetRx 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 AcetRx Pharmaceuticals' DSUVIA and ARX-04 development programs, including the FDA review of the DSUVIA NDA and the EMA review of the ARX-04 MAA, including possibility that the FDA or EMA may dispute or interpret differently clinical results obtained from the DSUVIA or ARX-04 Phase 2 and 3 studies; the ZALVISO development program, including successful completion of IAP312 and the resubmission of the ZALVISO NDA to the FDA; any delays or inability to obtain and maintain regulatory approval of its product candidates, including DSUVIA in the United States, ARX-04 in Europe and ZALVISO in the United States; the uncertain clinical development process; the success 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 Annual Report on Form 10-K filed with the SEC on March 3, 2017. 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.



To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/acetrx-pharmaceuticals-presenting-comprehensive-dsuvia-clinical-trial-results-at-asras-annual-regional-anesthesiology-and-acute-pain-medicine-meeting-300434984.html>

SOURCE AcetRx Pharmaceuticals, Inc.

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