



AcelRx Pharmaceuticals Unveiling Results of ARX-04 SAP303 Study in Post-Operative Setting at the Annual ASRA Pain Medicine Meeting

Nov 17, 2016

REDWOOD CITY, Calif., Nov. 17, 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, announced an upcoming presentation at the 15th Annual Pain Medicine Meeting of the American Society of Regional Anesthesia and Pain Medicine (ASRA). The presentation is part of the Emerging Technology Moderated Poster session and will mark the first presentation of complete results from the [Phase 3 SAP303 study](#) of ARX-04 (sufentanil sublingual tablet, 30 mcg). The study enrolled 140 patients aged ≥40 years who had undergone short-stay in-patient or out-patient surgery. ASRA's Annual Pain Medicine Meeting will take place November 17-19, 2016 in San Diego, CA.

As was first reported in September, treatment with ARX-04 in SAP303 was associated with a 49% reduction in mean pain intensity from baseline (from 6.19 to 3.17 on a 0-10 numeric rating scale) during the first 2 hours, and maintenance of that reduction for the duration of the 12-hour study period. Pain relief was reported as early as 15 minutes after the start of ARX-04 dosing, with the majority of patients experiencing an overall decline in pain levels from "high moderate" at baseline to "mild" by hour two. The most frequently reported adverse events in the study population were nausea (27%) and headache (6%). Baseline hepatic and/or renal impairment was present in 29% of patients, but no differences in adverse events were recorded between patients with normal and impaired liver or renal function.

Details on the presentation are as follows:

Title: A Phase 3 Open Label Study of the Sufentanil Sublingual Tablet 30mcg for Treatment of Acute Post-Operative Pain (Moderated Poster #3101)

Authors: Harold Minkowitz, MD of the Memorial Hermann Memorial City Medical Center in Houston, TX; David Leiman, MD of the Hermann Drive Surgical Hospital in Houston, TX; and Pamela P. Palmer, MD, PhD and Karen DiDonato, MSN, RN of AcelRx Pharmaceuticals.

Date/Time: Saturday, November 19, 2016; 10:45am-12:45pm

Location: Session MP-10, Indigo Room 202A, Hilton San Diego Bayfront Hotel

The American Society of Regional Anesthesia and Pain Medicine (ASRA) is one of the largest subspecialty medical societies in anesthesiology with more than 4,000 members in 60 countries and 6 continents. For more information on the organization or its Annual Pain Medicine Meeting, please visit www.asra.com.

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, where a commercial launch has begun, 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; the uncertain clinical development process; the success, cost and timing of all development activities and clinical trials; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx's U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on November 2, 2016. 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.



Logo - <http://photos.prnewswire.com/prnh/20130226/MM67303LOGO>

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/acelrx-pharmaceuticals-unveiling-results-of-arx-04-sap303-study-in-post-operative-setting-at-the-annual-asra-pain-medicine-meeting-300364611.html>

SOURCE AcelRx Pharmaceuticals, Inc.

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