



AcelRx Pharmaceuticals' ARX-04 Phase 3 Trial Met its Primary Endpoint, Reduced Pain Intensity in ER Patients with Moderate-to-Severe Acute Pain

Aug 15, 2016

- Topline SAP302 Results Presented at Military Health System Research Symposium -

REDWOOD CITY, Calif., Aug. 15, 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, reported topline results from the single-arm, open-label Phase 3 SAP302 trial ([NCT02447848](#)), which assessed ARX-04 (sufentanil sublingual tablet, 30 mcg) in patients who presented to the emergency room with moderate-to-severe acute pain associated with trauma or injury. Overall, the 76 adults treated with [ARX-04](#) in this study experienced a mean pain intensity difference to baseline (PID) of 2.9 from a baseline of 8.1, or 35%, on a 0 – 10 numeric rating scale at 60 minutes.

SAP302 enrolled patients in two cohorts. The initial phase enrolled 40 adults who were administered a single dose of ARX-04; and an extension phase enrolled 36 adults who were eligible to receive up to four doses of ARX-04, given hourly as needed for pain. [Interim results](#) from the first cohort were reported in February 2016, and showed that patients treated with a single dose of ARX-04 experienced a mean pain intensity decrease from baseline of 2.7 at 60 minutes. Patients in the second cohort reported a mean pain intensity decrease from baseline of 3.1 on the 0 – 10 pain intensity scale at 60 minutes. Of these 36 patients, seven received a second dose of ARX-04, and two received a third dose. For 75% of patients in the second cohort, a single dose of ARX-04 was sufficient for pain relief and only 8% of patients received morphine in addition to ARX-04.

In addition, ARX-04 demonstrated a predicted onset of activity in patients enrolled in SAP302. Patients reported a mean pain intensity decrease of 1.1 compared to baseline 15 minutes following first administration of ARX-04, and a decrease of 1.9 after 30 minutes.

Overall ARX-04 was well tolerated in this study, with 79% of patients reporting no adverse events. The most common adverse events reported in the study occurred with single-digit rates - the most common being nausea (9%), somnolence (5%) and vomiting (4%). All these events were rated as mild with the exception of one event of moderate nausea. Drug-induced cognitive impairment was not seen with ARX-04 in this study, as assessed using the validated Six-Item Screener.

"The Department of Defense, which has provided us with development funding for ARX-04, suggested that we conduct a cognitive impairment assessment to determine if ARX-04 causes cognitive deficiencies, which is an understandable concern when treating wounded soldiers on the battlefield," explained [Dr. Pamela Palmer](#), co-founder and chief medical officer of AcelRx Pharmaceuticals. "In addition to putting combat units in danger, drug-induced cognitive effects can impede diagnosis and treatment in a civilian emergency room. If borne out, ARX-04's onset of pain relief, sublingual dosage form and side effect profile could make it an attractive option for doctors considering opioid analgesic treatment in emergency rooms and field-based settings."

About MHSRS

The above results are being presented today at the 2016 Military Health System Research Symposium (MHSRS), the Department of Defense's premier scientific meeting. The MHSRS is being held at the Gaylord Palms Resort & Convention Center in Kissimmee, FL from August 15-18. It is a venue for communicating and discussing new scientific knowledge resulting from research and development aimed at optimizing care for members of the Uniformed Services in operational settings. It is the only military or civilian meeting that focuses specifically on the unique medical needs of the warfighter.

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 via a disposable, pre-filled, single-dose applicator (SDA). AcelRx is developing ARX 04 for the management of moderate-to-severe acute pain in a variety of medically supervised settings, including the emergency room, outpatient or ambulatory surgery, non-surgical patients experiencing pain in the hospital, and post-operative patients following short-stay surgery, who do not require more long-term patient-controlled analgesia (PCA).

The ARX-04 Phase 3 clinical program is comprised of three studies in patients with moderate-to-severe acute pain: SAP301, a double-blind, placebo-controlled trial in ambulatory abdominal surgery patients; SAP302, an open-label trial in adult emergency room patients; and SAP303, an open-label trial in postoperative patients. Results of SAP301, which were presented in 2015 at the American Society of Anesthesiologists annual meeting, may be viewed on the AcelRx [website](#).

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 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 a medically supervised setting; and Zalviso® (sufentanil sublingual tablet system) designed for the management of moderate-to-severe acute pain in adult patients in the hospital setting.

ARX-04 delivers 30 mcg sufentanil, a high therapeutic index opioid, sublingually through a disposable, pre-filled, single-dose applicator. AcelRx has reported positive results from the pivotal Phase 3 SAP301 ambulatory surgery study, and has recently completed SAP302 (study in emergency room patients) and SAP303 (study in post-operative patients 40 years and older). Zalviso delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. In response to the New Drug Application (NDA) AcelRx submitted to the U.S. Food and Drug Administration (FDA) seeking approval for Zalviso, AcelRx received a Complete Response Letter (CRL) on July 25, 2014. The

FDA has requested an additional clinical study (IAP312), which AcetRx is planning to initiate once supply testing is complete in order to support its NDA resubmission.

For additional information about AcetRx's clinical programs, please visit www.acetrx.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 AcetRx'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; AcetRx's pathway forward towards gaining approval of Zalviso in the U.S.; the anticipated timing, design and results of the IAP312 clinical trial for Zalviso; anticipated resubmission of the Zalviso NDA to the FDA including the scope of the resubmission and the timing of the resubmission, and FDA review time; and the therapeutic and commercial potential of AcetRx's product candidates, including potential market opportunities for ARX-04 and Zalviso. These forward-looking statements are based on AcetRx 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' ability to successfully complete Phase 3 clinical development of ARX-04; AcetRx's ability to successfully execute the pathway towards a resubmission of the Zalviso NDA to the FDA, including the initiation and completion of the IAP312 clinical study for Zalviso; 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 begin on time, have an effective clinical design, enroll a sufficient number of patients, or be initiated or completed on schedule, if at all; the success, cost and timing of all development activities and clinical trials, including the Phase 3 ARX-04 SAP302 and SAP303 trials, and the additional clinical trial for Zalviso, IAP312; the fact that the FDA may dispute or interpret differently clinical results obtained to date from the Phase 3 studies of ARX-04 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-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.



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

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/acetrx-pharmaceuticals-arx-04-phase-3-trial-met-its-primary-endpoint-reduced-pain-intensity-in-er-patients-with-moderate-to-severe-acute-pain-300312758.html>

SOURCE AcetRx Pharmaceuticals, Inc.

Gina Ford, RPh, MBA, Vice President, Commercial Strategy, 650.306.8241, gford@acetrx.com; or Brian Korb, The Trout Group LLC, 646.378.2923, bkorb@troutgroup.com