



AcelRx Pharmaceuticals Presents ARX-04 Dose-Finding Phase 2 Study Data at Anesthesia Medical Conference

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- 30 mcg sufentanil NanoTab treatment group experienced rapid onset of action with statistically significant pain relief and reduced pain intensity at 30 minutes -

REDWOOD CITY, Calif., Dec. 13, 2013 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute and breakthrough pain, today presented additional detail from the Phase 2 dose-finding study of ARX-04, an investigational single-dose sublingual sufentanil NanoTab for moderate-to-severe acute pain, for which topline results were reported in April 2013. Patients treated with the 30 mcg dose of sufentanil showed a rapid onset of action with a statistically significant beneficial difference in pain relief ($p < 0.001$) and pain intensity ($p < 0.01$) seen at 30 minutes after dosing compared to placebo. Dosing averaged every 2.4 hours over the duration of the 12-hour study. In addition, patient global assessment of the 30 mcg dose at 12 hours was superior to placebo ($p = 0.002$) with 43.6% vs. 5.0% of the patients responding good or excellent for overall pain control. The 20 mcg dose was not significant for either endpoint. This study was funded by a grant from the U.S. Army Medical Research and Materiel Command. These results are being presented at the 67th Annual PostGraduate Assembly in Anesthesia being held in New York City.

"These additional analyses of data from our Phase 2 study demonstrate a rapid onset of action and a sustained strong analgesic effect for ARX-04 (30 mcg), a non-invasive, healthcare provider-administered analgesic product candidate for the short-term treatment of moderate-to-severe acute pain where intravenous access may not be desirable or readily available," stated Dr. Pamela Palmer, Chief Medical Officer, AcelRx Pharmaceuticals. "These data will be reviewed in our End-of-Phase 2 meeting with the FDA later this month in order to define the Phase 3 development program for ARX-04, which we hope to initiate in the second half of 2014."

This dose-ranging study randomized 101 patients following bunionectomy surgery in a 2:2:1 ratio to 30 mcg sufentanil, 20 mcg sufentanil or placebo treatment arms. The intent-to-treat (ITT) population in this study averaged 42.5 years of age and was evenly balanced for males and females (51%:49%). Ninety-one percent of patients entering the study completed the full 12-hour study period. SPID-12 (Summed Pain Intensity Difference to baseline during the 12-hour study period) scores, the primary endpoint, were +6.53 for 30 mcg sufentanil-treated patients and -7.12 for placebo-treated patients, the difference between the two groups being highly statistically significant ($p = 0.003$). The 20 mcg sufentanil-treated patients did not achieve SPID-12 scores that differentiated from placebo. For the time-weighted sum of pain relief scores over the 12-hour study period, or TOTPAR12, there was a statistically significant difference in favor of the 30 mcg group over placebo (9.73 vs. 4.37 $p = 0.002$).

Two serious adverse events (SAEs), both in the 20 mcg-dose group, occurred one week after the study (surgical infections) and were deemed unrelated to study drug. All but two adverse events reported in the study were mild-to-moderate in nature with 58 patients (58%) reporting a total of 135 adverse events. The most frequently reported adverse events for all patients were nausea (30%), vomiting (17%), dizziness (14%) and somnolence (11%). Two patients discontinued treatment, one unrelated to study drug (anxiety/chest pain) and the other probably related to study drug (somnolence/respiratory depression), however both patients recovered without medical intervention.

About ARX-04

ARX-04 is a product candidate in development for the treatment of moderate-to-severe acute pain, consisting of sufentanil, a high therapeutic index opioid, formulated using AcelRx's proprietary NanoTab technology that enables rapid sublingual absorption when the NanoTab is placed under the tongue. As a result, sufentanil NanoTabs are designed to provide rapid onset of analgesia via a non-invasive route of administration and display a consistent pharmacokinetic profile due to a high percentage of drug being absorbed sublingually instead of through the gastrointestinal tract. ARX-04, which is administered by a healthcare professional using a simple, single dose administrator, may ultimately be proven beneficial in a variety of medically supervised settings, potentially including use in battlefield injury, by paramedics during patient transport, in the emergency room, for non-surgical patients experiencing pain in the hospital, or for post-operative patients, following either short-stay or ambulatory surgery who do not require more long-term patient-controlled analgesia (PCA). According to the Centers for Disease Control and Prevention data, there are more than 45 million injury-related emergency department visits and 43 million ambulatory surgery procedures annually in the United States.

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 and breakthrough pain. AcelRx's lead product candidate, Zalviso™, is designed to solve the problems associated with post-operative intravenous patient-controlled analgesia which has been shown to cause harm to patients following surgery because of the side effects of morphine, the invasive IV route of delivery and the complexity of infusion pumps. AcelRx has announced positive results from each of the three completed Phase 3 clinical trials for Zalviso, and has submitted an NDA to the FDA seeking approval for Zalviso in the treatment of moderate-to-severe acute pain in adult patients in the hospital setting. AcelRx has also announced positive top-line results for a Phase 2 trial for ARX-04, a product candidate for the treatment of moderate-to-severe acute pain in a medically supervised setting, funded through a grant from the U.S. Army Medical Research and Materiel Command. The company has two additional pain treatment product candidates, ARX-02 and ARX-03, which have completed Phase 2 clinical development. 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 clinical development of ARX-04, therapeutic and commercial potential of Zalviso and the anticipated timing, and therapeutic and commercial potential of ARX-04 and other AcelRx product candidates. These forward-looking statements are based on AcelRx's current expectations and inherently involve significant risks and uncertainties. AcelRx's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to: AcelRx's ability to receive regulatory approval for Zalviso, the fact that FDA may dispute or interpret differently clinical results obtained to date; the success, cost and timing of all product development activities and clinical trials related to ARX-04; any delays or inability to obtain and maintain regulatory approval of its product candidates, including Zalviso, in the United States and Europe; its ability to attract funding partners or collaborators with development, regulatory and commercialization expertise; its ability to obtain sufficient financing to commercialize Zalviso; the market potential for its product candidates, including

ARX-04; the accuracy of AcelRx's estimates regarding expenses, capital requirements and needs for financing; 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 5, 2013. 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.

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SOURCE AcelRx Pharmaceuticals, Inc.

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