AcelRx Announces Achievement of the Primary End-Point in Phase 3 Comparative Study Involving the Sufentanil NanoTab PCA System and Plans to Hold a Conference Call and Webcast Tomorrow to Discuss Top-Line Results

November 15, 2012

REDWOOD CITY, Calif., Nov. 14, 2012 /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, announced today it had met the primary endpoint in the Phase 3 non-inferiority study of the sublingual Sufentanil NanoTab PCA System vs. IV PCA with morphine. The top-line data is expected to be released prior to market opening on November 15, 2012, and following such release AcelRx management will host an investment-community conference call at 8:00 a.m. Eastern Time (5:00 a.m. Pacific Time) to discuss the Phase 3 top-line results.

The conference call and webcast will be held tomorrow, Thursday, November 15, 2012 at 8:00 a.m. Eastern Time (5:00 a.m. Pacific Time) to discuss the Phase 3 top-line results. To listen to the conference call, dial in approximately ten minutes before the scheduled call to (800) 860-2442 for domestic callers, (866) 605-3852 for Canadian callers, or (412) 858-4600 for international callers. Those interested in listening to the conference call live via the Internet may do so by visiting the Investor Relations section of the company's website at www.acelrx.com.

A webcast replay will be available on the AcelRx website for 90 days following the call by visiting the Investor Relations section of the company's website at www.acelrx.com.

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, the ARX-01 Sufentanil NanoTab PCA System, is currently in Phase 3 clinical development and is designed to solve problems associated with post-operative intravenous patient-controlled analgesia, including side effects of morphine, invasive IV route of delivery and the inherent potential for programming and delivery errors associated with the complexity of infusion pumps. AcelRx has two additional product candidates that have completed Phase 2 clinical development: ARX-02 for the treatment of cancer breakthrough pain and ARX-03 for mild sedation, anxiety reduction and pain relief for patients undergoing painful procedures in a physician's office. AcelRx has initiated a Phase 2 study for a fourth product candidate, ARX-04, a sufentanil formulation for the treatment of moderate-to-severe acute pain, funded through a grant from the U. S. Army Medical Research and Materiel Command. 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 AcelRx Pharmaceuticals' product candidates, including the release ARX-01 top-line clinical trial data, the release and anticipated timing of additional ARX-01 clinical trial data, the potential filing of an NDA for the ARX-01 and the timing thereof, therapeutic and commercial potential of ARX-01 and the anticipated timing and therapeutic and commercial potential of other AcelRx Pharmaceuticals' product candidates. These forward-looking statements are based on AcelRx Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. AcelRx Pharmaceuticals' 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: the ability of AcelRx Pharmaceuticals to successfully complete the clinical trials for ARX-01, that fact that subsequent analyses of the full data set may lead to different, including less favorable, interpretations of the results than the analyses conducted to date or may identify important implications of the study that are not reflected in these statements, or be subject to differing interpretations by the regulatory agencies; the success, cost and timing of all product development activities and clinical trials; the uncertain clinical development process, including the risk that clinical trials, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all; any delays or inability to obtain regulatory approval of its product candidates in the United States and Europe; its ability to obtain adequate clinical supplies of the drug and device components of its product candidates; its ability to attract funding partners or collaborators with development, regulatory and commercialization expertise; its ability to obtain sufficient financing to complete development and registration of its product candidates in the United States and Europe; its ability to obtain and maintain regulatory approvals of its product candidates in the United States and Europe; the market potential for its product candidates; the accuracy of AcelRx Pharmaceuticals' estimates regarding expenses, capital requirements and needs for financing; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx Pharmaceuticals' U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q for the three months ended September 30, 2012. AcelRx Pharmaceuticals 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.

SOURCE AcelRx Pharmaceuticals, Inc.

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