AcelRx Announces Initiation of Phase 3 Clinical Program for ARX-01, the Sufentanil NanoTab PCA System for the Treatment of Post-Operative Pain

First Subject Dosed in Abdominal Surgery Trial with Top-Line Data Expected in H2 2012

REDWOOD CITY, Calif.; March 6, 2012

AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), ("AcelRx"), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute and breakthrough pain, reported dosing of the first patient in a Phase 3 study for ARX-01, the Sufentanil NanoTab PCA System, its novel sublingual patient-controlled analgesia system. This first ARX-01 Phase 3 study is a randomized, double-blind, placebo-controlled efficacy and safety trial in adults following open abdominal surgery. Approximately 150 adults, randomized 2:1 to active or placebo groups, will be treated for post-operative pain for a minimum of 48 hours and, as needed, up to 72 hours after randomization. The study will be conducted at 12 academic and community hospitals in the United States.

The remainder of the planned Phase 3 clinical program for ARX-01 includes a second randomized, double-blind, placebo-controlled efficacy and safety study comparing Sufentanil NanoTabs to placebo for post-operative pain control following major joint replacement surgery, and an open-label active-comparator study comparing ARX-01 to the current standard of care, intravenous patient-controlled analgesia, or IV PCA, with morphine.

"We are extremely pleased to have our ARX-01 Phase 3 clinical program underway. This year is an exciting time for AcelRx, with the delivery of top-line data from all three Phase 3 clinical trials expected by late 2012 or early 2013," said Richard King, AcelRx's Chief Executive Officer. Mr. King added, "We hope to be in a position to file an NDA with the FDA in mid-2013 for ARX-01. We believe ARX-01 is highly differentiated from the current standard of care for post-operative pain management, IV PCA. We look forward to the time when ARX-01 will be available to patients and health care providers as a non-invasive, pre-programmed, high therapeutic index opioid alternative to IV PCA."

About Post-Operative Pain

Acute pain management in the hospital, in particular post-operative analgesia, remains a challenge for healthcare providers with up to 75% of patients reporting inadequate pain relief after surgery. Inadequate treatment of post-surgical pain can lead to decreased mobility, which increases the risks for the medical complications, including deep vein thrombosis and partial lung collapse, potentially resulting in extended hospital stays. Over 23 million procedures per year result in moderate to severe post-operative pain in the major pharmaceutical markets (US, 5 main EU countries and Japan), resulting in $5.1 billion of acute pain treatment product sales. Current standard of care for managing post-operative pain is IV PCA, typically utilizing morphine or hydromorphone. However, there are many deficiencies associated with the current use of IV PCA that can negatively impact patient safety, well-
being and recovery. These include drug-related side effects associated with morphine or hydromorphone, complications associated with IV delivery, and medication delivery errors typically associated with misprogramming of the complex IV PCA pumps.

About ARX-01, the Sufentanil NanoTab PCA System

ARX-01 is a pre-programmed, non-invasive, handheld system that allows post-operative patients to self-dose with sublingual Sufentanil NanoTabs to manage their post-operative pain. The ARX-01 System is designed to address the limitations of IV PCA by offering:

**A high therapeutic index opioid**: Because ARX-01 uses the high therapeutic index opioid Sufentanil, it offers post-operative pain patients the potential for effective patient-controlled analgesia with a low incidence of drug-related side effects. Published data on IV PCA side-effect profiles suggests that somnolence (~50% of patients) and oxygen desaturation (~10% of patients) is unacceptably high. In our Phase 2 clinical studies, patients dosing over 12 hours with Sufentanil NanoTabs (15 mcg) exhibited a low incidence of somnolence (3%) and oxygen desaturation (1%).

**A non-invasive route of delivery**: The sublingual route of delivery used in ARX-01 provides rapid onset of analgesia, therefore eliminating the risk of IV-related analgesic gaps and IV complications, such as catheter-related infections. In addition, because patients are not tethered to IV tubing and a pump for pain relief, ARX-01 allows for ease of patient mobility.

**A simple, pre-programmed PCA solution**: ARX-01 is a preprogrammed PCA System designed to eliminate the risk of pump programming errors, which are a potential source of patient harm.

About AcelRx Pharmaceuticals, Inc.

Based in Redwood City, CA, AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX) 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, which is currently in Phase 3 clinical development, 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 inherent potential for programming and delivery errors associated with the complexity of infusion pumps. AcelRx has two additional product candidates which have completed Phase 2 clinical development: ARX-02 for the treatment of cancer breakthrough pain, and ARX-03 for providing mild sedation, anxiety reduction and pain relief for patients undergoing painful procedures in a physician's office. A fourth product candidate, ARX-04, is a sufentanil product for the treatment of moderate-to-severe acute pain that is expected to enter Phase 2 clinical development in the first quarter of 2012 under a grant from the US Army Medical Research and Material Command.
Forward Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to the planned or anticipated future clinical development of AcelRx Pharmaceuticals' product candidates, including the initiation of the first Phase 3 clinical study for ARX-01, the timing of the top-line data from all three clinical trials, the timing of submission of an NDA with the FDA, and the therapeutic potential of 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 success, cost and timing of AcelRx Pharmaceuticals' product development activities and clinical trials; the uncertain clinical development process, including the risk that planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be initiated or completed on schedule, if at all; any delays or inability to obtain, regulatory approval of its product candidates; its ability to obtain adequate clinical supplies of the drug and device components of its product candidates, including ARX-01; 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; 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 quarter ended September 30, 2011. 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.

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