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

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First Subject Dosed in Open-Label, Active-Comparator Trial

REDWOOD CITY, Calif., April 12, 2012 /PRNewswire via COMTEX/ --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, today reported dosing of the first patient in the second of three planned Phase 3 studies that will form the basis of a planned New Drug Application (NDA) for the Sufentanil NanoTab® PCA System, ARX-01. Utilizing a multicenter, randomized, open-label, parallel-group design, the study will compare the efficacy and safety of the Sufentanil NanoTab PCA System to the standard of care, IV PCA with morphine, in the treatment of acute post-operative pain immediately after major abdominal or orthopedic surgery. The primary objective of the study is to demonstrate non-inferiority of ARX-01 to IV PCA with morphine as determined by patient global satisfaction with the method of pain relief. Approximately 400 adult patients, randomized 1:1 to treatment with ARX-01 or IV PCA with morphine, will be treated for post-operative pain for a minimum of 48 hours after randomization. The study will be conducted at approximately 32 academic and community hospitals in the United States with top-line data expected in second half of 2012.

In March 2012, AcelRx initiated its first Phase 3 clinical study for ARX-01, a randomized, double-blind, placebo-controlled efficacy and safety study comparing ARX-01 to placebo for post-operative pain control following major open abdominal surgery. Data from this study is expected in second half of 2012. A third Phase 3 clinical study for ARX-01, expected to start in the third quarter of 2012, will be a randomized, double-blind, placebo-controlled efficacy and safety study comparing ARX-01 to placebo in treating post-operative pain following major joint replacement surgery.

"We are extremely pleased to have our second ARX-01 Phase 3 clinical trial underway. This study is expected to meet several objectives. Firstly, in addition to the two placebo-controlled studies, data from this active-comparator study will complete our ARX-01 safety database enabling review for marketing approval by regulatory agencies in the US and Europe. Secondly, positive results from this study demonstrating that pre-programmed, non-invasive delivery of Sufentanil NanoTabs provide non-inferior pain relief compared to IV PCA with morphine could support commercial adoption. Finally, secondary endpoint data from this study including comparison of average dosing intervals, sedation scores, system-related events and ease of care questionnaires, could support the pharmacoeconomic advantage of ARX-01, which we believe will help support adoption of the product in the US, and enable pricing of the product in Europe," said Richard King, AcelRx's Chief Executive Officer. Mr. King added, "This year is an exciting time for AcelRx, with the delivery of top-line data from all three ARX-01 Phase 3 clinical trials expected by late 2012 or early 2013."

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 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 in 2008. 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 up to 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 pre-programmed 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 second 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 third and final 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, the therapeutic potential of AcelRx Pharmaceuticals' product candidates and the pace of adoption and commercialization of ARX-01 in US and Europe. 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' US Securities and Exchange Commission filings and reports, including its Annual Report on Form 10-K for the year ended December 31, 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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