

AcelRx Announces \$5.6 Million Department of Defense Grant to Develop ARX-04, a New Acute Pain Product Candidate

REDWOOD CITY, Calif., May 31, 2011 /PRNewswire via COMTEX/ --

AcelRx Pharmaceuticals, Inc. (NASDAQ: ACRX)(AcelRx), today announced that the US Army Medical Research and Materiel Command (USAMRMC) has awarded AcelRx a \$5.6 million grant to support the development of a new product candidate, ARX-04, a proprietary non-invasive, fast-onset sublingual product for the treatment of moderate-to-severe acute pain. Commenting on the award, Richard King, AcelRx President and Chief Executive Officer stated, "ARX-04, a single dose, higher strength iteration of our ARX-01 product, represents a promising new application of our proprietary NanoTab® technology for sublingual delivery of sufentanil, and has the potential to safely provide rapid onset of analgesia for patients in acute pain, both on the battlefield and in civilian settings of trauma or injury." Mr. King added, "USAMRMC has provided AcelRx with a grant to support development of ARX-04 through completion of a Phase 2 study, which we will begin in the second half of 2011." Under the terms of the grant, the USAMRMC will reimburse AcelRx for development, manufacturing and clinical costs necessary to prepare for and complete the planned Phase 2 dose-finding trial in a study of acute moderate-to-severe pain, and to prepare to enter Phase 3 development.

About Acute Pain

In situations of trauma or injury, it is advantageous to have a rapid-acting, non-invasive method of treating acute pain. In the battlefield, in the emergency room and in ambulatory care environments, patients often do not have immediate intravenous (IV) access available. Intramuscular injections are a current standard of care on the battlefield, but they are invasive, painful, and present an increased risk of infection to both patient and health care professional. In addition, in cases of severe trauma where the patient is often in hypovolemic shock and muscles are not well perfused, pain medication given by intramuscular injection may not readily reach the blood stream to provide pain relief, rendering this route of delivery suboptimal. Oral pills and liquids generally have slow and erratic onset of analgesia. Even patients with IV access may have undesirable side effects with the commonly used IV opioids morphine and hydromorphone, such as sedation or oxygen desaturation. Moreover, IV dosing results in high peak plasma levels, thereby limiting the opioid dose and requiring frequent redosing intervals to titrate to satisfactory analgesia. Additional treatment options are needed which can safely and rapidly treat acute pain, in both civilian and military settings.

About ARX-04

ARX-04 is a non-invasive, acute pain product candidate that features sufentanil, a high therapeutic index opioid in AcelRx's proprietary NanoTab technology that enables rapid sublingual absorption when the NanoTab is placed under the tongue. As a result, sufentanil NanoTabs can provide rapid onset of analgesia and display a consistent pharmacokinetic profile due to a high percentage of drug being absorbed sublingually instead of through the gastrointestinal tract. In the Phase 2 study of ARX-04, two different doses of sufentanil will be evaluated in patients suffering from moderate-to-severe acute pain,

with the goal of determining an appropriate dose to take into Phase 3. In addition to battlefield casualty treatment, if approved, we anticipate that ARX-04 could be useful in a variety of medically supervised settings, including 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.

About AcclRx Pharmaceuticals, Inc.

Based in Redwood City, CA, AcclRx 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. AcclRx's lead product candidate, the ARX-01 SufentanilNanoTab PCA System, which is entering 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. AcclRx 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. ARX-04 will soon enter Phase 2 clinical development for the management of acute pain in a medically supervised setting.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to the US Army Medical Research and Material Command grant for research and development of AcclRx Pharmaceuticals' ARX-04 product candidate, potential market for the ARX-04 product candidate and its applications, the AcclRx Pharmaceuticals' statements relating to ARX-04 Phase 2 clinical trial, the funding and timing of the clinical trial and product candidate development. These forward-looking statements are based on the company's current expectations and inherently involve significant risks and uncertainties. AcclRx 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 AcclRx Pharmaceutical's product development activities and clinical trials; its ability to obtain and maintain regulatory approval of its product candidates, including any new product candidates; its ability to obtain funding for its operations and new product development; its plans to research, develop and commercialize its product candidates, including new product candidates; its ability to attract funding partners or collaborators with development, regulatory and commercialization expertise; the accuracy of AcclRx Pharmaceutical's estimates regarding expenses, capital requirements and needs for financing; and other risks detailed in the "Risk Factors" and elsewhere in AcclRx Pharmaceuticals' Securities and Exchange Commission filings and reports, including its Annual Report on Form 10-K for the year ended December 31, 2010, and its Form 10-Q for the quarter ending March 31, 2011. AcclRx 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 AcclRx Pharmaceuticals, Inc.