AcelRx Pharmaceuticals Doses the First Patients in ARX-04 Phase 2 Clinical Study

The Associated Press

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 announced that it has dosed the first subjects in a Phase 2, placebo-controlled, dose-finding study of its ARX-04 sufentanil NanoTab product candidate. This study will enroll approximately 100 patients following bunionectomy surgery, randomized into one of three groups; 20 mcg sufentanil NanoTab, 30 mcg sufentanil NanoTab or placebo, administered by healthcare personnel, as needed every hour.

The study will evaluate the ability of sufentanil NanoTabs to manage moderate-to-severe acute pain over the first 12 hours following bunionectomy, and correlate the pain response with sufentanil pharmacokinetics. AcelRx is conducting the study with funding provided by a grant from the U.S. Army Medical Research and Materiel Command, or USAMRMC.

"ARX-04, a single-dose applicator containing a single sufentanil NanoTab, represents a promising new application of our proprietary NanoTab@ technology for sublingual delivery of sufentanil by healthcare personnel, 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," stated Richard King, AcelRx's president and CEO.

In May 2011, USAMRMC awarded AcelRx a $5.6 million grant to support the development of ARX-04, a proprietary non-invasive, fast-onset sublingual product candidate for the treatment of moderate-to-severe acute pain. In accordance with the development plans of the grant, AcelRx filed the IND with the FDA during October 2011 and on November 1, 2012 initiated the Phase 2 study following protocol approval by the USAMRMC.

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, 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 in a non-invasive method of administration and display a consistent pharmacokinetic profile due to a high percentage of drug being absorbed sublingually instead of through the gastrointestinal tract. In this Phase 2 study of ARX-04, two different doses, 20 mcg and 30 mcg of sufentanil will be evaluated in patients experiencing moderate-to-severe acute pain, in order to determine an appropriate dose to advance into Phase 3. We believe ARX-04 may ultimately be proven beneficial in a variety of medically supervised settings, including use in battlefield casualty treatment, 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 (CDC) data, there are more than 45 million injury-related emergency department visits and 43 million ambulatory surgery procedures annually in the United States.

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, or IV, access available. Intramuscular injections are the 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 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 USAMRMC. For additional information about AcelRx's clinical programs please visit www.acelrx.com [1].

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 anticipated timing for clinical trials and therapeutic and commercial potential of AcelRx Pharmaceuticals' product candidates, including the study enrollment, safety and market potential of ARX-04. 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, including the Phase 2 ARX-04 clinical trial; 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 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 June 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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