AcelRx Pharmaceuticals Provides Clinical Trial Updates

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Continued progress towards NDA submission for Sufentanil NanoTab PCA System in Q3 2013

REDWOOD CITY, Calif., Feb. 19, 2013 /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, today announced continuing progress on its two remaining Phase 3 trials of the Sufentanil NanoTab PCA System being studied in post-operative pain. The first of those studies in patients after major abdominal surgery completed the last patient earlier this quarter, and is expected to provide data later this quarter. The second study, in patients after major orthopedic surgery, continues to enroll patients, with the last patient expected to enroll around the end of the first quarter of 2013, and data expected in the second quarter. A New Drug Application (NDA) submission for the NanoTab System remains on track for the third quarter of 2013. In addition, a Phase 2 clinical trial with ARX-04, a sufentanil formulation for the treatment of moderate-to-severe acute pain, has completed dosing and results from this study are expected to be available in the second quarter of 2013.

"We look forward to sharing the top-line results from our abdominal surgery pain study with our lead product candidate, the Sufentanil NanoTab PCA System, later this quarter and remain on track for an NDA submission later this year," said Richard King, president and chief executive officer of AcelRx.

Status of Ongoing Clinical Trials

- The last patient has completed the Sufentanil NanoTab PCA System Phase 3 double-blind, placebo-controlled post-operative pain study conducted in patients following open abdominal surgery. The study, initiated in March 2012, enrolled 178 patients at 14 sites. The study is designed to assess the ability of sufentanil, delivered through the NanoTab System to control moderate-to-severe post-operative pain over 48 to 72 hours compared to a placebo delivered through the NanoTab System. The study will also assess the tolerability, safety, and ease of use of the NanoTab System by nurses and patients. Top-line results are expected in the first quarter of 2013.
- A second placebo-controlled Phase 3 trial with the Sufentanil NanoTab PCA System is being conducted at approximately 32 sites in patients following hip or knee replacement surgery. Targeting enrollment of approximately 400 patients, dosing of the final subject in this study is expected around the end of the first quarter of 2013. The primary endpoint for both the abdominal and orthopedic placebo-controlled Phase 3 studies is the sum of pain intensity difference to baseline (SPID) over 48 hours. Top-line results should be available for the orthopedic study during the second quarter of 2013.
- Dosing of the last patient in a Phase 2, placebo-controlled, dose-finding study of the Company's ARX-04 sufentanil NanoTab product has completed. This study, which began in November 2012, enrolled 101 patients following bunionectomy surgery, randomized into one of three groups: 20 mcg sufentanil NanoTab, 30 mcg sufentanil NanoTab or placebo. Each dose was administered by healthcare personnel, as requested by the patient, up to a maximum of one dose every hour. The study is designed to evaluate the ability of sufentanil NanoTabs to manage moderate-to-severe acute pain over the first 12 hours following bunionectomy surgery. ARX-04 is a sublingual sufentanil product candidate designed to provide a non-invasive, fast-onset treatment of patients with moderate-to-sever acute pain, both on the battlefield and in civilian settings of trauma or injury. AcelRx is conducting the study at two sites with funding provided by a $5.6 million grant from the U.S. Army Medical Research and Materiel Command (USAMRMC). Top-line results from the trial are expected during the second quarter of 2013.

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 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 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 mild sedation, anxiety reduction and pain relief for patients undergoing painful procedures in a physician's office. AcelRx has completed enrollment in 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 USAMRMC. 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 of ARX-01 clinical trial data, the release of ARX-04 clinical trial data, the potential submission of an NDA for ARX-01 and the timing hereof, the therapeutic and commercial potential of ARX-01 and the anticipated timing and therapeutic and commercial potential of other AcelRx Pharmaceuticals product candidates including 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 ability of AcelRx Pharmaceuticals to successfully complete the final clinical trial for ARX-01; the duration of time required to assess clinical trial results once the dosing of patients is completed; 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; the final Phase 3 study enrolls 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 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 Current Report on Form 8-K filed with the SEC on December 7, 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.

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