AcelRx Pharmaceuticals Presents Positive Clinical Data for the Sufentanil NanoTab PCA System at ASRA Medical Meeting

May 02, 2013

- Additional Phase 3 analysis show significantly faster reduction in pain and fewer patients with oxygen desaturation events for Sufentanil NanoTab PCA System than IV PCA with morphine -

- Sufentanil NanoTab PCA System remains on track for a Q3 2013 NDA submission -

REDWOOD CITY, Calif., May 2, 2013 /PRNewswire/ -- 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 additional clinical results for its lead product candidate, the Sufentanil NanoTab PCA System for the treatment of moderate-to-severe acute pain in the hospital setting. These data are being presented in five posters at the American Society of Regional Anesthesia and Pain Medicine (ASRA) spring meeting held May 2 to May 5, 2013 in Boston, MA. New analyses from the Phase 3 comparison trial of the NanoTab System to intravenous patient-controlled analgesia (IV PCA) with morphine (see press release dated November 15, 2012) demonstrate that sufentanil delivered via the NanoTab System has a significantly greater pain intensity reduction in the first four hours after starting treatment than IV PCA morphine ($p<0.01$). In addition, there were fewer patients throughout the study that experienced oxygen desaturation events below 95% in the Sufentanil NanoTab PCA System group than in the IV PCA morphine group ($p=0.028$). Oxygen saturation is a measure of a patient's respiratory function and can be affected negatively by opioids. A decrease in oxygen saturation can be linked to the serious adverse event of respiratory depression.

"Obtaining effective control over post-operative pain early on is critical not only for patient satisfaction, but to avoid the deleterious effects of under-treatment of pain, such as pulmonary complications and an increased stress response" remarked Marc Huntoon, MD, Professor and Chief, Division of Pain Medicine at Vanderbilt University in Nashville TN. "Providing rapid, effective analgesia following major surgery while reducing oxygen desaturation events is an important advance in treatment of post-operative pain," added Dr. Huntoon.

Four additional posters presented at the meeting highlighted recently released results from a placebo-controlled Phase 3 study conducted in abdominal surgery patients, new pharmacokinetic data from a study evaluating different oral-transmucosal routes of delivery of sufentanil NanoTabs, design features for the NanoTab System, and new data from three Human Factors studies describing ease of set-up and use of the NanoTab System for patients and healthcare personnel.

"We have significant data to present at meetings during the next year based on the ongoing analysis of our recent clinical trials," stated Dr. Mike Royal, chief, clinical affairs for AcelRx. "The well-published high therapeutic index for sufentanil and its short brain equilibration time is being reinforced by the clinical data that we are collecting," added Dr. Royal.

"We are excited to present this additional data at the ASRA meeting regarding our NanoTab System. We are particularly pleased by the rapid reduction in pain intensity after treatment is started, and the reduced number of patients experiencing oxygen desaturation events, an important safety measure, when using the NanoTab System," stated Richard King, president and CEO of AcelRx. "We remain on track to submit an NDA for the NanoTab System later this year."

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, 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 announced results from two Phase 3 clinical trials for the NanoTab System, and a third Phase 3 study has completed enrollment, with data expected in the second quarter of 2013. A New Drug Application submission is planned for the third quarter of 2013. AcelRx recently announced positive top-line results for a Phase 2 trial for ARX-04, a sufentanil formulation for the treatment of moderate-to-severe acute pain, funded through a grant from USAMRMC. The company has two additional pain treatment product candidates, ARX-02 and ARX-03, which have completed Phase 2 clinical development. 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 the NanoTab System and ARX -04 top-line clinical trial data, the release and anticipated timing of additional NanoTab System clinical trial data, the potential submission of an NDA for NanoTab System and the timing thereof, therapeutic and commercial potential of NanoTab System and the anticipated timing and therapeutic and commercial potential of other 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 ability of AcelRx Pharmaceuticals to successfully complete the clinical trials for the sufentanil NanoTab System, that fact that subsequent analyses of the data may lead to different (including less favorable) interpretations of the results than the analyses conducted to date, or be subject to differing interpretations by the regulatory agencies; 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, or be completed on schedule; any delays or inability to obtain and maintain regulatory approval of its product candidates in the United States and Europe; its ability to attract funding partners or collaborators with development, regulatory and commercialization expertise; its ability to obtain sufficient financing to complete registration of its product candidates in the United States and Europe; the market potential for its product candidates; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx Pharmaceuticals' U.S. Securities and Exchange Commission filings and reports, including its Annual Report on Form 10-K filed with the SEC on March 12, 2013. 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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