AcelRx Pharmaceuticals Receives Two Notices of Allowance for Small-Volume Oral Transmucosal Dosage Forms

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First US allowances could provide for intellectual property protection for AcelRx pipeline of NanoTab® pain products until at least 2029.

REDWOOD CITY, Calif., April 11, 2012 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (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 the U.S. Patent and Trademark Office (USPTO) has issued AcelRx two Notices of Allowance for the patent applications entitled "Small-Volume Oral Transmucosal Dosage Forms" and "Bioadhesive Drug Formulations for Oral Transmucosal Delivery." The patents to be issued from these applications describe a method of treating pain by adhering a small-volume solid tablet containing sufentanil to the oral mucosa, as well as compositions and dosage forms broadly covering NanoTab formulations. The patents to be issued can be kept in force for sufentanil NanoTab based products through at least February of 2029.

A related European patent, EP2114383B1, was previously issued by the European Patent Office (EPO) in June 2010 and AcelRx is also prosecuting similar claims internationally through the Patent Cooperation Treaty (PCT).

"These are important additions to our patent portfolio and strengthen our ability to protect our proprietary technology as we advance clinical development of the ARX-01 sublingual sufentanil PCA system for management of moderate to severe acute pain in the hospital setting," said Richard King, AcelRx's President and CEO. Mr. King added, "We are focused on continued expansion of our patent portfolio as we further investigate the safety and efficacy profile of our sublingual sufentanil NanoTabs."

These allowances issued by the USPTO are in relation to sublingual sufentanil NanoTabs. AcelRx exclusively owns the underlying patent applications, which when issued will individually and collectively provide domestic protection for each of the Company's four development programs. The 11/650,174 patent application covers AcelRx's proprietary NanoTab technology for delivering sufentanil with claims to a method for treating pain by adhering a small volume (3-15 mcL) substantially homogenous solid tablet containing the active ingredient sufentanil to the oral mucosa of a subject while generating a minimal saliva response and delivering the majority of the drug through the transmucosal route resulting in consistent pharmacokinetics. The 11/825,251 patent application contains broad claims to sufentanil-containing bioadhesive tablets up to 50 microliters in volume which generate a minimal saliva response and deliver the majority of the active ingredient through the transmucosal route.

AcelRx also holds a related European patent EP2114383, which covers small-volume NanoTab® dosage forms for transmucosal administration containing the opioid sufentanil. The European patent covers elements of AcelRx's dispensing technology and also provides patent protection of specific pharmacokinetic parameters derived from sublingual administration using the NanoTab technology. AcelRx currently has more than 50 pending worldwide patent applications and continues to file additional new patent applications to further strengthen its market exclusivity.

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 USAMRMC.

Forward Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to AcelRx Pharmaceuticals' patent portfolio, including the likely issuance and useful life of the pending US patent for a method of treating pain by administering a small-volume solid tablet containing sufentanil by adhering to the oral mucosa, the continued expansion of its patent protection, market exclusivity, its ability to protect its proprietary technology, the scope of patent protection when issued, and planned or anticipated future clinical development of AcelRx Pharmaceuticals' product candidates, including the timing of the top-line data from its clinical trials, the timing of submission of an NDA with the FDA, and the therapeutic potential of 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 success, cost and timing of AcelRx Pharmaceuticals' patent prosecution strategy and product development activities and clinical trials; its ability to protect its proprietary technology, including the risks that pending patent applications may not result in issued patents; 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; 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

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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