AcelRx Pharmaceuticals Receives International Standards Organization (ISO) 13485:2003 Certification of its Quality Management System

November 10, 2014

REDWOOD CITY, Calif., Nov. 10, 2014 /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 that it has been granted International Standards Organization (ISO) 13485:2003 certification of its quality management system, an internationally recognized quality standard for medical devices issued by the British Standards Institution (BSI).

ISO 13485:2003 certification recognizes that consistent quality policies and procedures are in place at AcelRx for the development, design and manufacturing of medical devices. The certification indicates that AcelRx has successfully implemented a quality system that conforms to ISO 13485 standards for medical devices. Certification to this standard is one of the key regulatory requirements for a CE Mark in the European Union as well as requirements in other international markets. The certification applies to the Redwood City, CA location which designs, manufactures and distributes finished medical devices.

"The ISO certification is an important milestone for AcelRx as we work together with Gruenenthal towards bringing Zalviso to the European market," stated Richard King, president and CEO of AcelRx. "The certification confirms that our Quality System meets the highest standards."

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, Zalviso, is designed to improve the management of moderate-to-severe acute pain in adult patients in the hospital setting by utilizing a high therapeutic index opioid, through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. AcelRx has announced positive results from each of the three completed Phase 3 clinical trials for Zalviso, and has submitted an NDA to the FDA seeking approval for Zalviso in the treatment of moderate-to-severe acute pain in adult patients in the hospital setting and on July 25th, received a Complete Response Letter from the FDA. AcelRx plans to initiate a Phase 3 clinical trial for ARX-04, a product candidate for the treatment of moderate-to-severe acute pain in a medically supervised setting, by the end of 2014. 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 company's Zalviso NDA and the Complete Response Letter ("CRL"), the recent meeting held with the FDA to discuss the CRL, our plans to address the issues raised in the CRL, our anticipated resubmission of the Zalviso NDA to the FDA, including the scope of the resubmission and the timing of the resubmission and FDA review time, planned initiation of the Phase 3 clinical trial for ARX-04, and the therapeutic and commercial potential of AcelRx Pharmaceuticals' product candidates, including Zalviso. 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: AcelRx Pharmaceuticals' ability to receive regulatory approval for Zalviso; any delays or inability to obtain and maintain regulatory approval of its product candidates, including Zalviso, in the United States and Europe; AcelRx's ability to build an effective commercial organization; its ability to obtain sufficient financing to commercialize Zalviso and proceed with clinical development of ARX-04; the success, cost and timing of all product development activities and clinical trials, including the planned Phase 3 ARX-04 trial; 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 Quarterly Report on Form 10-Q filed with the SEC on August 11, 2014. 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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