



AcelRx Pharmaceuticals Receives CE Mark Approval for Zalviso

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REDWOOD CITY, Calif., Dec. 2, 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 received CE Mark approval (Conformite Europeenne) for the Zalviso device. Zalviso is a drug-device combination product utilizing the opioid agonist sufentanil formulated in a proprietary sublingual tablet formulation and delivered through a pre-programmed, non-invasive proprietary delivery device. AcelRx has partnered with the Grunenthal Group to commercialize Zalviso in the European Union and Australia. AcelRx had previously announced that in July 2014, Grunenthal had submitted a Marketing Authorization Application (MAA) to the European Medicines Authority for Zalviso for the management of moderate to severe acute pain in adult patients in a medically supervised environment. Obtaining the CE Mark is an important step in the potential approval of the Zalviso MAA.

"The CE Mark approval is an essential regulatory milestone for commercialization and further approval of the Zalviso MAA in Europe," said Richard King, president and CEO of AcelRx. "We are pleased to have received the CE Mark as it shows that AcelRx has the capability to manufacture and develop a device that meets commercial regulatory requirements."

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. 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, or 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, timing and potential approval of the MAA for Zalviso in Europe, 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 November 10, 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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Timothy E. Morris, Chief Financial Officer, 650.216.3511, tmorris@acelrx.com, Brian Korb, The Trout Group LLC, 646.378.2923, bkorb@troutgroup.com