



Zalviso™ New Drug Application Accepted for Filing by FDA

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REDWOOD CITY, Calif., Dec. 2, 2013 /PRNewswire/ -- AcetRx 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 the Zalviso™ New Drug Application (NDA) was accepted for filing by the FDA on November 26, 2013. The acceptance for filing of the NDA indicates the FDA has determined that the application is sufficiently complete to permit a substantive review.

"We are extremely pleased with the filing of our NDA for Zalviso, representing achievement of another critical milestone for AcetRx," stated Richard King, president and CEO of AcetRx. "Zalviso, if approved, will provide hospitalized patients with a non-programmable, non-invasive, patient-controlled treatment option for the management of moderate-to-severe acute pain with a rapid onset of pain relief compared to the commonly used, intravenous patient controlled analgesia systems that typically utilize morphine."

The NDA, submitted on September 27, 2013, seeks approval for the marketing and sale of Zalviso for the management of moderate-to-severe acute pain in adult patients in the hospital setting. The NDA submission is based primarily on data from a Phase 3 registration program that included two double-blind randomized placebo-controlled clinical trials, one conducted in patients following major abdominal surgery, the other in patients following major joint replacement surgery. Additionally, a Phase 3 open-label active-comparator trial was conducted in patients following either major abdominal or orthopedic surgery, comparing Zalviso to the current standard of care, intravenous patient-controlled analgesia (IV PCA) with morphine. Zalviso successfully achieved the primary efficacy endpoints for each of these studies. Treatment-emergent adverse events were typical of opioid usage post-operatively, were generally mild-to-moderate in nature, and were similar in both active- and placebo-treatment groups for the majority of adverse events.

About Zalviso

Zalviso is an investigational pre-programmed, non-invasive, handheld system that allows hospital patients with moderate-to-severe acute pain to self-dose with sublingual sufentanil microtablets to manage their pain. Zalviso is designed to address the limitations of IV PCA by offering:

- *A high therapeutic index opioid* - Zalviso uses the high therapeutic index opioid sufentanil. It offers hospitalized adult patients with moderate-to-severe acute pain the potential for effective patient-controlled analgesia with a low incidence of drug-related side effects.
- *A non-invasive route of delivery* - The sublingual route of delivery used by Zalviso provides rapid onset of analgesia, and also eliminates the risk of IV-related analgesic gaps and IV complications, such as catheter-related infections in IV PCA treated patients. In addition, because Zalviso patients do not require direct connection to an IV PCA infusion pump through IV tubing, Zalviso allows for ease of patient mobility.
- *A simple, pre-programmed PCA solution* – Zalviso is a pre-programmed PCA system designed to eliminate the risk of infusion pump programming errors.

About Moderate-to-Severe Acute Pain

Moderate-to-severe acute pain management in the hospital remains a challenge for healthcare providers with up to 75% of patients reporting inadequate pain relief following surgery. Inadequate treatment of moderate-to-severe pain can lead to decreased mobility, which increases the risks for serious medical complications, including deep vein thrombosis and partial lung collapse, potentially resulting in extended hospital stays. Approximately 12 million surgical procedures per year result in moderate-to-severe pain in the U.S., with an additional 7.4 million hospital inpatients in the U.S. annually experiencing moderate-to-severe acute pain from other, non-post surgical, medical conditions. Currently, patients experiencing moderate-to-severe acute pain in the hospital may have IV PCA treatment, typically utilizing morphine or hydromorphone. However, there are deficiencies associated with the current use of IV PCA that can negatively impact patient safety, well-being and recovery. These include drug-related side effects associated with morphine or hydromorphone, complications associated with IV delivery and medication delivery errors typically associated with misprogramming of the complex IV PCA pumps.

About AcetRx Pharmaceuticals, Inc.

AcetRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute and breakthrough pain. AcetRx's lead product candidate, Zalviso™, 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. AcetRx 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 to be used to treat moderate-to-severe acute pain in the hospital setting. AcetRx has also announced positive top-line results for a Phase 2 trial for ARX-04, a product candidate for the treatment of moderate-to-severe acute pain in a medically supervised setting, funded through a grant from the U.S. Army Medical Research and Materiel Command. 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 AcetRx's clinical programs, please visit www.acetrx.com.

Forward Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to the anticipated receipt of the 74-day filing letter from the FDA related to Zalviso submission, potential approval of the NDA for Zalviso and the timing thereof, the therapeutic and commercial potential of Zalviso and the anticipated timing, and therapeutic and commercial potential of other AcetRx product candidates. These forward-looking statements are based on AcetRx's current expectations and inherently involve significant risks and uncertainties. AcetRx's 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's ability to receive regulatory approval for Zalviso, the fact that FDA may dispute or interpret differently positive clinical results obtained to date; any delays or inability to obtain and maintain regulatory approval of its product candidates, including Zalviso, 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 commercialize Zalviso; the market potential for its product candidates; the accuracy of AcelRx's estimates regarding expenses, capital requirements and needs for financing; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx's U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on November 5, 2013. AcelRx 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.

(Logo: <http://photos.prnewswire.com/prnh/20130226/MM67303LOGO>)

SOURCE AcelRx Pharmaceuticals, Inc.

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