



AcelRx Provides Regulatory Update on Zalviso

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REDWOOD CITY, Calif., March 9, 2015 /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 pain, today provided an update on the timing and potential content of the resubmission of the New Drug Application ("NDA") for Zalviso.

AcelRx late last week received correspondence from the Food and Drug Administration ("FDA") stating that in addition to the bench testing and two Human Factors studies it has performed, an additional clinical study is needed to assess the risk of inadvertent dispensing and overall risk of dispensing failures. AcelRx had previously obtained confirmation from the FDA that the protocol designs for the bench testing evaluating dispensing failures and the Human Factors studies evaluating inadvertent dispensing were acceptable to the FDA.

AcelRx plans to meet with the FDA to discuss and clarify the agency's belief that an additional clinical study is needed, and the potential design and objectives of such a study. As a result of this FDA communication and the need for clarity with FDA, AcelRx will not be making the Zalviso NDA resubmission this quarter. AcelRx will provide an update on the timing of the resubmission of the Zalviso NDA after AcelRx obtains more information from the FDA.

The Complete Response Letter received by AcelRx in July 2014 in response to the Zalviso NDA contained requests for additional information on the Zalviso System to ensure proper use of the device. The requests included provision of data demonstrating a reduction in the incidence of system errors, changes to the Instructions for Use for the device, and additional data to support the shelf life of the product. In the CRL, there were no requests to conduct additional human clinical studies. The CRL specifically identified Human Factors studies as appropriate to assess the changes to the instructions for use for the device.

Conference Call

AcelRx will conduct a conference call and webcast today, March 9, at 4:30 p.m. Eastern time (1:30 p.m. Pacific time) to discuss this update, its financial results and program updates. To listen to the conference call, dial in approximately ten minutes before the scheduled call to 1-866-361-2335 for domestic callers, 1-855-669-9657 for Canadian callers, or 1-412-902-4204 for international callers. Those interested in listening to the conference call live via the Internet may do so by visiting the Investors section of the company's website at www.acelrx.com and selecting the Webcast link for the Q4 2014 earnings conference call. A webcast replay will be available on the AcelRx website for 90 days following the call by visiting the Investors section of the company's website at www.acelrx.com.

About Zalviso™

Zalviso is an investigational pre-programmed, non-invasive system to allow hospital patients with moderate-to-severe acute pain to self-dose with sublingual sufentanil tablets to manage their pain. Zalviso consists of sufentanil tablets delivered by the Zalviso System, a needle-free, hand-held, patient-administered, pain management system (together, "Zalviso"). Zalviso is designed to help address certain problems associated with post-operative intravenous patient-controlled analgesia, by offering:

- A high therapeutic index opioid: Zalviso uses sufentanil, an opioid that has a high therapeutic index. The therapeutic index is the ratio of the effective dose versus the lethal dose. In animal studies, the therapeutic index for sufentanil was approximately 100 times larger than fentanyl and 300 times larger than morphine.
- A non-invasive route of delivery: Zalviso utilizes a sufentanil tablet which allows for a sublingual (under the tongue) route of delivery. Sufentanil is highly lipophilic which provides for rapid absorption in the fatty cells (or mucosal tissue) found under the tongue and for rapid transit across the blood-brain barrier to reach the mu-opioid receptors in the brain. The sublingual delivery used by Zalviso provides rapid onset of analgesia. The sublingual delivery system also eliminates the risk of IV-related analgesic gaps and IV complications, such as catheter-related infections. In addition, because patients do not require direct connection to an IV PCA infusion pump through IV tubing, Zalviso allows for ease of patient mobility.
- A pre-programmed PCA solution: Zalviso allows patients to self-dose sufentanil sublingual tablets via a pre-programmed, secure system designed to eliminate the risk of programming errors.

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, 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 25, 2014, 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 process and timing of anticipated future development of AcelRx's product candidates, including Zalviso and ARX-04; the Zalviso NDA submission and the CRL; the correspondence received from the FDA requesting a clinical trial to address risk of inadvertent dispensing and overall risk of dispensing failures; the tasks we have completed to address the issues raised in the CRL, and 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; the impact, if any, of the FDA's review of the amendments to the Zalviso NDA that were not previously reviewed; ; and the therapeutic and commercial potential of AcelRx Pharmaceuticals' product candidates, including Zalviso and ARX-04.

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 timely resubmit the Zalviso NDA to the FDA; potential additional clinical trials necessary in order to resubmit the Zalviso NDA; AcelRx's 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; its ability to obtain sufficient financing to receive regulatory approval for and commercialize Zalviso and complete 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; 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 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.

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/acelrx-provides-regulatory-update-on-zalviso-300047133.html>

SOURCE AcelRx Pharmaceuticals, Inc.

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