



AcelRx Receives Notice of Eligibility for Centralized Review from European Medicines Agency for the Sufentanil NanoTab® PCA System

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Centralized review process used for products that provide a significant therapeutic, scientific or technical innovation to patient health

REDWOOD CITY, Calif., Oct. 3, 2012 /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 a decision by the European Medicines Agency, or EMA, to permit registration of the Sufentanil NanoTab PCA System (ARX-01) via the centralized procedure under Article 3(2) (b) of Regulation EC 726/2004. This procedure will allow AcelRx to submit a single Marketing Authorization Application, or MAA, to the EMA for approval to market ARX-01 in all 27 European Union, or EU, member states, as well as in the 4 European Free Trade Association, or EFTA, countries, through a single evaluation that will be carried out through the Committee for Medicinal Products for Human Use. The 31 EU / EFTA countries represent a population of over 500 million people, with more than 20 million patients undergoing surgery each year resulting in moderate to severe pain in the days after surgery.

ARX-01 is a novel, non-invasive, sublingual patient-controlled analgesia (PCA) system currently in three Phase 3 clinical trials for the treatment of post-operative pain. Top line results from these trials are expected to be available later this year and during the first quarter of 2013. Assuming positive results in this Phase 3 program, AcelRx plans to submit a New Drug Application, or NDA, to the United States Food and Drug Administration in the third quarter of 2013. Based on informal scientific advice meetings held with two national European regulatory authorities, AcelRx believes that the data compiled for the NDA will also be sufficient to file an MAA in Europe.

"This decision by the EMA allows us to pursue registration of ARX-01 through the more efficient centralized review process, rather than separate applications for approval in each country," said Richard King, AcelRx's president and CEO. "Registration via the Centralized Procedure is typically reserved for products with significant therapeutic, scientific or technical innovation, and reflects the genuinely novel approach to post-operative pain management that is inherent in the design of our non-invasive, preprogrammed Sufentanil NanoTab PCA System."

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, the ARX-01 Sufentanil NanoTab PCA System, is currently in Phase 3 clinical development and is designed to solve problems associated with post-operative intravenous patient-controlled analgesia, including side effects of morphine, 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 that have completed Phase 2 clinical development: ARX-02 for the treatment of cancer breakthrough pain and ARX-03 for mild sedation, anxiety reduction and pain relief for patients undergoing painful procedures in a physician's office. AcelRx plans to initiate a Phase 2 study for a fourth product candidate, ARX-04, a sufentanil formulation for the treatment of moderate-to-severe acute pain, funded through a grant from USAMRMC. 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 an MAA submission to the EMA, the planned or anticipated future clinical development of AcelRx Pharmaceuticals' product candidates, including the anticipated timing for clinical trials, the timing of the top line data from all three Phase 3 clinical trials, the timing of submission of an NDA to the FDA and therapeutic and commercial 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' product development activities and clinical trials; the uncertain clinical development process, including the risk that planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be initiated or completed on schedule, if at all; any delays or inability to obtain regulatory approval of its product candidates in the United States and Europe; its ability to obtain adequate clinical supplies of the drug and device components of its product candidates; its ability to attract funding partners or collaborators with development, regulatory and commercialization expertise; 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 in the United States and Europe; the market potential for its product candidates; the accuracy of AcelRx Pharmaceuticals' 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 for the three months ended June 30, 2012. 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.

SOURCE AcelRx Pharmaceuticals, Inc.

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