AcelRx Awarded Contract from Department of Defense to Advance ARX-04

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REDWOOD CITY, Calif., May 14, 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 announced it has entered into Contract No. W81XWH-15-C-0046 worth up to $17.0 million, supported by the United States Army Medical Research and Materiel Command (USAMRMC) within the U.S. Department of Defense (DoD). The contract provides partial funding for ongoing development of ARX-04, including Phase 3 clinical, manufacturing and regulatory activities. ARX-04 is in development as a non-invasive, single-use 30 mcg sufentanil sublingual tablet in a disposable, pre-filled, single-dose applicator (SDA), for the anticipated treatment of moderate-to-severe acute pain in a medically supervised setting.

"We recently announced the initiation of the pivotal Phase 3 study of ARX-04 and are now very pleased to announce the DoD's continued support of ARX-04. The funding, together with our existing resources, will allow us to complete the Phase 3 development program, continue with manufacturing activities, and ready the product for the potential submission of a New Drug Application (NDA). We are excited to continue our relationship with the DoD, which began in 2011 through a $5.6 million grant to fund Phase 2 development. We believe ARX-04 can potentially provide great benefit to our servicemen and women in the armed forces and presents promising commercial opportunities in a wide range of medically-supervised settings such as emergency rooms, and following short-stay surgeries," stated Howie Rosen, AcelRx interim Chief Executive Officer.

Under the terms of the contract, commencing in Q2 2015, the DoD will reimburse AcelRx for costs incurred for development, manufacturing and clinical costs outlined in the contract, including reimbursement for certain personnel and overhead expenses. These development activities are intended to include completion of the Phase 3 clinical program and manufacturing development activities over the next 18-months.

About ARX-04

ARX-04 consists of a 30 mcg sufentanil sublingual tablet, in a pre-filled single-dose applicator (SDA). ARX-04 is non-invasive, single-use and disposable, allowing healthcare professionals to administer a sufentanil tablet under a patient's tongue to manage their moderate-to-severe acute pain. AcelRx's proprietary tablet formulation enables sublingual sufentanil absorption when a tablet is placed under the tongue, thereby providing analgesia with a consistent pharmacokinetic profile, due to a high percentage of drug being absorbed sublingually instead of through the gastrointestinal tract. We believe ARX-04 may be a candidate for use in a variety of medically supervised settings to manage moderate-to-severe pain, including in emergency room patients; post-operative patients who are transitioning from the operating room to the recovery floor; patients who are recovering from either short-stay or ambulatory surgery and do not require more long-term patient-controlled analgesia; treatment of battlefield casualties; and patients being transported by paramedics. According to the National Emergency Department Sample, there were more than 104 million adult emergency room visits in the U.S. during 2011, of which it is estimated that more than 48 million were associated with moderate-to-severe acute pain; while in the five largest markets in Europe there were more than 91 million adult emergency room visits during 2011, of which it is estimated more than 34 million were associated with moderate-to-severe acute pain.

About USAMRMC

The USAMRMC is the Army's medical materiel developer, with responsibility for medical research, development, and acquisition and medical logistics management. The USAMRMC manages and executes research in five basic areas: military infectious diseases, combat casualty care, military operational medicine, chemical biological defense, and clinical and rehabilitative medicine.

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 has initiated a Phase 3 clinical trial for ARX-04 and is actively recruiting for that trial. In addition to ARX-04, AcelRx's lead product candidate, Zalviso, is designed for 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 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 (CRL) from the FDA. In March 2015, AcelRx received correspondence from the FDA stating that in addition to the bench testing and two Human Factors studies AcelRx has performed to address dispensing issues raised in the CRL, an additional clinical trial is needed to assess the risk of inadvertent dispensing and overall risk of dispensing failures. AcelRx submitted a formal meeting request to the FDA and this request has been denied. AcelRx is currently evaluating its next steps to seek a pathway forward towards gaining approval of Zalviso in the U.S., including potential additional clinical studies, additional Human Factors studies, or the dispute resolution processes provided for by the FDA. 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; statements related to the completion of enrollment in ARX-04's Phase 3 trial and anticipated timing of the trial's top line results; availability and amount of funding to support ARX-04's development including potential filing of an NDA; 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 complete Phase 3 development for ARX-04, file an NDA and to receive regulatory approval for ARX-04; the success, cost and timing of all product development activities and clinical trials, including the Phase 3 ARX-04 trial; the market potential for its product candidates, including Zalviso and ARX-04; the ability to maintain compliance with contractual compliance matters and requirements; 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 May 5, 2015. 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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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/acelrx-awarded-contract-from-department-of-defense-to-advance-arx-04-300083208.html

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