



European Medicines Agency Begins Evaluation of Marketing Application for Sublingual Sufentanil 30 mcg Tablet (ARX-04) for Moderate-to-Severe Acute Pain

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CHMP Opinion Expected First Half 2018

REDWOOD CITY, Calif., March 28, 2017 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of moderate-to-severe acute pain, announced that the European Medicines Agency (EMA) has notified the company that the ARX-04 (sufentanil sublingual tablet, 30 mcg) Marketing Authorisation Application (MAA) has passed validation, and that the scientific review of the MAA is underway. The MAA for ARX-04 (known as DSUVIA™ in the U.S.) was filed in early March 2017 for the treatment of patients with moderate-to-severe acute pain in a medically supervised setting. AcelRx expects an opinion on the MAA from the Committee for Medicinal Products for Human Use (CHMP) in the first half of 2018.

"With regulatory filings for DSUVIA and ARX-04 now under review at the FDA and EMA, respectively, AcelRx has achieved an important milestone towards potentially having a commercial stage asset in multiple markets," stated Vincent Angotti, AcelRx's chief executive officer. Mr. Angotti added, "We believe there is a significant opportunity in Europe for a product that allows healthcare professionals to efficiently deliver a 30 mcg dose of sublingual sufentanil through a pre-filled, single-dose applicator to patients suffering from moderate-to-severe acute pain."

The ARX-04 market in Europe is comprised of approximately 67 million adults who experience moderate-to-severe acute pain following short-stay surgery in hospitals and ambulatory surgery centers, or who receive care by ambulance services or in emergency departments for trauma or injuries.

About ARX-04 (known as DSUVIA™ in the US)

ARX-04 is a non-invasive investigational product candidate consisting of a 30 mcg sufentanil tablet delivered sublingually by a healthcare professional using a disposable, pre-filled, single-dose applicator (SDA). Dosing is as needed (prn) subject to a one hour minimum interval between dose administrations. Sufentanil is a synthetic opioid analgesic with a high therapeutic index and no known active metabolites.

AcelRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of moderate-to-severe acute pain. An NDA for DSUVIA (sufentanil sublingual tablet, 30 mcg) with a proposed indication for the treatment of moderate-to-severe acute pain in medically supervised settings, was accepted for filing by the FDA.

The Company's follow on product candidate, ZALVISO® (sufentanil sublingual tablet system), designed for the management of moderate-to-severe acute pain in adult patients in the hospital setting, is currently enrolling patients in a Phase 3 clinical trial, IAP312. ZALVISO delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. ZALVISO is approved in the EU for the management of acute postoperative pain in a hospital setting and is investigational and in late-stage development in the U.S. Grunenthal Group holds the rights for ZALVISO in Europe, where a commercial launch has begun.

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, DSUVIA™ (sufentanil sublingual tablet, 30 mcg), known as ARX-04 outside the United States, and ZALVISO® (sufentanil sublingual tablet system), including U.S. Food and Drug Administration, or FDA, review of the New Drug Application, or NDA, for DSUVIA; the potential approval of the DSUVIA NDA by the FDA; the DSUVIA and ARX-04 clinical trial results; AcelRx's pathway forward towards gaining approval of ZALVISO in the U.S., including successful completion of the IAP312 clinical study for ZALVISO; and the therapeutic and commercial potential of AcelRx's product candidates, including potential market opportunities for DSUVIA, ARX-04 and ZALVISO. These forward-looking statements are based on AcelRx Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. AcelRx Pharmaceuticals' actual results and timing of events could differ materially from those anticipated in such forward-looking statements, and as a result of these risks and uncertainties, which include, without limitation, risks related to AcelRx Pharmaceuticals' DSUVIA and ARX-04 development programs, including the FDA review of the DSUVIA NDA and the possibility that the FDA may dispute or interpret differently clinical results obtained from the DSUVIA Phase 3 studies; the ZALVISO development program, including successful completion of IAP312 and the resubmission of the ZALVISO NDA to the FDA; any delays or inability to obtain and maintain regulatory approval of its product candidates, including DSUVIA in the United States, ARX-04 in Europe and ZALVISO in the United States; the uncertain clinical development process; the success, cost and timing of all development activities and clinical trials; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx's U.S. Securities and Exchange Commission filings and reports, including its Annual Report on Form 10-K filed with the SEC on March 3, 2017. 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.



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SOURCE AcelRx Pharmaceuticals, Inc.

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