AcelRx receives positive CHMP opinion for DZUVEO™ for management of acute moderate to severe pain in medically monitored settings

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DZUVEO is AcelRx's second developed sublingual sufentanil-based product to receive positive CHMP opinion, with Zalviso® already approved

Resubmission of New Drug Application for DSUVIA™ (known as DZUVEO in Europe) to the FDA in the U.S. is planned for Q2 2018

REDWOOD CITY, Calif., April 27, 2018 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), (AcelRx or the Company), a specialty pharmaceutical company focused on innovative therapies for use in medically supervised settings, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion, recommending approval of DZUVEO (known as DSUVIA™ in the U.S.) for the management of acute moderate to severe pain in adults in medically monitored settings.

"The CHMP positive opinion recognizes the compelling efficacy and safety profile of DZUVEO and is a significant step forward in bringing a novel, non-invasive medicine that could potentially transform the management of moderate to severe acute pain in medically monitored settings for healthcare systems, providers and patients in Europe," said Vince Angotti, Chief Executive Officer of AcelRx. "We believe the market opportunity is significant, with annually over 51 million patients visiting emergency departments and 16 million patients post-surgery experiencing moderate to severe acute pain in just the five largest EU countries."

The CHMP positive opinion is now referred to the European Commission, which grants a centralized marketing authorization with unified labeling that is valid in the 28 countries of the European Union (EU), as well as European Economic Area members, Iceland, Liechtenstein and Norway. AcelRx anticipates that the European Commission decision will be adopted within approximately two to three months.

Based on the clear path provided by the FDA Type A meeting and subsequent successful completion of the Human Factors study, the Company is planning to resubmit the New Drug Application for DSUVIA (known as DZUVEO in Europe) with the U.S. Food and Drug Administration (FDA) in the second quarter of 2018.

About DZUVEO (known as DSUVIA in the U.S.)

DZUVEO, known as DSUVIA™ (sufentanil sublingual tablet, 30 microgram) in the U.S., is designed to reduce acute moderate-to-severe pain and address dosing errors associated with IV administration via its non-invasive single-dose applicator (SDA) in medically monitored settings. Sufentanil is an opioid analgesic currently marketed for intravenous (IV) and epidural anesthesia and analgesia. The sufentanil pharmacokinetic profile when delivered sublingually potentially avoids the high peak plasma levels and short duration of action observed with IV administration. In the US, the Company is planning to submit a New Drug Application (NDA) for DSUVIA with the FDA in Q2 2018.

About AcelRx Pharmaceuticals, Inc.

AcelRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings. AcelRx's proprietary, non-invasive sublingual formulation technology delivers sufentanil with consistent pharmacokinetic profiles. The Company has two product candidates including DSUVIA ™ (sufentanil sublingual tablet, 30 mcg), known as DZUVEO outside the United States, with a proposed indication for the treatment of moderate-to-severe acute pain in medically supervised (or monitored) settings, and Zalviso® (sufentanil sublingual tablet system, SST system, 15 mcg) being developed as an innovatively designed patient-controlled analgesia (PCA) system for reduction of moderate-to-severe acute pain in medically supervised settings.

For additional information about AcelRx's clinical programs, please visit www.acelrx.com.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to the potential approval of DZUVEO by the European Commission, the size and significance of a potential market for DZUVEO in Europe, and the process and timing of an NDA resubmission for DSUVIA with the FDA. These forward-looking statements are based on AcelRx's current expectations and involve significant risks and uncertainties. AcelRx's actual results and timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, including, without limitation: risks related to the possibility that the results of the Company's HF study may be disputed or interpreted differently by the FDA such that it results in further action being required by the Company impacting the Company's planned NDA submission for DSUVIA; any delays or the inability to obtain and maintain regulatory approval of DSUVIA in the United States, DZUVEO in Europe and ZALVISO in the United States; 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 9, 2018. 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, except as required by law.

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