AcelRx receives European Commission approval for DZUVEO™

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AcelRx's DZUVEO receives EU approval for management of acute moderate to severe pain in medically monitored settings

REDWOOD CITY, Calif., June 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 European Commission (EC) has approved DZUVEO (under development in the U.S. as DSUVIA™) for the management of acute moderate to severe pain in adults in medically monitored settings.

"The EC approval is an important milestone for AcelRx, and an exciting new opportunity for healthcare providers for managing acute moderate to severe pain in medically monitored settings. The current standard of care in these settings is primarily intravenous opioids," said Vince Angotti, Chief Executive Officer of AcelRx. "DZUVEO is a novel, non-invasive, sublingual tablet that we expect will challenge the current standard of care and provide a new option to healthcare practitioners that does not require the time, expense and effort to start an intravenous line."

DZUVEO represents the second EC approval for an AcelRx developed product, with the first being ZALVISO, which is currently being marketed in Europe by Grünenthal.

AcelRx previously announced the acceptance of the resubmitted New Drug Application for DSUVIA (approved in Europe as DZUVEO) by the U.S. Food and Drug Administration, for which the FDA has assigned a PDUFA (Prescription Drug User Fee Act) date of November 3, 2018.

About DZUVEO (tradename of DSUVIA in the U.S.)
DZUVEO (sufentanil sublingual tablet, 30 microgram), under development as DSUVIA in the U.S., is designed to reduce acute moderate-to-severe pain in medically monitored settings and address dosing errors associated with intravenous (IV) administration via its non-invasive single-dose applicator (SDA). Sufentanil is an opioid analgesic currently marketed for IV and epidural anesthesia and analgesia. The sufentanil pharmacokinetic profile when delivered sublingually avoids the high peak plasma levels and short duration of action observed with IV administration while still providing rapid pain relief. The safety and clinical utility of DZUVEO has been established in patients following multiple types of surgery, as well as in patients presenting to the emergency room with moderate to severe pain due to trauma, injury or illness. In the U.S., the U.S. Food and Drug Administration assigned the Company a Prescription Drug User Fee Act (PDUFA) date of November 3, 2018 for a decision on its resubmitted DSUVIA NDA (New Drug Application).

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 in the United States, 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 a non-invasive patient-controlled analgesia (PCA) system for treatment of moderate to severe acute pain in medically supervised settings. The Company has received EC approval for Zalviso and DZUVEO for marketing in the Europe.

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, the statement related to the size and significance of a potential market for DZUVEO in Europe and the potential that DZUVEO will challenge the standard of care in the management of acute moderate to severe pain. This and similar 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, any delays or the inability to obtain and maintain market acceptancy of DZUVEO in Europe, or any other risks described in the "Risk Factors" and elsewhere in AcelRx's U.S. Securities and Exchange Commission (SEC) filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on May 10, 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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