



AcelRx Announces Agreement with FDA Addressing the Warning Letter Received for DSUVIA® Promotional Materials

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HAYWARD, Calif., June 17, 2021 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), (AcelRx), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings, today announced it has reached agreement with the Food and Drug Administration (FDA) with regards to finalizing corrective actions AcelRx has taken or plans to take in response to the previously announced FDA warning letter, dated February 11, 2021, regarding certain DSUVIA promotional materials.

The FDA has agreed with AcelRx's proposed plan to update certain promotional materials, including providing a letter to healthcare professionals (DHCP letter) explaining the corrections to the discontinued promotional materials. AcelRx will also include this DHCP letter on the [DSUVIA.com](https://www.dsuvia.com) website for a period of eight months. All promotional materials currently in use by AcelRx's commercial team have been updated to address the FDA's concerns. AcelRx expects to receive a close-out letter from the FDA after the DHCP letters have been sent to the identified healthcare professionals and the letter has been posted on the website for eight months.

About DSUVIA (sufentanil sublingual tablet), 30 mcg

DSUVIA®, known as DZUVEO® in Europe, is indicated for use in adults in certified medically supervised healthcare settings, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic, and for which alternative treatments are inadequate. DSUVIA was designed to provide rapid analgesia via a non-invasive route and to eliminate dosing errors associated with intravenous (IV) administration. DSUVIA is a single-strength solid dosage form administered sublingually via a single-dose applicator (SDA) by healthcare professionals. Sufentanil is an opioid analgesic previously only 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. The European Commission approved DZUVEO for marketing in Europe and the Company is currently in discussions with potential European marketing partners.

This release is intended for investors only. For more information, including important safety information and black box warning for DSUVIA, please visit www.dsuvia.com.

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 one approved product in the U.S., DSUVIA® (sufentanil sublingual tablet, 30 mcg), known as DZUVEO® in Europe, indicated for the management of acute pain severe enough to require an opioid analgesic for adult patients in certified medically supervised healthcare settings, and one product candidate, Zalviso® (sufentanil sublingual tablet system, SST system, 15 mcg), an investigational product in the U.S., is being developed as an innovatively designed patient-controlled analgesia (PCA) system for reduction of moderate-to-severe acute pain in medically supervised settings. DZUVEO and Zalviso are both approved products in Europe.

For additional information about AcelRx, please visit www.acelrx.com.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to the FDA warning letter, including the expected receipt of a close-out letter from the FDA. These and any other forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking terminology such as "believes," "expects," "anticipates," "may," "will," "should," "seeks," "approximately," "intends," "plans," "estimates," or the negative of these words or other comparable terminology. The discussion of strategy, plans or intentions may also include forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those projected, anticipated or implied by such statements. In addition, such risks and uncertainties may include, but are not limited to, those described in the Company's annual, quarterly and current reports (i.e., Form 10-K, Form 10-Q and Form 8-K) as filed or furnished with the Securities and Exchange Commission (SEC). You are cautioned not to place undue reliance on any such forward-looking statements, which speak only as of the date such statements were first made. The Company's SEC reports are available at www.acelrx.com under the "Investors" tab. Except to the extent required by law, the Company undertakes no obligation to publicly release the result of any revisions to these forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.



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