AcelRx Enters into Licensing Agreement for DZUVEO® in Europe and In-licensing Agreement for Two Products in the U.S.

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AcelRx to receive up to approximately $55 million in combined up-front and sales-based milestone payments for DZUVEO licensing agreement

AcelRx obtains the rights to file NDAs and commercialize two innovative pre-filled syringe product candidates for the U.S.

HAYWARD, Calif., July 14, 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 agreements with Laboratoire Aguettant (Aguettant) providing Aguettant with a license to commercialize DZUVEO in Europe, and providing AcelRx with two innovative pre-filled syringe product candidates for the U.S.

Under the DZUVEO licensing agreement, Aguettant will have the right to commercialize DZUVEO in Europe. AcelRx is entitled to receive up to approximately $55 million in a combination of up-front and sales-based milestone payments at various annual sales levels from Aguettant, along with revenue share payments ranging from 35% to 45% of net sales. AcelRx will manufacture and supply DZUVEO to Aguettant at an agreed supply price.

Under the terms of a separate licensing agreement, AcelRx obtained the rights to file NDAs, and subject to U.S. Food and Drug Administration approval, commercialize in the United States two of Aguettant's innovative, EU-approved, pre-filled syringe products – ready-to-use ephedrine and phenylephrine. Aguettant has the right to receive up to $24 million in sales-based milestone payments, at various annual sales levels up to $60 million, along with revenue share payments of 40 to 45% of the net sales of the two pre-filled syringe products, if approved in the U.S. by the Food and Drug Administration.

"We are excited to enter into a European collaboration for DZUVEO with Aguettant, a well-known, innovative European pharmaceutical company focused on the acute care space across 70 countries," said Vince Angotti, Chief Executive Officer at AcelRx. "This collaboration provides a strategic fit for DZUVEO given Aguettant's existing product portfolio. Having the ability to commercialize two product candidates in the United States with a track record of success in Europe aligns with our strategy of building a complementary product portfolio to DSUVIA while limiting the cost of development," continued Angotti.

"DZUVEO complements our existing product portfolio and we're delighted about this strategic opportunity to partner with AcelRx," said Eric Rougemond, Chief Executive Officer at Laboratoire Aguettant. "Our worldwide presence in the acute care space makes us an ideal European partner for DZUVEO. Partnering with AcelRx to commercialize two of our key acute care products in the U.S. further reinforces our mutual commitment to this strategic partnership."

The Fulford Group and Karana Biotech provided strategic and transactional advisory services to AcelRx.

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 for the management of acute moderate to severe pain in adults in medically monitored settings.

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.

About Laboratoire Aguettant

Aguettant is an independent pharmaceutical company dedicated to the development, manufacturing and distribution of innovative injectable medicines. Aguettant specializes in acute care settings, mainly anaesthesia, critical care and emergency, with a constant focus on redefining drug delivery standards to reduce risk for users and patients. Founded in Lyon, France in 1903, Laboratoire Aguettant has a strong foundation in Europe and is present in 70 countries globally through its affiliates and partners' network. For more information about the company, visit its website: www.aguettant-corporate.com

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to the commercial opportunity of AcelRx's agreements with Aguettant, the submission of new drug applications, the potential approval of product candidates by the U.S. Food and Drug Administration, and the ability to successfully manufacture DZUVEO to meet the requirements of Aguettant. 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, including, without limitation, risks related to delays in, or AcelRx's inability to obtain, regulatory approval for product candidates, the ability to obtain sufficient financing to commercialize product candidates, and the market potential for product candidates. 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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Raffi Asadorian, CFO, AcelRx, 650-216-3500, investors@acelrx.com