AcelRx Pharmaceuticals Joins Russell 3000 and Russell 2000 Indexes

June 27, 2016

REDWOOD CITY, Calif., June 27, 2016 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute pain, today announced that the company has joined the broad-market Russell 3000 and Russell 2000 Indexes according to the final membership lists posted June 24th, 2016.

The Russell 2000® Index measures the performance of the small-cap segment of the U.S. equity market and is a subset of the Russell 3000®, representing approximately 10% of the total market capitalization of that index. Membership in the Russell 3000® Index includes automatic inclusion in the appropriate growth and style indexes. FTSE Russell determines membership for its Russell indexes by objective, market-capitalization rankings and style attributes.

Indexes provided by FTSE Russell, a leading global index provider, are widely used by investment managers and institutional investors for index funds and as benchmarks for active investment strategies. Approximately $6 trillion in assets are benchmarked against the Russell US indexes.

About AcelRx Pharmaceuticals, Inc.

AcelRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute pain. The company's late-stage pipeline includes ARX-04 (sufentanil sublingual tablet, 30 mcg) designed for the treatment of moderate-to-severe acute pain in a medically supervised setting; and Zalviso® (sufentanil sublingual tablet system) designed for the management of moderate-to-severe acute pain in adult patients in the hospital setting.

ARX-04 delivers 30 mcg sufentanil, a high therapeutic index opioid, sublingually through a disposable, pre-filled, single-dose applicator. AcelRx has reported positive results from the pivotal Phase 3 SAP301 ambulatory surgery study, and has advanced ARX-04 into a study (SAP-302) in emergency room patients. In addition, AcelRx intends to initiate SAP303 in the first quarter of 2016, with a focus on enrolling patients greater than 40 years of age, allowing for administration of ARX-04 for up to 12 hours. Zalviso delivers 15 mcg sufentanil sublingually through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. In response to the New Drug Application (NDA) AcelRx submitted to the U.S. Food and Drug Administration (FDA) seeking approval for Zalviso, AcelRx received a Complete Response Letter (CRL) on July 25, 2014. The FDA has requested an additional clinical study (IAP312), which AcelRx is planning to initiate in the first quarter of 2016, to support resubmission of the NDA.

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, ARX-04 (sufentanil sublingual tablet, 30 mcg) and Zalviso® (sufentanil sublingual tablet system), including the planned initiation of the IAP312 clinical trial for Zalviso; anticipated resubmission of the Zalviso NDA to the U.S. Food and Drug Administration, or FDA; the timing of completion of ARX -04 clinical program and submission of ARX-04 NDA to the FDA; and the therapeutic and commercial potential of AcelRx's product candidates, including 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' ability to complete Phase 3 clinical development of ARX-04 and support ARX-04 development under the contract with the Department of Defense; AcelRx's ability to successfully execute the pathway towards a resubmission of the Zalviso NDA to the FDA, including the initiation and completion of the IAP312 clinical study for Zalviso; any delays or inability to obtain and maintain regulatory approval of its product candidates, including ARX-04 in the United States and Europe, and Zalviso in the United States; the uncertain clinical development process, including adverse events; the risk that planned clinical trials may not begin on time, have an effective clinical design, enroll a sufficient number of patients, or be initiated or completed on schedule, if at all; the success, cost and timing of all development activities and clinical trials, including the Phase 3 ARX-04 SAP302 and SAP303 trials, and the additional clinical trial for Zalviso, IAP312; the fact that the FDA may dispute or interpret differently clinical results obtained to date from the Phase 3 SAP301 study of ARX-04; the market potential for AcelRx's product candidates; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx's U.S. Securities and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on May 2, 2016. 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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