



**AcelRx and Grünenthal Announce Submission of European Marketing Authorization Application for ZALVISO™**

- MAA submission triggers \$5 million milestone payment to AcelRx

**Redwood City, California and Aachen, Germany – July 7, 2014** - AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX) and Grünenthal Group announced today that Grünenthal has submitted a Marketing Authorization Application (MAA) to the European Medicines Authority for ZALVISO™ for the management of moderate to severe acute pain in adult patients in a medically supervised environment. ZALVISO is a drug-device combination product utilizing the opioid agonist sufentanil formulated in a proprietary sublingual tablet formulation and delivered through a pre-programmed, non-invasive proprietary delivery device. AcelRx and Grünenthal entered into license and supply agreements for ZALVISO in the EU, Australia and certain other countries in December 2013.

Under the terms of the license agreement, AcelRx will receive a cash payment of \$5 million for the MAA submission. AcelRx is eligible to receive an additional \$15 million milestone payment upon the approval of the MAA. After approval by EMA, AcelRx is eligible to receive approximately \$200 million in additional milestone payments, based upon successful regulatory and product development efforts and net sales target achievements. Grünenthal will also make tiered royalty, supply and trademark fee payments in the mid-teens up to the twenty percent range, on net sales of ZALVISO in the Grünenthal territory. With the partnership Grünenthal, a family-owned global pharmaceutical company headquartered in Aachen, Germany, significantly strengthens its hospital franchise and underlines its strong market position as a pain specialist in the pharmaceutical market.

“We are pleased with the timely progress and collaborative nature of our relationship with Grünenthal which has enabled the ZALVISO MAA to be submitted on schedule,” said Richard King, President and CEO of AcelRx Pharmaceuticals, Inc. “We look forward to the time when the benefits of ZALVISO might be available to all medically supervised patients in moderate to severe pain in the European Union.”

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“This important step is a key milestone in bringing a new treatment option to patients. Through the license agreement with AcclRx Grünenthal is again emphasizing its commitment to pain patients as an independent, global pharmaceutical company with long-time experience in the development of innovative and effective pain treatments,” said Grünenthal Chief Executive Officer Prof. Dr. Eric-Paul Pâques.

Under the terms of the collaboration, Grünenthal will be responsible for all commercial activities for ZALVISO, including obtaining and maintaining pharmaceutical product regulatory approval in the Grünenthal territory. AcclRx will be responsible for obtaining and maintaining device regulatory approval in the Grünenthal territory and manufacturing and supply of ZALVISO to Grünenthal for commercial sales and clinical trials.

Currently there are 19 million surgical procedures with associated moderate-to-severe pain in the European Union on an annual basis for which the use of ZALVISO could be suitable. The regulatory review by EMA is expected to take twelve to sixteen months.

### **About ZALVISO**

ZALVISO is an investigational pre-programmed, non-invasive, handheld system that allows hospital patients with moderate-to-severe acute pain to self-dose with sublingual sufentanil tablets to manage their pain. ZALVISO is designed to help address certain problems associated with post-operative intravenous patient-controlled analgesia, which has been shown to cause harm to patients following surgery because of the side effects of morphine, the invasive IV route of delivery and the complexity of infusion pumps.

AcclRx retains all rights to ZALVISO in North America, Asia, Latin America and Middle East/Africa.

### **About AcclRx Pharmaceuticals, Inc.**

AcclRx Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute and breakthrough pain. AcclRx's lead product candidate, ZALVISO, is designed to improve the management of moderate-to-severe acute pain in adult patients in the hospital setting by utilizing a high therapeutic index opioid, through a non-invasive delivery route via a pre-programmed, patient-controlled analgesia device. AcclRx has announced positive results from each of the three completed Phase 3 clinical trials for ZALVISO, and has submitted an NDA to the FDA seeking approval for ZALVISO in the treatment of moderate-to-severe acute pain in adult

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patients in the hospital setting. AcelRx plans to initiate a Phase 3 clinical trial for ARX-04, a product candidate for the treatment of moderate-to-severe acute pain in a medically supervised setting, during the second half of 2014. The company has two additional pain treatment product candidates, ARX-02 and ARX-03, which have completed Phase 2 clinical development. For additional information about AcelRx's clinical programs, please visit [www.acelrx.com](http://www.acelrx.com).

### **About Grünenthal**

The Grünenthal Group is an independent, family-owned, international research-based pharmaceutical company headquartered in Aachen, Germany. Building on its unique position in pain treatment, its objective is to become the most patient-centric company in the field of pain and thus to be a leader in therapy innovation.

Grünenthal is one of the last five remaining research-oriented pharmaceutical companies with headquarters in Germany which sustainably invests in research and development. Research and development costs amounted to about 27 percent of revenues in 2013. Grünenthal's research and development strategy concentrates on selected fields of therapy and state-of-the-art technologies. We are intensely focused on discovering new ways to treat pain better and more effectively, with fewer side-effects than current therapies.

Altogether, the Grünenthal Group has affiliates in 25 countries worldwide. Grünenthal products are sold in more than 155 countries and approx. 5,500 employees are working for the Grünenthal Group worldwide. In 2013, Grünenthal achieved revenues of €901 mn.

More information: [www.grunenthal.com](http://www.grunenthal.com).

### **Forward Looking Statements**

This press release contains forward-looking statements, including, but not limited to, statements related to potential approval of the NDA for Zalviso in the U.S. and the timing thereof, the potential of approval of the MAA for Zalviso in the EU and the timing thereof, the ability to successfully manufacture Zalviso to meet the requirements of Grünenthal and the therapeutic and commercial potential of Zalviso in the Grünenthal territory. These forward-looking statements are based on AcelRx's current expectations and inherently involve significant risks and uncertainties.

AcelRx's actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to: AcelRx's ability to receive regulatory approval for Zalviso; any delays or inability to obtain and maintain regulatory approval of AcelRx's product candidates, including Zalviso, in the United States, Europe, Australia and other countries; the ability to attract additional funding partners or collaborators with development, regulatory and commercialization expertise; the ability to obtain sufficient financing to commercialize Zalviso; the market potential for AcelRx's other product candidates; the accuracy of AcelRx's estimates regarding expenses, capital requirements and needs for financing; and other risks detailed in the "Risk Factors" and elsewhere in AcelRx's U.S. Securities

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and Exchange Commission filings and reports, including its Quarterly Report on Form 10-Q filed with the SEC on May 8, 2014. 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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