



AcelRx Announces Publication of Zalviso Phase 3 Abdominal Trial Results

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Results indicate Zalviso controlled moderate-to-severe acute pain following abdominal surgery better than placebo, with similar side effect profile

REDWOOD CITY, Calif., Oct. 22, 2014 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (NASDAQ: ACRX) today announced that results from the IAP310 study have been published in *Regional Anesthesia and Pain Medicine (RAPM)*, a peer-reviewed journal with broad, multidisciplinary readership. IAP310 was a randomized, placebo-controlled, Phase 3 trial evaluating the safety and efficacy of Zalviso, also referred to as the sufentanil sublingual tablet system (SSTS), for the treatment of post-operative pain in patients following open abdominal surgery. Zalviso is an investigational patient-controlled analgesia drug/device candidate currently under review by the Food and Drug Administration (FDA). The study met its primary endpoint, demonstrating that Zalviso was significantly better at managing pain over 48 hours as measured by Summed Pain Intensity Difference to Baseline (SPID-48), than placebo ($p=0.001$). Zalviso-treated patients had pain scores that separated from placebo-treated patients within 1 hour after study initiation. The IAP310 study results had been previously reported, however this publication represents the first time the results have been included in a peer-reviewed journal.

Treatment-related adverse events were similar between the two groups, with fewer Zalviso patients dropping out of the study due to inadequate analgesia compared to placebo (17.4% vs 31.8%; $p=0.035$) and using approximately half as much rescue morphine over the duration of the trial (1.8 doses vs. 3.8 doses). As a secondary endpoint, a validated ease-of-care questionnaire was administered to patients and healthcare providers. Both groups gave Zalviso a total overall rating above 4.0 on a scale of 0-5. The authors conclude that Zalviso may integrate well with a multimodal approach to acute pain management in the hospital setting.

The manuscript titled "Sufentanil Sublingual Tablet System for the Management of Postoperative Pain Following Open Abdominal Surgery: A Randomized, Placebo-Controlled Study" is available to read in full online.

Link to view article:

http://journals.lww.com/rapm/Abstract/onlinefirst/Sufentanil_Sublingual_Tablet_System_for_the.99572.aspx

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 and breakthrough pain. AcelRx'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. AcelRx 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 patients in the hospital setting and on July 25th, received a Complete Response Letter from the FDA. 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, by the end 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.



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To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/acelrx-announces-publication-of-zalviso-phase-3-abdominal-trial-results-525544180.html>

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Timothy E. Morris, Chief Financial Officer, 650.216.3511, tmorris@acelrx.com, Brian Korb, The Trout Group LLC, 646.378.2923, bkorb@troutgroup.com