



Zalviso™ Phase 3 Orthopedic Results Published In Anesthesiology Demonstrate Significant Reductions In Post-Operative Pain

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

REDWOOD CITY, Calif., July 2, 2015 /PRNewswire/ -- AcelRx Pharmaceuticals, Inc. (Nasdaq: ACRX), a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for the treatment of acute and breakthrough pain, today announced that results from the IAP311 study have been published in *Anesthesiology*. IAP311 was a randomized, double-blind placebo-controlled, Phase 3 trial evaluating the safety and efficacy of Zalviso, also referred to in the publication as the sufentanil sublingual tablet system (SSTS), for the treatment of moderate-to-severe post-operative pain in patients following major joint replacement surgery. Zalviso is an investigational patient-controlled analgesia (PCA) drug/device candidate currently under review by the United States 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 relief scores superior to placebo-treated patients within 45 minutes of study initiation. The IAP311 study results had been previously reported; however, this publication represents the first time the results have been included in a peer-reviewed journal.

"While opioids remain a critical component of multimodal post-operative analgesia, what's new and novel about Zalviso is that it is non-invasive and can be safely controlled by the patient," said lead investigator Maurice Jove, MD, Medical Director of the Joint Solutions Center at Dekalb Medical Center in Decatur, GA. "For patients, this means that Zalviso, if approved, could potentially offer an effective alternative to standard intravenous PCA."

Reports of treatment-related adverse events were similar between the two groups, with the exception of nausea and itching, which were higher in the Zalviso group. It was noted that fewer Zalviso patients dropped out of the study due to inadequate analgesia compared to placebo (14% vs 48%; $p < 0.001$) and used approximately half as much rescue morphine over the duration of the trial (2.3 doses vs. 4.0 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.

"In addition to the rapid and consistent pain control we observed with Zalviso in this study", stated AcelRx Chief Medical Officer, Pamela Palmer, MD, PhD, "we were particularly encouraged by the outcomes of the ease-of-use questionnaire. It is crucial that healthcare providers feel that Zalviso not only meets the pain management needs of their patients, but that it is easy to use and reliable, which we believe is indicated by the favorable scores that were recorded."

The manuscript titled "Sufentanil Sublingual Tablet System for the Management of Postoperative Pain after Knee and Hip Arthroplasty" is available to read in full online.

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 for 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, has submitted a New Drug Application, or 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 25, 2014, received a Complete Response Letter (CRL) from the FDA. In March 2015, AcelRx received correspondence from the FDA stating that in addition to the bench testing and two Human Factors studies AcelRx has performed to address the dispensing issues raised in the CRL, an additional clinical study is needed to assess the risk of inadvertent dispensing and overall risk of dispensing failures. AcelRx submitted a formal meeting request to the FDA and this request was denied. AcelRx is currently evaluating its next steps with regards to the U.S. regulatory process for Zalviso. In March 2015, AcelRx initiated SAP-301, a pivotal Phase 3 study for ARX-04, a product candidate for the treatment of moderate-to-severe acute pain in a medically supervised setting. 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/zalviso-phase-3-orthopedic-results-published-in-anesthesiology-demonstrate-significant-reductions-in-post-operative-pain-300107561.html>

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